UNIVERSITY OF ILLINOIS
AT CHICAGO

Animal Care (ACC) and Institutional
Biosafety Committees (IBC) (MC 672)
Office for the Protection of Research Subjects
Office of the Vice Chancellor for Research
206 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

August 11, 2006

Edward Hammond
Director US Office
Sunshine Project
PO Box 41987
Austin, TX 78704

Dear Mr. Hammond:

I am again sending you the enclosed materials. This is my second attempt to send these material. The first was sent to the above listed address via certified mail and returned to the University of Illinois at Chicago on August 11th as unclaimed mail. Please find enclosed the minutes from the Institutional Biosafety Committee meetings at the University of Illinois at Chicago.

Sincerely,

Mary Bowman

Mary B. Bowman, PhD

UIC

Phone (312) 996-7427 • Fax (312) 996-9088

UNIVERSITY OF ILLINOIS
AT CHICAGO

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Biosafety Committees (IBC) (MC 672)
Office for the Protection of Research Subjects
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201 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

June 8, 2006

Edward Hammond
Director US Office
Sunshine Project
PO Box 41987
Austin, Texas 78704

Dear Mr. Hammond:

Enclosed are minutes from the Institutional Biosafety Committee meetings at University of Illinois at Chicago that were requested by the Sunshine Project under Section IV-B-2-a-7 of the *NIH Guidelines* as part of the 2006 Sunshine Project survey of Institutional Biosafety Committees. Information redacted is consistent with guidance provided by the Office of Biotechnology Activities (http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm).

Please direct any further correspondence to me at the number listed below.

Sincerely,

Mary B. Bowman, PhD

Cc: University Counsel Office
Dr. Eric Gislason, Vice Chancellor for Research
Dr. Larry Danziger, Associate Vice Chancellor for Research

UIC

Phone (312) 996-7427 • Fax (312) 996-9088

Institutional Biosafety Committee
Minutes of
May 15, 2003
2:00 P.M.- Room 307 C AOB

PRESENT: Dr. Alexander Neyfakh (Chair), Dr. Aixa Alfonso, Dr. Paul Goldspink, Dr. William Henrickson, Dr. Randal Jaffe, Mr. Terrance Larwin, and Ms. Sheila White

ABSENT: Dr. Edward Cohen, Dr. Jeffrey Fortman, Dr. Thomas Hope, and Dr. Lon Kaufman

STAFF: Dr. Mary Bowman

1. **Announcements-**

   Dr. Bowman informed the Committee that it was essential to conduct the meeting according to the agenda to ensure that all items on the agenda could be covered during the meeting. If Committee members have new issues they would like discussed at a meeting, these items could be added to the agenda under new business via announcement at the meeting or by contacting Dr. Bowman and having the item added to the agenda prior to distribution.

   Dr. Bowman reminded the Committee that their packets contained the IBC Calendar for the next year. She directed the Committee's attention to the deadlines for protocol submission, the deadlines for all prereview forms to be returned to the IBC office, and the meeting dates. She reminded the Committee to circle their recommendations on the prereview form.

2. **Minutes of April 8, 2003-**

   The minutes of the April 8, 2003 meeting were approved pending minor editorial changes.

3. **Old Business-**

   a. **Levels of Approved Pending-**

      Dr. Bowman suggested to the Committee that when protocols are approved pending by the Committee that there be three levels of review for revisions. The first level would be administrative for minor clarifications requested by the Committee. These revisions could be reviewed and approved by the IBC administrator. The second level of review would be by the chair or the chair's designee. This level would be

for revisions requiring the specific scientific expertise of the chair or his designee. The chair or his designee would have the authority to review and approve the revisions. The last level of review for revisions would be by special subcommittee. This level of review would be determined at Committee meetings on a case-by-case basis. The special subcommittee would consist of members of the full committee who will review the revisions and have the authority to approve these revisions or request additional clarifications. A motion to approve these three levels of review for protocols approved pending clarification passed unanimously. Dr. Bowman stated that the levels of review for revisions of approved pending protocols would be incorporated into the UIC IBC review process document.

4. **Protocol Summary Reports-**

   a. **Revised April Report-**

      Dr. Bowman summarized the protocols (**03-009, 03-011 and 03-015**) that were eligible for expedited review and that were approved during the prereview process by the three reviewers without clarifications. Each is conducted at BSL1 level.

03-003 - The Role of c-Rel on DC Function and Immunotolerance-

Following discussion that concerns had been raised during prereview as to the type of vector system that would be used and whether flow cytometry would be conducted, Dr. Bowman directed the Committee to the revisions made by the PI indicating that the vector used is a plasmid only capable of replicating in bacteria- E. coli and that flow cytometry would be conducted in a closed system without generation of aerosols. A motion to approve this protocol passed unanimously.

03-004 - Cell Biology of Filovirus Entry-

Following discussion that there were several concerns raised during the prereview process regarding whether live virus would be used, the origin of the plasmids, which cells would be used for transfection, whether genes would be transfected together, whether either gene coded for a virulent factor and the nature of the pseudotype HIV that is used, Dr. Bowman directed the Committee to the revisions made by the PI. The PI indicated in the revisions that only plasmids containing the two genes would be used, one gene (GP40) might be considered to play a role in pathogenesis, but it would be in a plasmid not capable of replicating in mammalian cells, and the pseudotype HIV lacks a large deletion and is not capable of back mutation. The Committee agreed that all concerns raised during prereview had been addressed. Dr. Bowman stated that currently GP40 was a select agent and that the PI would need to complete the select agent

registration process prior to initiation of the work. A motion to approve this protocol passed unanimously with the following condition.

a. Condition: All select agent requirements of the CDC regarding use and registration must be completed in approved prior to obtaining the agent and initiation work with this agent.

03-005 - Influence of DNA Methylation on Replication and Growth of Bacteria with Multiple Chromosomes-

Dr. Bowman stated that this protocol was similar to protocol 03-008. Bacterial genes would be propagated in V. Cholerae in this protocol and in bacteria not pathogenic to humans in protocol 03-008. Following discussion that concerns were raised during prereview as to the nature (function and pathogenicity) of the genes being cloned into V. cholerae and that an SOP needed to be developed by the PI for handling the bacteria and disposing of infectious waste, Dr. Bowman directed the Committee to the revisions submitted by the PI. Dr. Neyfakh had reviewed the revisions and felt that they had addressed the concerns raised during preview. The PI has developed a SOP and the genes being cloned are important for viability of certain strains of bacteria and their overexpression is often detrimental to bacteria viability; therefore, it would not render bacteria more virulent. A motion to approve this protocol passed unanimously.

03-006 - Cytokine Modulation of Collagen Gene Expression: Signal Integration by Coactivators-

Dr. Bowman stated that the issue of decontamination of waste material raised during prereview had been addressed. She stated that the PI had provided documentation regarding chemical and BBP training, but it was outdated. Documentation regarding shipping and receiving training had not been provided. A motion to approve this protocol pending clarifications passed unanimously.

a. Verification of chemical safety training needs to be provided. Documentation should be provided for verification that PI and personnel involved in the project have undergone chemical safety training is outdated. Training must be completed on an annual basis. Training is available online through the EHSO website at https://tigger.uic.edu/htbin/bluestem/doc.cgi/depts/envh/index.html. Click on the information for chemical safety courses.
b. Verification of bloodborne pathogen (BBP) training needs to be provided. Documentation provided for verification of BBP training is outdated. Training must be completed on an annual basis. The schedule of training sessions is available on the EHSO website listed above.
c. Verification of shipping and receiving training on hazardous materials needs to be provided. Training is available online through the EHSO website at https://tigger.uic.edu/htbin/bluestem/doc.cgi/depts/envh/index.html for all

ground transport. Click on the information for chemical safety courses. If shipping occurs by air, then contact Terry Lawrin, the UIC biosafety officer at 996-3701 regarding IATA training.

03-007 - Molecular Basis of Fibrosis: Regulation of Collagen Gene Expression by TGF-β–

Dr. Bowman stated that the issue of decontamination of waste material raised during prereview had been addressed. She stated that the PI had not provided documentation regarding chemical and BBP training. A motion to approve this protocol pending clarifications passed unanimously.

a. Verification of chemical safety training needs to be provided. Training must be completed on an annual basis. Training is available online through the EHSO website at https://tigger.uic.edu/htbin/bluestem/doc.cgi/depts/envh/index.html. Click on the information for chemical safety courses.
b. Verification of bloodborne pathogen (BBP) training needs to be provided. Documentation provided for verification of BBP training is outdated. Training must be completed on an annual basis. The schedule of training sessions is available on the EHSO website listed above.
c. Verification of shipping and receiving training on hazardous materials needs to be provided. Training is available online through the EHSO website at https://tigger.uic.edu/htbin/bluestem/doc.cgi/depts/envh/index.html for all ground transport. Click on the information for chemical safety courses. If shipping occurs by air, then contact Terry Lawrin, the UIC biosafety officer at 996-3701 regarding IATA training.

03-008 - Influence of DNA Methylation on Replication and Growth of Bacteria with Multiple Chromosomes-

Dr. Bowman stated that this protocol was similar to protocol 03-005. Bacterial genes would be propagated in bacteria not pathogenic to humans in this protocol. One of the bacteria (A. tumefaciens) is pathogenic in plants, but it would not be used in this capacity in this protocol. Following discussion that all concerns raised during prereview had been addressed, a motion to approve this protocol passed unanimously.

03-010 - Macrophage Cholesterol Metabolism and ApoE Synthesis-

Dr. Bowman stated that the only concern raised during prereview was in regards to the nature of the macrophages to be used. Two conditions of approval were also raised during prereview regarding location of the lab and inspection of the lab when the PI arrives on campus. She indicated that the PI isolates macrophages from human circulating monocytes purchased from a commercial vendor and that primary cultures of

macrophages would be obtained from rats and mice. She stated that the PI has a currently approved ACC for this research. A motion to approve this protocol with the following conditions passed unanimously.

a. Condition: PI must contact Terry Lawrin (413-3701), biosafety officer at UIC, to schedule inspection of lab prior to initiation of studies.
b. Condition: PI must notify IBC of lab in which work will be conducted and where reagents related to project (e.g., vectors, etc.) will be stored.

03-012 - Development and Testing of siRNA -Based Therapeutic Agents-

Dr. Bowman stated that there were no concerns raised during the prereview process. The PI will be moving to new laboratory space and will need to have the new laboratory inspected prior to the initiation of studies in that laboratory. A motion to approve this protocol with the following condition passed unanimously.

a. Condition: When PI moves to new laboratory space [redacted], PI must contact Terry Lawrin (413-3701), biosafety officer at UIC, to schedule inspection of new lab prior to initiation of studies in that laboratory.

03-013 - Role of Cyclin-Dependent Kinases in Exit from Quiescence, Differentiation, Apoptosis and Oncogenesis-

Following discussion that concerns were raised during prereview that the work proposed in this protocol should be conducted at the BSL2 level and appropriate safety precautions needed to be described, Dr. Bowman directed the Committee to revisions submitted by the PI. The PI indicated that the work would be conducted at BSL2 and indicated the safety precautions that would be used during the conduct of the work. Dr. Bowman reminded the Committee that the PI would be inserting potential oncogenes into retroviral vectors, which is not recommended by the manufacturer of retroviral vectors. The consensus of the Committee was to reiterate that this should be done with caution due to the possibility of insertional mutagenesis. A motion to approve this protocol with the following caution passed unanimously.

a. Caution: The Committee reminds the investigator and personnel to use caution in handling retroviral vectors with potential oncogenes inserted due to the potential of infecting human cells when packaged using amphotropic, dualtropic, or pantropic packaging cell lines.

03-014 - Molecular Mechanisms Regulating Bile Duct Epithelia Response to Bile Duct Obstruction-

Following discussion that the PI had addressed the issues raised during prereview regarding attenuation of the vector, housing and use of infected animals, and safety precautions that would be used, a motion to approve this protocol pending the following concerns passed unanimously.

a. Please state that recombinant adenovirus will be transported from investigators lab to the [redacted] in a sealed container (e.g., plastic container with sealed lid).

03-016 - Lentiviral Delivery of GDNF and Bcl-2 in [redacted] Models of Parkinson's Disease-

The Committee discussed the concerns raised during the prereview process as to how the vector is attenuated, transport of the vector, safety precautions used during injection and training. The Committee also discussed that Bcl-2 could be a potential oncogene when mutated and a caution regarding its insertion into retroviral vectors should be reiterated to the PI. Following discussion, a motion to approve this protocol pending the following clarifications and caution passed unanimously.

a. Caution: The Committee reminds the investigator and personnel to use caution in handling retroviral vectors with potential oncogenes inserted due to the potential of infecting human cells when packaged using amphotropic, dualtropic, or pantropic packaging cell lines.
b. PI needs to expand description of precautions, especially during the injection phase into the brain. Describe personnel protective equipment.
c. Please discuss what has been done to vector to prevent transmission (e.g., specifically how has the vector been attenuated?).
d. Describe how the vector is transported to UIC. It should be transported in a sealed container.
e. Indicate who has received IATA training for shipping and receiving.
f. Indicate if all personnel handling materials have had bloodborne pathogen training. Indicate where training occurred and provide verification of training.

b. May Protocol Report-

03-017 - Discovery of Hematopoietic and Tumor Supressor Genes-

Dr. Bowman stated that there were no concerns raised during the prereview process for this protocol. A motion to approve this protocol passed unanimously.

03-018 - Functional Studies of Hematopoietic and Tumor Supressor Genes-

Dr. Bowman stated that the purpose of this protocol is similar to 03-017, however the PI would be inserting potential oncogenes into retroviral vectors using mammalian

packaging cell lines. The consensus of the Committee was to reiterate that this should be done with due caution due to the possibility of insertional mutagenesis. A motion to approve this protocol pending the following concerns and caution passed unanimously.

a. Caution: The Committee reminds the investigator and personnel to use caution in handling retroviral vectors with potential oncogenes inserted due to the potential of infecting human cells when packaged using amphotropic, dualtropic, or pantropic packaging cell lines.
b. In section II, check off use of vector-host systems using risk group 2 agents.
c. Please complete Form B and indicate specifically what safety precautions will be used to prevent accident gene transfer. (e.g., use of biosafety cabinet, personnel protective equipment).

03-019 - Gene Expression in Muscle Using Adenoviral-Mediated Gene Transfer-

Following discussion that the PI needed to indicate how virus was amplified, what safety precautions would be taken (waste and protective equipment) and clarify in whose laboratory the work would be conducted, a motion to approve this protocol was passed by all those eligible to vote in accordance with UIC policy and guidelines (1 abstention).

a. In Form A, in the section on protocol description, the following concerns need to be addressed:
    i. Please indicate how the virus will be amplified (e.g., which packaging cell line will be used?).
    ii. Please indicate the source of muscle genes (humans or rodents?).
    iii. Please indicate the origin of the cell lines to be used.
b. In Form B, section F, please indicate how the "viral" waste will be disposed and what protective measures will be used.
c. Please clarify in whose laboratory work will be conducted.

03-020 - Antibody-Directed Gene Delivery to the Pulmonary Circulation-

Following discussion that there were a significant number of concerns raised in the prereview process regarding the nature of vector to be used, that the PI did not currently have approval for rDNA use in animals, and the safety precautions that would be implemented, a motion to defer this protocol pending revisions prior to rereview by the Committee passed unanimously.

a. In Form A, section II, the following concerns need to be addressed:
    i. Use of rDNA in whole animals is checked. A more detailed description of what will be done in animals should be provided under protocol description section.

ii. ACC protocol 02-146 does not list the use of rDNA in animals. This protocol must be modified and appendix 2 submitted in order to use rDNA in whole animals.
iii. Vector-host box should be checked if PI is using BSL2 level virus.

b. In Form A, under protocol description, please provide additional information on murine leukemia virus or viruses that will be used. Indicate if virus is attenuated and if so, how it is attenuated. Please note that murine retroviral vectors that contain less than 50% of their respective parental viral genome and that have been demonstrated to be free of detectable replication competent retrovirus can be maintained, handled, and administered, under BSL1 containment. However, many commercially available vectors are produced from Moloney murine leukemia virus and manufacturer's recommendations are for use at BSL2 since there is risk of insertional mutagenesis.
c. PI needs to set-up a laboratory inspection with EHSO. Call Terry Lawrin at 3-3701. Please confirm whether laboratory contains biosafety cabinet.
d. If virus is BSL2, PI needs to complete a current Form B and indicate specifically what safety precautions will be used in the laboratory and at BRL. In addition, if BSL2, PI will need to house animals in Biohazard room at BRL.
e. Please contact Dr. Mary Bowman (996-7427) to discuss these concerns.

03-021 - Regulation of Muscle Gene Expression-

Following discussion that the PI needed to expand the description of the expression vector for kinase proteins and include genes of interest that will be used for constructs in the production of transgenic mice, a motion to approve this protocol pending the following clarifications passed unanimously.

a. In Form A, section I, remove check mark from first box.
b. In Form A, section on protocol description, the following concerns need to be addressed:
    i. Indicate if experiments involving expression vectors for kinases will be done in vitro or in vivo and which expression vectors will be used (plasmids?, viral vectors- which ones?).
    ii. If they will be used in vivo then ACC protocol 03-076 will need to be modified to include the expression of specific kinases.
    iii. Indicate the gene(s) of interest that will be used for transgenic production.

5. Adverse Event Reports-

[redacted]

[redacted]

6. **New Business-**

There was no new business for discussion by the Committee.

The meeting was adjourned at 3:30 PM.

Institutional Biosafety Committee
Minutes of
July 10, 2003
2:00 P.M.- Room 307 C AOB

PRESENT: Dr. Alexander Neyfakh (Chair), Dr. Aixa Alfonso, Mr. Richard Anderson, Dr. Paul Goldspink, Dr. William Henrickson, Dr. Lon Kaufman, Mr. Terrance Larwin, Ms. Geraldine Minley, and Dr. Maria Rudisch

ABSENT: Dr. Edward Cohen, Dr. Jeffrey Fortman, Dr. Thomas Hope, Dr. Randal Jaffe, and Ms. Sheila White

STAFF: Dr. Mary Bowman (absent), Ms. Joe Ann Ferguson

GUEST: [redacted]

1. **Announcements-**

   Dr. Neyfakh announced to the Committee that there were two new community members, Ms. Geraldine Minley and Dr. Maria Rudish. He asked the members of the Committee to introduce themselves.

   Dr. Neyfakh informed the Committee that the IBC website had been updated and all new polices and forms are now available. He also reminded the Committee that meetings would be on a monthly basis.

2. **Minutes of April 8, 2003-**

   The minutes of the May 15, 2003 meeting were approved pending minor editorial changes.

3. **Old Business-**

There was no old business for discussion by the Committee.

4. **Protocol Summary Reports-**

   a. **July 2003 Protocol Report**

03-020 - Antibody-Directed Gene Delivery to the Pulmonary Circulation -

The Committee discussed the following issues: 1) that there the original protocol was deferred due to lack of information on viruses to be used and animal work to be preformed, 2) that the first revision did not contain specific information on the virus used to determine biosafety level, 3) that the investigator had provided a second revision indicating that the virus was an amphotopic MoMu-retrovirus that was pseudotyped for only binding IgG and was incapable of infecting human cells due to lack of the envelope protein and that the PI would receive the viral vector in this manner, 4) that the laboratory had been inspected and was only suitable for BSL1 with the current arrangement, and 5) that the PI should be reminded that any modification in the protocol needed to be submitted to the Committee for approval prior to initiation. Following this discussion, the Committee approved the protocol.

03-023- Expression of Recombinant Plant Proteins -

The Committee discussed the following issues: 1) that enzymes involved in photosynthesis were being studied, 2) that the PI had experience with the proposed recombinant techniques, 3) that the safety office had major concerns related to the organization of the laboratory and the overall poor results of this investigator on safety issues during general laboratory inspections, 4) extensive discussion related to the charge of the IBC in safety matters related to issues outside of assessing the biological risk of the proposed project and 5) whether the Committee or the EHSO should address these issues. Following this discussion, the Committee approved the protocol and agreed that by consensus that the investigator should improve the safety condition of the laboratory.

5. Adverse Event Reports-

a. Protocol 02-023-

Dr. Neyfahk directed the Committee's attention to the incident report related to protocol 02-023. The Committee discussed the incident that occurred in the PI's laboratory on June 19, 2003 related to a housekeeping worker who was injured by a Pasteur pipette that punctured a biohazard bag. Mr. Anderson and Mr. Lawrin indicated that the pipettes had not been disposed of in the proper manner. Mr. Lawrin directed the Committee's attention to the notice from the [redacted] Facilities Manager and stated that this would be an appropriate method of disposal. Dr. Neyfakh suggested that the Committee should sent the PI a letter reiterating the appropriate method by which sharps waste should be disposed. The committee was in agreement of this suggestion.

b. Protocol 01-018-

Dr. Neyfahk informed the Committee that an adverse event had occurred on related [redacted]

c. Protocol 98-026-

Dr. Neyfahk directed the Committee's attention to the report [redacted]

6. New Business-

There was no new business for discussion by the Committee.

The meeting was adjourned at 3:00 PM.

Institutional Biosafety Committee
Minutes of
August 14, 2003
2:00 P.M.- Room 307 C AOB

PRESENT: Dr. Alexander Neyfakh (Chair), Mr. Richard Anderson, Dr. Jeffrey Fortman, Dr. William Henrickson, Dr. Randal Jaffe, Dr. Lon Kaufman Mr. Terrance Larwin, Dr. Maria Rudisch and Ms. Sheila White

ABSENT: Dr. Aixa Alfonso, Dr. Edward Cohen, Dr. Paul Goldspink, Dr. Thomas Hope, and Ms. Geraldine Minley

STAFF: Dr. Mary Bowman

1. **Announcements-**

   There were no announcements.

2. **Minutes of July 10, 2003-**

   The minutes of the July 10, 2003 meeting were approved pending minor editorial changes.

3. **Old Business-**

   a. **Notice to Principal Investigators on Modifications-**

   Dr. Bowman informed the committee that all approval letters contain language which specifically informs investigators that they must report significant modifications to their protocol to the IBC office prior to initiation of the change and that in some instances, the modification must be approved by the IBC prior to initiation of the change.

   b. **Charge of the IBC-**

   Dr. Bowman informed the committee that the charge of the IBC was to evaluate research involving rDNA and/or the use of infectious agents and to assess the biological risk of that research. This charge did not include an assessment of the chemical risk of the research or extend to chemical hazards in the laboratory. She also informed the committee that the University was initiating a campus-wide committee, which would undertake the chemical safety aspects into account.

c. **Update on Protocol 03-023-**

Mr. Lawrin informed the Committee that he had contacted the PI and due to vacations schedules, the PI and he had not met yet to discuss cleaning the PI's laboratory. He planned to recontact the PI to set a meeting and put a plan of action in place.

4. **August Protocol Summary Reports-**

I-02-080- Downstream Effectors of BRCA1-Depedent Genomic Instability- Modification-

Following discussion that the PI was requesting to use a virus which was not infectious to vertebrates to infect insect cells to express proteins of interest and that this modification had less risk than studies already approved on the protocol, a motion to approve this modification passed unanimously.

I-03-005- Influence of DNA Methylation on Replication and Growth of Bacteria with Mutiple Chromosomes- Modification-

Following discussion that the PI was requesting to extend the list of organisms under study, that the new organisms had properties similar to those already approved and that no rDNA work would be conducted with the new organisms, a motion to approve this modification passed unanimously.

I-03-024- Stress Response to Catechol Estrogen Metabolites Role in Carcinogenesis

Following discussion that there was significant information missing from the description of the protocol to adequately evaluate it, a motion to defer the protocol passed unanimously. Deferral was with the understanding that clarifications needed to be addressed prior to rereview.

a. Biosafety Level should be listed at BSL2.
b. All Personnel working with human cell lines need to complete Bloodborne pathogen training on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.

c. Vector types (plasmids, retroviral, etc.) should be identified. If project used category type II vector-hosts, then nature of vector needs to be described (e.g., wild-type, attenuated- if so, how?, host range, packaging cells, etc.).
d. Safety procedures for using BSL2 level reagents need to be indicated as well as decontamination procedures.

I-03-025- Adenoviral Vectors for Metabolic Gene Infection in Isolated Heart Cells and In Vivo Rat

The following issues were discussed: 1) E1 and E3 genes are the most common deletions in Ad 5 vectors and these genes are deleted because E1 controls replication and its removal renders the virus replication deficient and E3 is commonly removed to allow larger genes to be inserted into the vector, 2) that information should be provided on the IBC web site to inform investigators of the need for BBP training and shipping and receiving training as it is common clarifications on many protocols, and 3) additional details related to the waste stream (e.g., bedding, cages, etc.) should be included in the protocol under safety precautions. Following discussion, a motion to approve the protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Section VI. e, please address the following concerns:
    i. Please indicate that rats infected with adenoviral vectors will be maintained in [redacted] biohazard room for the 72 hours post-injection.
    ii. Please indicate that all infected animals will be maintained in microisolator cages and manipulated in Biosafety Cabinet.
    iii. Please indicate that all cages in which infected animals will be housed will be processed in a manner consistent with [redacted] Standard Operating Procedures for handling biohazard contaminated materials.
b. Appendix 1, please address the following concerns regarding personnel training:
    i. All personnel working with animals on this protocol will need to undergo biohazard training at [redacted] with [redacted]. If this training has already been completed, please indicate when it was completed (month, year).
    ii. All personnel working on protocol need to undergo Bloodborne Pathogen training on a yearly basis. Please provide verification of training. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.
    iii. Personnel in laboratory who are responsible for shipping and receiving potentially infectious agents (adenoviral vectors and packaging cells) need to provide verification of shipping and receiving training. Training is required every two years.

Contact Terry Lawrin, UIC biosafety officer, at 996-3701 for training disc.

iv. Several additional personnel are listed on ACC protocols 00-102 and 03-115. If these personnel will work with infected animal cells in vitro or infected animals, they must be listed on this IBC protocol and all training issue listed above would apply.

I-03-026- Effect of Dynamic Magnetic Fields and Zinc Gluconate in Human Pathogens E. Coli and S. Aureus-

Following discussion that there was not adequate information provided to evaluate the protocol, a motion to defer this protocol passed unanimously. Deferral was with the understanding that clarifications needed to be addressed prior to rereview.

a. In Section I. a, please indicate the type of bacteria that will be used and the strains used.
b. In Section I. e, please indicate the location of lab in which work will take place.
c. In Section I. f, please indicate the location of lab in which bacteria will be stored.
d. In Section I. h, please indicate the highest BSL required for the project.
e. In Section II a, b, and c, please provide a more extensive explanation of the work being conducted and the safety procedures used. With this information provided, the committee can not adequately review this protocol.
f. Appendix 1, please complete personnel appendix as indicated on form.

I-03-027- Molecular Analysis of Motor Proteins and Regulatory Pathways-

Following discussion that the project should be conducted at BSL2 and that all personnel needed BBP training and shipping and receiving training by members of the laboratory needed to be completed, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. Please provide documentation from company on attenuation of vectors (e.g., packaging inserts or information from instructions on kits may contain this information).
b. Section II, box 1 should be check for use of adenoviral vectors.
c. Section V. c, BSL should be marked as 2. Project uses human and green monkey cells and adenoviral vectors. All of these require BSL2.
d. Section VI should be completed.
e. Appendix 1, please address the following concerns:
    i. All Personnel working with human cell lines need to complete Bloodborne pathogen training on a yearly basis. Please

provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.

ii. Personnel in laboratory who are responsible for shipping and receiving potentially infectious agents (adenoviral vectors and packaging cells) need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 996-3701 for training disc.

I-03-028- Biochemical Study of Na, K-ATPase and hCTR1 (Supported by: GM039500-17, HL30315-20, GM07166-01)

Following discussion that Bacmid was a plasmid and that if human cell lines are used that all personnel needed BBP training, a motion to approve the protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Section IV. c, please address the following concerns:
   i. Please indicate if all vectors are plasmids or are some vectors derived form Risk Group 2, 3 or 4 agents. Section II of protocol indicates that these type of vectors/host will be used. If so, please elaborate on these vectors in section Ivc.
   ii. Please indicate what DNA is being cloned from a Risk Group 2, 3, or 4 agent and what agents it will be cloned. Section II of protocol indicates that this type of work will be conducted.
   iii. Indicate the source of cell lines (e.g., dog, human, etc.).
b. Appendix 1, all personnel working with human cell lines need to complete Bloodborne pathogen training on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.

I-03-029- Recombinant Protein Production

The following issues were discussed: 1) that this protocol was a master protocol for the [redacted] and that specific modifications would need to be submitted and reviewed by the chair and BSO or their designees prior to the initiation of individual projects and 2) that administratively approved modifications to this protocol would be reported to the committee via the monthly report. Following discussion, a motion to approve this protocol was passed by all those eligible to vote in accordance with UIC policies and procedures (1 abstention). Approval was with the understanding that it is pending the following clarifications.

a. Condition: This protocol when all clarifications have been addressed will be approved as a master protocol. Modifications will be required for each new project that is proposed. The modifications must be submitted and approved prior to initiating the new projects.
b. Section II box 1, this should be checked if viral vectors will be used (SV40, EBV).
c. Section IV a, protocol should indicate that this is a service laboratory and that this is a master protocol. The protocol should also indicate that modifications will be submitted and approved prior to initiation of each new project.
d. Section IV c, please address the following concerns:
    i. Indicate which natural exchangers will be used. Some natural exchanges in the NIH Guidelines list are Risk Group 2 agents.
    ii. Indicate the source of the genes that will be expressed. Will any be from Risk Group 2, 3, or 4 agents? Will any toxins be expressed?
    iii. Please indicate the maximum volumes that will be handled.
e. Section V. c, BSL 2 should be checked. A number of the cell lines indicated are of human or non-human primate origin and require BSL 2.
f. Section VI, please complete this section and indicate specifically safety practices.
g. Appendix 1, all personnel working with human cell lines need to complete Bloodborne pathogen training on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.

I-03-030- Bacterial Virulence Testing of 5 Strains of Sphingomonas Elodea

[redacted]

5. Adverse Event Reports-

Dr. Bowman directed the Committee's attention to the summary report of adverse events on protocol 01-013. [redacted]

6. New Business-

a. IBC Manual-

Dr. Bowman informed the Committee that she had prepared a reference manual for the Committee to use as a resource guide. The manual contained copies of the NIH Guidelines, the BMBL, the OSHA Bloodborne pathogen standard and the UIC Exposure Control Plan related to the standard, all UIC IBC Policies and Forms. She stated that at the next meeting the UIC Biosafety Manual would also be distributed.

The meeting was adjourned at 3:10 PM.

Institutional Biosafety Committee
Minutes of
September 11, 2003
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Alexander Neyfakh (Chair), Mr. Richard Anderson, Dr. Edward Cohen, Dr. Jeffrey Fortman, Dr. Paul Goldspink, Dr. Randal Jaffe, Mr. Terrance Larwin, Ms. Geraldine Minley, Dr. Maria Rudisch and Ms. Sheila White

ABSENT: Dr. Aixa Alfonso, Dr. William Hendrickson, Dr. Thomas Hope, and Dr. Lon Kaufman

STAFF: Dr. Mary Bowman

GUEST: [redacted]

1. **Announcements-**

Dr. Bowman informed the Committee that the PI of protocol 03-035 would be attending a portion of the meeting to address any concerns the committee had regarding his protocol. Drs. Neyfakh and Cohen indicated that they would participate in the discussion of this protocol, but would abstain from voting on the protocol due to conflicts of interest.

Dr. Bowman also informed the Committee that discussion of an Emergency Spill Policy would be tabled until the October to allow for adequate discussion of the policy due to the anticipated length of this meeting.

2. **Minutes of August 14, 2003-**

The minutes of the August 14, 2003 meeting were approved pending minor editorial changes.

3. **Old Business-**

   a. **Update on Protocol 03-023-**

Mr. Lawrin and Mr. Anderson informed the Committee that EHSO had met with the PI of protocol 03-023 and the department head regarding the PI's laboratory. Mr. Anderson stated that the meeting was productive and that the PI is working on addressing concerns that were raised in previous inspections. Mr. Anderson also stated that the PI's laboratory would be reinspected on

October 22, 2003 and the Committee would be informed of the outcome of that inspection at the November meeting.

b. Update on Protocol 03-030-

Dr. Bowman informed the Committee that the IBC office had received additional information from the PI of protocol 03-030 [redacted]

4. **September Protocol Summary Reports-**

I-03-033- Artifical Ligands for the Nuclear Import Receptor Importin Alpha and Unnatural Amino Acid Mutagenesis-

Dr. Neyfakh informed the Committee that this BSL1 protocol involving rDNA research exempt from NIH Guidelines was approved by expedited review according to UIC policies and procedures.

I-03-024- Stress Response to Catechol Estrogen Metabolites Role in Carcinogenesis

Following discussion that this protocol had been deferred at the August meeting and that the PI had addressed all concerns of the Committee including the issues regarding the vectors to be used, the BSL the project should be conducted at, the decontamination procedures and BBP training, a motion to approve this protocol passed unanimously.

I-03-031- Detection of Virulent Mycobacterium in Mice BCG Vaccine

Following discussion that the PI would only be handling sample lots of live bacteria that were in the final testing prior to release by the FDA for marketing, that for greater than

15 years no animal had died due to virulent mycobacterium, and that based on the BMBL only handling of cultures or procedures involving aerosolized delivery needed to be conducted at BSL3, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form B, item I h, please indicate that BSL2 with BSL3 practices will be used for manipulation of the vaccine (e.g., filling syringes, diluting samples) and injection of animals.
b. In Form B, item II b, please indicate what will happen to animals post-injection (e.g., how are they monitored and for how long?). Also, please indicate what specimen work (e.g., dilution of vaccine) will occur at UIC. PI should indicate that all work will take place in biosafety cabinet.
c. PI needs to complete Appendix 1 for personnel training. Personnel will require training in BSL3 practices, please indicate how this will occur.

I-03-032- Regulation of Mitogenesis and Apoptosis by G12 and G13 Proteins

Following discussion that the protocol involved the use of cell lines of human and nonhuman primate origin and should be conducted at BSL2 and that personnel required BBP training, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. Some of the cell lines are BSL2 (all cell lines of human origin and COS cells) and these aspects of the project need to be conducted at BSL2.
b. Some of the cell lines are of human origin. All Personnel working with human cell lines need to complete Bloodborne pathogen training on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.

I-03-034- A Phase I Dose-Ranging Study of the Safety, Tolerability, and Immunogenicity of the [redacted] Trivalent Adenovirus Serotype 5 HIV-1 gag/pol/nef Vaccine in a Prime-Boost Regimen

Following discussion that [redacted]

I-03-035- Therapeutic Interventions Against SARS-CoV-

The PI of this protocol attended this portion of the meeting to discuss the nature of the work and address concerns by the Committee members. The Committee introduced

themselves to the PI. The PI provided an overview of the importance of the work, the overall goal of the research, and the steps that his laboratory has taken in preparation for starting this work (e.g., hiring a postdoctoral associate with BSL3 experience, discussion with another colleagues at UIC conducting BSL3 research). The Committee discussed with the PI how the samples of live virus would be handled in the laboratory, the amount of live virus that would be handled, the procedures for transport of virus for irradiation, the procedures for verifying that all virus was killed by irradiation, the procedures for training personnel, the procedures for decontamination and spills, and the procedures for an exposure control plan. The Committee thanked the PI for the additional information provided and informed him that he would be notified of the Committee's decision in writing. Following the PI's departure, the Committee further discussed that the work conducted with rDNA would need to be at BSL3 since the virus could not be irradiated prior to isolation of the RNA, that the nature of the rDNA work needed to be clarified, and that the PI needed to provide in writing detailed standard operating procedures for all aspects of the project involving use of live virus. Following this discussion, a motion to approve this protocol was unanimously passed by all those eligible to vote in accordance with UIC policies and procedures (2 abstentions). Approval was with the understanding that it is pending the following clarifications and these clarifications would be reviewed by a special subcommittee consisting of Committee members, Dr. Fortman, Dr. Goldspink, Dr. Hope, Mr. Lawrin, Dr. Neyfakh, and outside reviewer, [redacted] with the authority to approve or require further clarification in the revised protocol.

a. In Form A, item 1, please remove number from box 3 as no human studies will be conducted.
b. In Form A, item IV a, it is not clear in which species polyclonal antibodies will be raised. If the polyclonal antibody production refers to the initial test bleeds of mice prior for determination of antibody titer, this should be clear. If it refers to production in rabbits, this should also be clear. Please indicate that a protocol will be submitted to the ACC for review and approval of animal work prior to initiation of these aspects of this protocol. Also, this suggests that the only purpose for rDNA is for production of Spike protein for injection, but section A IV c, suggests that in vitro transformation studies will be done. What is the purpose of those studies?
c. In Form A, item IV c, please provide a more **detailed** description of how RNA will be isolated for preparation of rDNA. This will need to be done starting with live virus, as irradiated virus will have too much nucleotide damage to be useful. Description should also include how the purity of RNA (no live virus) will be documented. Describe the work that will be conducted at BSL3 vs. BSL2 levels.
d. In Form A, item V a, the location of work must be in the BSL 3 facility as it will start with live virus.
e. In Form A, item V c, the highest level must be BSL3 as it will again start with live virus. Also, work with non-human primate and human cell lines must be done at BSL2; therefore the lowest level is BSL2.In Form A, item VI a and b, complete these answers.

f. In Form A, item VI c, SARS is considered a human pathogen, box 3 should be also be marked.
g. In Form A, item VI d, please indicate which protein or proteins will be produced.
h. In Form A, item VI e, please indicate specific BSL 3 practices. The practices listed are fine for BSL2, but use of a biosafety cabinet should be included.
i. In Form B, item I c, please list the maximum volume of live virus that will be handled and that will be in the lab at any one time.
j. In Form B, item I g, SARS is not a select agent, but a it's use and access is controlled. This should be marked "NO".
k. In Form B, item III b, the following concerns need to be addressed:
    i. Provided detailed standard operating procedures (SOP) for procedures involving live virus. These should include the following:
        1. Personnel Protective Equipment SOP- Include all equipment that should be worn when handling or working around live virus.
        2. Amplification of Virus SOP- Include all steps for handling and use.
        3. Transportation of Virus for Irradiation SOP- Include containment packaging and the caveat that if the packing is accidentally dropped during transport, it will be returned to the biosafety cabinet for examination of possible breakage prior to going to the irradiator.
        4. Irradiation of Virus SOP- this should include the volume and concentration of virus to be irradiated, the number of rads, and the time of exposure, as well as, a justification for using that amount of irradiation (e.g., how do you know that amount will kill the virus?). Due to the variable amount of irradiation that will be received within the unit depending on placement and volume, the Committee suggests that the PI consult with a physicist prior to preparing this SOP.
        5. Verification of Complete Inactivation of Virus SOP- Include the specific doses (volume/concentration) that will be tested with an indication that the highest dose will be at least 100-fold greater than what will be injected into mice, as well as, the length of time each test will be run (e.g., 2 weeks). Also, since cell lysis is a "bioassay", the committee requests that the PI also perform a more sensitive test to document viral death.
        6. Exposure Control Plan SOP- Please consult with the [redacted] to develop this plan.
        7. Neutralizing Studies- Include all steps for handling and use.
        8. Accidental Spill Plan- Indicate how spills will be handled.

ii. A description of the work to be conducted in mice with irradiated virus should be listed here. Please indicate that a protocol will be submitted to the ACC for review and approval of animal work prior to initiation of these aspects of this protocol.

l. In Form B, item III c, the following concerns need to be addressed:
   i. Please indicate that all infected waste will be decontaminated daily by autoclaving.
   ii. Please indicate how Biosafety Cabinet will be decontaminated.
   iii. Please indicate that Emergency Plans (Accidental Spill, Exposure Control) and Decontamination Plan will be posted in laboratory.

m. In Appendix 1, the following concerns need to be addressed:
   i. Please list new personnel that the PI has hired for the project along with qualifications. Remove to be hired from protocol.
   ii. Please indicate the training that will take place with EHSO regarding biosafety and respiratory apparatus training. Please provide verification for all personnel that that training has been completed.
   iii. Bloodborne pathogen training is required for the use of human cell lines. Please provide verification of that training.
   iv. Please indicate that new personnel will be added to the protocol via a letter of modification to the chair of the IBC and that prior to working with live virus all training most be verified by the IBC.

5. Adverse Event Reports-

No Adverse Events were reported.

6. New Business-

No new business was discussed.

The meeting was adjourned at 3:50 PM.

Institutional Biosafety Committee
Minutes of
October 9, 2003
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Alexander Neyfakh (Chair), Dr. Aixa Alfonso, Mr. Richard Anderson, Dr. Edward Cohen, Dr. Jeffrey Fortman, Dr. Paul Goldspink, Dr. William Hendrickson, Dr. Thomas Hope, Dr. Randal Jaffe, Ms. Geraldine Minley, Dr. Maria Rudisch and Ms. Sheila White

ABSENT: Mr. Terrance Larwin and Dr. Lon Kaufman

STAFF: Dr. Mary Bowman

1. **Announcements-**

Mr. Anderson informed the Committee that the Federal Aviation Administration was beginning to fine institutions that were not properly enforcing the International Air Transport Association (IATA) Training for shipping and receiving of infectious biological hazards. He reminded the Committee that IATA training must be verified for protocols, which require shipping or receiving of infectious biological hazards by air.

Dr. Bowman informed the Committee there was a handout of revisions to protocol 03-048, which would be discussed under item 4.

2. **Minutes of August 14, 2003-**

The minutes of the September 11, 2003 meeting were approved pending minor editorial changes.

3. **Old Business-**

No Old Business

4. **October Protocol Summary Reports-**

I-03-038- Analysis of Products of E. Coli Genes-

I-03-049- Contractile Protein Biochemistry-

Dr. Neyfakh informed the Committee that the BSL1 protocols involving rDNA research exempt from NIH Guidelines referenced above were approved by expedited review according to UIC policies and procedures.

I-03-016- Lentiviral Delivery of GDNF and Bcl-2 in Monkey Models of Parkinson's Disease- Modification-

Dr. Neyfakh informed the Committee the PI was requesting a modification to his currently approved protocol to perform intracranial delivery of rhesus stem cells transfected with lentivirus expressing GDNF (ex vivo transfection) and that transfection would be conducted at [redacted] and transfected cells would be shipped directly to [redacted]. The current protocol was approved for direct delivery of lentivirus into the brain. A motion to approve this protocol passed unanimously.

I-03-036- BRK/Sik Tyrosine Kinase Signaling in Oral Cancer-

Following discussion that a more detailed description of the stable transfection experiments was required and that verification that all personnel working with human cells had completed bloodborne pathogen training was required, and that for the website and forms needed to include training information, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IV c, a description of the stable transfection experiments needs to be provided. (e.g., What will be done? Which vectors will be used?) If PI is using retroviral vectors, then Form A, II, box 1 should be checked.
b. In Form A, item VI e, please complete this section listing the BSL 2 procedures that will be used for this project.
c. All Personnel working with human cell lines need to complete Bloodborne pathogen training on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.

I-03-037- Studies on the DDB and Cullin Genes-

Following discussion that additional details regarding the adenoviral and retroviral vectors needed to be included, that there appeared to be confusion as to whether rDNA would be administered directly to animals or whether this involved production of transgenic animals, and that IATA training needed to be completed, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item II, box 1, this should be checked for the use of adenoviral and retroviral vectors.
b. In Form A, item IV c, the following concerns need to be addressed:
    i. Please provide a more complete description of the adenoviral and retroviral vectors to be used.
    ii. The research aspect involving animals is not clear.
        1. If PI will be conducting studies on whole animals, elaborate on what will be injected and for what purpose. Additionally, neither ACC number provided (02-069 & 02-212) is approved for administration of rDNA to whole animals. One or both ACC protocols will need to be modified if this work is to be done.
        2. If PI will not be administering rDNA to whole animals, then the Box in Form A, section II should not be marked and ACC numbers should be removed from this section. Note: This section does not refer to the production of transgenic animals. This is covered in Form A, item III.
        3. If PI is making constructs that will be used to create transgenic animals this should be indicated. If transgenic animals are already produced or the RRC will produce the transgenic for PI, then details of transgenic production (e.g., injection of embryos) do not need to be included in this section.
c. In Form A, item V c, BSL should be 2 for use of adenoviral and retroviral vectors.
d. In Form A, item VI, this section must be completed in total. Also, several sources of DNA are listed in item IV, but only one source is listed here. Please clarify. Personnel in laboratory that are responsible for shipping and receiving potentially infectious agents (adenoviral vectors and packaging cells) need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 996-3701 for training disc.

I-03-039- Cloning Non-Toxic Genes in Baker's Yeast and E. Coli K-12 Hosts-

Following discussion that the PI should elaborate on the description of the studies being conducted, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IV c, the description of the studied being conducted should be elaborated. Please clarify what is actually being measured or assayed in these experiments?
b. In Appendix 1, please indicate the number of years of experience personnel have with these procedures.

I-03-040- Pdp1 Gene in Drosophia Growth and Development-

Following discussion that the type of vectors used and the containment conditions for transgenic flies needed to be indicated, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IV c, please indicate the types of vectors used (e.g., plasmids?) and the types of expression systems (e.g., yeast?, E.coli K-12?). What precautions are used for containment of transgenic flies?
b. Appendix 1, please complete for all personnel working with rDNA in the laboratory.

I-03-041- The Molecular Biology of Selective Ciliates-

Following discussion that the PI had addressed the clarifications raised during prereview, a motion to approve this protocol passed unanimously by all those eligible to vote in accordance with UIC policies and procedures (1 abstention).

I-03-042- Regulation of [redacted] Uterine Proteins During Implantation-

Following discussion that the PI had addressed the clarifications raised during prereview, a motion to approve this protocol passed unanimously by all those eligible to vote in accordance with UIC policies and procedures (1 abstention).

I-03-043- Secretions of the Mammalian Oviduct-

Following discussion that the PI had addressed the clarifications raised during prereview, a motion to approve this protocol passed unanimously by all those eligible to vote in accordance with UIC policies and procedures (1 abstention).

I-03-044- Glycosyltransferases and Their Products-

Following discussion that the work should be conducted at BSL2 due to the use of human cells and that verification that all personnel working with human cells had completed bloodborne pathogen training was required, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item II, please check boxes 6 and 8 if they apply.
b. In Form A, item V c, please check BSL2 for the use of human cell lines.

c. In Form A, item VI e, please answer for BSL2 work.
d. All Personnel working with human cell lines need to complete Bloodborne pathogen training on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.

I-03-045- Regulation of Brain Inflammatory Gene Expression-
Following discussion that the work should be conducted at BSL2 due to the use of human cells and that verification that all personnel working with human cells had completed bloodborne pathogen training was required, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item V c, please check BSL2 for the use of human cell lines.
b. In Form A, item VI e, please answer for BSL2 work.
c. All Personnel working with human cell lines need to complete Bloodborne pathogen training on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.

I-03-046- Regulation of Phospholipase C Epsilon and Its Role in Pathophysiological Disorders-

Following discussion that the work should be conducted at BSL2 due to the use of human cells and that verification that all personnel working with human cells had completed bloodborne pathogen training was required, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item VI e, PI should indicate that athymic mice will be injected in a biosafety cabinet.
b. All Personnel working with human cell lines need to complete Bloodborne pathogen training on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.

I-03-047- Stress-Impaired Oxygen Dependent Transcription in Wounds

Following discussion that there were insufficient details provided to determine if human studies were going to be conducted, what animal studies were proposed, who was

working on protocol and verification of bloodborne pathogen training, a motion to defer this protocol passed unanimously. Deferral was with the understanding that it is pending the following clarifications prior to rereview.

a. In Form A, item II, provide an ACC number covering studies in whole animals.
b. In Form A, item IV c, the following concerns need to be addressed:
    i. Please expand the description of the laboratory work regarding the human studies. What human studies will be conducted? Only in vitro? Cell lines? Primary cultures?
    ii. Please indicate whether all vectors will be plasmid vectors including those used in the laboratory.
    iii. Please indicate which genes will be used in vivo in animal models and which animal model will be used (e.g., how will wounds be created and treated. Also, whether some "treatments" will exacerbate the healing process.
c. In Form A, item V c, this should be marked BSL2 if any human tissues or cell lines will be used.
d. In Form A, item VI a-e, this appears to be inconsistent with other information provided, as some genes should be isolated form human sources, which are not indicated here. In addition, item e must be completed for BSL 2 work.
e. Appendix 1, please complete this appendix for all personnel working under this protocol.
c. All Personnel working with human cell lines need to complete Bloodborne pathogen training on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.
f. Laboratory will require an inspection from EHSO. Please contact Terry Lawrin at 413-3701 to schedule inspection.

I-03-048- Sequence Analysis of Duck Hepatitis Type 1- Associated Adenovirus-

Following discussion that subsequent to prereview the PI had submitted a revised protocol addressing some of the issues raised by the reviewers, that the intended purpose of the protocol was to isolate and sequence an associated adenovirus and that the a condition that the PI would need to seek IBC approval if additional work with live virus or rDNA were to be done and whether this type of hepatitis was infectious to humans, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications and condition.

a. In Form B, item I a, please clarify if duck hepatitis type 1 virus is the same as any of the human hepatitis viruses. If so, which one?

b. In Form B, item I d, is the hepatitis type I virus or the associated adenovirus thought to be pathogenic to humans or is this unknown? If it is not pathogenic to humans, then RG 1 should be marked.
c. Condition: This protocol will be approved for the isolation of DNA from the sample and determination of the identity of the adenovirus associated with the sample. Should additional work involving live virus or rDNA need to be done, a modification of this IBC must be submitted and approved prior to initiation of that work.

I-03-050- Evaluation of Plant Extracts and Pure Compounds as Inhibitors of HIV-1 Replication-

Following discussion that this was a well-written through protocol, that there were no concerns raised during prereview, and whether the PI would need to ship or receive any infectious agents, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was with the following condition.

a. Condition: Prior to receiving additional infectious agents for this protocol or shipping samples containing infectious agents, PI must complete IATA shipping and receiving training. Please contact the UIC biosafety officer, Terry Lawrin, at 413-3701 regarding this training. Once training is complete, a copy of the verification of training should be submitted to the IBC office as documentation.

I-03-051- Screening of Plant Extracts and Pure Compounds as Inhibitors of Plasmodium Falciparum-

Following discussion that this was a well-written protocol, that there was only a minor clarification raised during prereview, and whether the PI would need to ship or receive any infectious agents, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarification and condition.

a. In Form B, item II c, PI should indicate that all manipulations of mice take place in biosafety room within a biosafety cabinet.
b. Condition: Prior to receiving additional infectious agents for this protocol or shipping samples containing infectious agents, PI must complete IATA shipping and receiving training. Please contact the UIC biosafety officer, Terry Lawrin, at 413-3701 regarding this training. Once training is complete, a copy of the verification of training should be submitted to the IBC office as documentation.

I-03-034- A Phase I Dose-Ranging Study of the Safety, Tolerability, and Immunogenicity of the [redacted] Trivalent Adenovirus Serotype 5 HIV-1 gag/pol/nef Vaccine in a Prime-Boost Regimen-

The Committee discussed the following issues: 1) that the PI and Sponsor had addressed the concerns of the Committee from the previous meeting, 2) that in other clinical trials viral shedding had not be seen, 3) that the probability of a transcomplementation or recombination event was very low with a concomitant active adenoviral infection, 4) that the probability was equally as low or lower of a double recombination event with concomitant adenovirus and HIV infections and was not seen in HIV infected patients, 5) that the consent form had addressed the risks associated with human gene therapy, and 6) whether a request for an autopsy needed to be part of this type of consent form. Following discussion, a motion to approve this protocol passed unanimously.

5. Adverse Event Reports-

[redacted]

6. New Business-

Dr. Bowman reminded the Committee that according to the *NIH Guidelines* that one of the responsibilities of the Committee was to adopt emergency plans covering accidental spills and personnel contamination resulting from rDNA research. She stated that these plans should also cover infectious agents as this was now part of the charge of the IBC. Dr. Bowman directed the Committee's attention to the excerpt from UIC Biosafety Manual on Biohazardous Material Spills, Section 5.12 and portions of Appendix E. The meeting was adjourned at 3:50 PM. She stated that this excerpt contained a thorough plan for dealing both small and large spills in and outside of the biological safety cabinet and within a centrifuge, as well as, a special appendices for BSL3 laboratories. Following discussion that the current plan in the biosafety manual was complete and consistent with CDC recommendations and other federal regulations, a motion to adopt the UIC Biosafety Manual's Plans on Biohazardous Material Spills Section 5.12 and Appendix E- Biosafety Level 3 Spill Protocol passed unanimously.

The meeting was adjourned at 3:50 PM

Institutional Biosafety Committee
Minutes of
November 13, 2003
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Alexander Neyfakh (Chair), Dr. Aixa Alfonso, Dr. Jeffrey Fortman, , Dr. William Hendrickson, , Dr. Randal Jaffe, Mr. Terrance Larwin, Ms. Geraldine Minley, Dr. Maria Rudisch

ABSENT: Mr. Richard Anderson, Dr. Edward Cohen, Dr. Paul Goldspink, Dr. Thomas Hope, Dr. Lon Kaufman, and Ms. Sheila White

STAFF: Dr. Mary Bowman

1. **Announcements-**

The Committee reviewed membership of the IBC and attendance at monthly meetings. Dr. Bowman discussed with the Committee how pre-review forms and protocols would be sent to reviewers. In the future, prereview forms will be emailed to each reviewer and the protocols will be delivered via fax.

2. **Minutes of October 9, 2003-**

   The minutes of the October 9, 2003 meeting were approved pending minor editorial changes.

3. **Old Business-**

   a. **Update on Protocol 03-034-**

Dr. Bowman informed the Committee that [redacted]

   b. **Update on Protocol 03-035-**

Dr. Bowman informed the Committee that the special subcommittee formed by the IBC for review of revisions to protocol 03-035 had reviewed two rounds of revisions and approved this protocol.

4. **November Protocol Summary Reports-**

I-03-052- Roles of Cell Cycle Control Proteins in Mouse Development and Tumorigenesis

Following discussion that the PI had addressed all of the concerns raised during pre-review, except for bloodborne pathogen training (BBPT) of all personnel listed on the protocol, that aspects of the protocol may not involve use of human cells and require BBPT, that approval letters of this and other protocols with a similar issue should restrict use of human cells/tissues to those that are trained, a motion to approve this protocol with the following condition passed unanimously.

> Condition: The following personnel are approved for use of materials (human cells) requiring bloodborne pathogen training (BBPT): *List of personnel with BBPT.* As additional personnel are trained, please forward verification of training to the IBC office so that approval can be updated. Note that OSHA requires yearly BBPT.

I-03-053- Regulation of Uterine Proteins During Implantation in the [redacted]
Following discussion that the description of the work did not include any reference to baboons and should be elaborated upon and that the project should be conducted at BSL2 and required verification of BBPT, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item IV c, the description of the work being conducted is incomplete. There is no mention of [redacted] in this section or elsewhere in the protocol, but title indicates that work involves [redacted]. Please clarify. Also, how does in situ hybridization relate to rDNA in this protocol. Are probes being generated from plasmids? Please elaborate on the techniques being used (e.g, which cell types will be transfected, etc.?).
b. In Form A, item V c, please check BSL2 for the use of human cell lines.
c. In Form A, item VI e, please answer for BSL2 work.
d. Appendix 1 for all personnel working on the project needs to be completed.
e. All Personnel working with human cell lines need to complete Bloodborne pathogen training on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.

I-03-054- Signal Transduction Mechanisms in Muscle Cells

Following discussion that the PI had address all of the Committee's concerns, except BBPT of all personnel, and that the genes of interest were cloned from the mouse, a motion to approve this protocol with the following condition passed unanimously.

> Condition: The following personnel are approved for use of materials (human cells) requiring bloodborne pathogen training (BBPT): *List of personnel with BBPT.* As additional personnel are trained, please forward verification of training to the IBC office so that approval can be updated. Note that OSHA requires yearly BBPT.

I-03-055- Role of Forkhead Box (Fox) and Hepatocyte Nuclear Factor 6 (HNF-6) Transcription Factors in Mouse Liver Regeneration, Differentiation and Cancer

Following discussion that the PI had addressed a portion of the concerns raised during prereview, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item II, box 4, ACC protocol 03-030 does not include the use of rDNA in whole animals. This number should be removed from this section or a modification to this ACC protocol must be submitted to add this procedure. Since it is indicated in the protocol that you do not plan to do this now in whole animals, the Committee suggest removing this number. The procedure can be added to this protocol and the ACC protocol at a future date by submitting modifications to both. If you choose to list protocol 02-044, then a description of what will be done to the animals regarding rDNA injections needs to be put in Form A, item IV c and the safety precautions need to be listed in Form A, item VI e.
b. In Form A, item VI e, please answer for BSL2 work. This section needs to also include the specific practices and procedures used in the laboratory (e.g., biosafety cabinet, gloves, masks, and decontamination procedures).
c. Please indicate whether or not packaging cell lines are of human origin. If so, then all Personnel working with human cell lines need to complete Bloodborne pathogen training on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.
d. Personnel involved with shipping and receiving of potential infectious agents (adenoviruses and retroviruses) must complete IATA shipping and receiving training or provide documentation of completion within last 2 years. Please contact the UIC Biosafety Officer, Terry Lawrin, at 413-3701 to obtain information on IATA training.

I-03-056- Gene Regulation in Yersinia Enterocolitica

Following discussion that the facilities listed were not adequate for BSL2 procedures, due to lack of a sink in the room, that the bacteria would need to be transported between the hood and the incubator in the PI's laboratory and transport procedures were not described and the procedures occurring in the PI's laboratory were not outlined, a motion to defer this protocol passed unanimously. Deferral was with the understanding that it was pending the following clarifications prior to rereview.

a. In Form A, item IV c, the following concerns need to be addressed:
    i. Please elaborate on what type of preparations will be transported to room [redacted]. All cultivation or work involving open containers with live bacteria must be conducted within the biosafety cabinet in an appropriate room.
    ii. Describe the transport of infectious materials and rDNA from one laboratory to another. How will these materials be contained? How will personnel be prepared for potential spills during transport?
    iii. Please elaborate on whether or not transfection with virulence genes will make E. coli strains or Yersinia enterocolitica more virulent? If so, in what will this occur?
b. In Form A, item V a, the facilities in room [redacted] are not adequate for BSL2 work. A handwashing station must be present within the BSL2 laboratory (where the work is being conducted ([redacted]). Either a plumbed handwashing station must be installed or a new room with biosafety cabinet must be specified for this work. Biosafety cabinet certification for the cabinet in room [redacted] is out-of-date. Cabinet must be recertified and documentation of certification needs to be provided.
c. In Form A, item VI e, please describe clean-up procedures. Is hood decontaminated after use and if so, how?
d. Appendix 1 for all personnel working on the project needs to be completed.
e. If additional work with Yersinia enterocolitica that does not involve rDNA will also be conducted, the PI must also complete IBC Form B.

5. Adverse Event Report-

There were no adverse events for discussion.

6. New Business

a. Human Gene Transfer Protocols Facilities-

Dr. Bowman directed the Committee's attention to the documents related to a course on human gene transfer. She stated that the course information provided contained specific information as to one institution's practices for human gene transfer studies and various

articles on safety precautions needed for human gene transfer studies. Mr. Lawrin stated that UIC needed to establish a policy for these types of studies as to how and where they can be conducted and what precautions are needed to protect the subject receiving the human gene therapy, the personnel administering the therapy and potentially those who are in contact with the personnel receiving the human gene transfer product. The Committee extensively discussed whether the IBC should establish a policy or guidelines for human gene transfer studies, whether each type of vector and how it's delivered should be considered, whether it was the within their charge, and whether additional expertise should be sought in the establish of a policy or guideline for human gene transfer studies. The Committee also discussed what type of facilities and precautions are needed for different types of studies including protocol 03-034. It was the consensus of the Committee that a letter be drafted to the institutional official recommending that a special subcommittee be appointed to develop guidelines for human gene transfer studies. The letter should indicate that the subcommittee should at a minimum consist of IBC members, as well as, representatives from hospital infection control, employee health service and the section of infectious disease.

The meeting was adjourned at 3:15 PM

Institutional Biosafety Committee
Minutes of
December 11, 2003
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Alexander Neyfakh (Chair), Dr. Aixa Alfonso, Mr. Richard Anderson, Dr. Mary Bowman, Dr. Jeffrey Fortman, Dr. Paul Goldspink, Dr. Thomas Hope, Mr. Terrance Larwin, Dr. Maria Rudisch and Ms. Sheila White

ABSENT: Dr. Edward Cohen, Dr. William Hendrickson, Dr. Randal Jaffe, and Dr. Lon Kaufman, and Ms. Geraldine Minley

1. **Announcements-**

Dr. Bowman informed the Committee that she had been appointed to the Committee as a voting member by the Institutional Official. Dr. Bowman also informed the Committee that there were two additional items for discussion under new business. Modification of protocol 02-046 was added as item a and Certification of Biosafety Cabinets was added as item b under new business, respectively.

2. **Minutes of November 13, 2003-**

The minutes of the November 13, 2003 meeting were approved pending minor editorial changes.

3. **Old Business-**

No Old Business

4. **December Protocol Summary Reports-**

I-03-060- Role of Ypt Gtpases in Vesicular Transport

Dr. Neyfakh informed the Committee that the BSL1 protocol involving rDNA research exempt from NIH Guidelines referenced above was approved by expedited review according to UIC policies and procedures.

I-03-057- Usage of Recombinant Adenovirus to Express Genes in Mice

Following discussion that the PI needed to indicate how the adenovirus was rendered replication incompetent, that the PI needed to indicate that the animal work was

conducted in a biosafety cabinet and that verification of BBP and IATA training was required, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IVc, please indicate how the adenovirus was made replication defective (e.g. what's missing?).
b. In Form A, item VI e, please indicate the animals are injected and maintained in the BRL biosafety room.
c. All Personnel working with human cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. *Note: verification of College of Dentistry BBPT training qualifies.* If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.
d. Personnel in laboratory that are responsible for shipping and receiving potentially infectious agents (adenoviral vectors and packaging cells) need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 996-3701 for training disc.

I-03-058- Genetic Methods of Remedying Disease-

Following discussion that it was unclear as to whether the PI was conducting whole animal studies and if so, that these studies had not been described, that the PI had not described the retroviruses being used and how they are rendered replication defective, that description of the project was needed to be elaborated upon and that the PI had not signed the assurances, a motion to defer this protocol passed unanimously. Deferral was with the understanding that it is pending the following clarifications prior to rereview.

a. In Form A, item II box 3, this section indicates that whole animals will be used; however, the description in Form A IV c does not contain any indication of in vivo studies involving animals. If whole animal studies will not be conducted, remove the check from the box and the "pending" form the protocol number.
b. In Form A, item IV a, the description of the project needs to be elaborated upon. An extremely broad range of genes, when defective or mutated could cause disease. Is the PI focusing on specific classes of genes or specific diseases?
c. In Form A, item IV c, the following concerns need to be addressed:
    i. If whole animal studies will be done provide a brief overview of the animal studies (e.g., animal model used, what's injected, how and where procedures take place).
    ii. Describe the source of the retrovirus used (e.g., MMLV) and how the virus is made replication defective (e.g., what's missing?)

d. In Form A, please list date of last lab inspection.
e. In Form A, item VI e, 70% ethanol is considered a poor disinfectant. Use of 10% bleach or an EPA listed disinfected is required. However, please note that items which are autoclaved should not be exposed to bleach prior to autoclaving as dried bleach can be explosive. In addition, this section should indicate where studies involving animals will take place and where animals will be maintained.
f. In Form A, item VII a, b, and c, signatures are missing from first three assurance. These must be signed.
g. All Personnel working with human cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.
h. Personnel in laboratory that are responsible for shipping and receiving potentially infectious agents (adenoviral vectors and packaging cells) need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 996-3701 for training disc.
i. Condition: Prior to initiation of any studies involving whole animals, the PI must submit and have approved an ACC protocol for this project. In addition, Prior to initiating the studies involving the use of MHV the PI is required to review/develop containment procedures with Dr. Artwohl to minimize the potential the MHV is introduced into the MBRB barrier facility.
j. Caution: The Committee reminds the investigator and personnel to use caution in handling retroviral vectors with potential oncogenes inserted due to the potential of infecting human cells when packaged using amphotropic, dualtropic, or pantropic packaging cell lines.

I-03-059- Botanical Dietary Supplements for Women's Health (NIH/NCCAM P50 Center)-

Following discussion that the laboratory needed to be inspected, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, please list date of last lab inspection. Please contact Mr. Terry Lawrin, UIC biosafety officer, at 413-3701 to schedule an inspection.
b. All Personnel working with human cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule. PLEASE note that pending completion of inspection, final approval letter will restrict approval for use of human cell lines to those who have completed BBPT.

I-03-061- Molecular Basis of PAX3-FKHR Induced Oncogenesis-

Following discussion that although the PI had only listed cell lines of mouse origin, cell lines of nonhuman primate origin might be used in the context of this protocol based on conversation with BSO which would require BSL2 conditions and that this point needed clarification, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

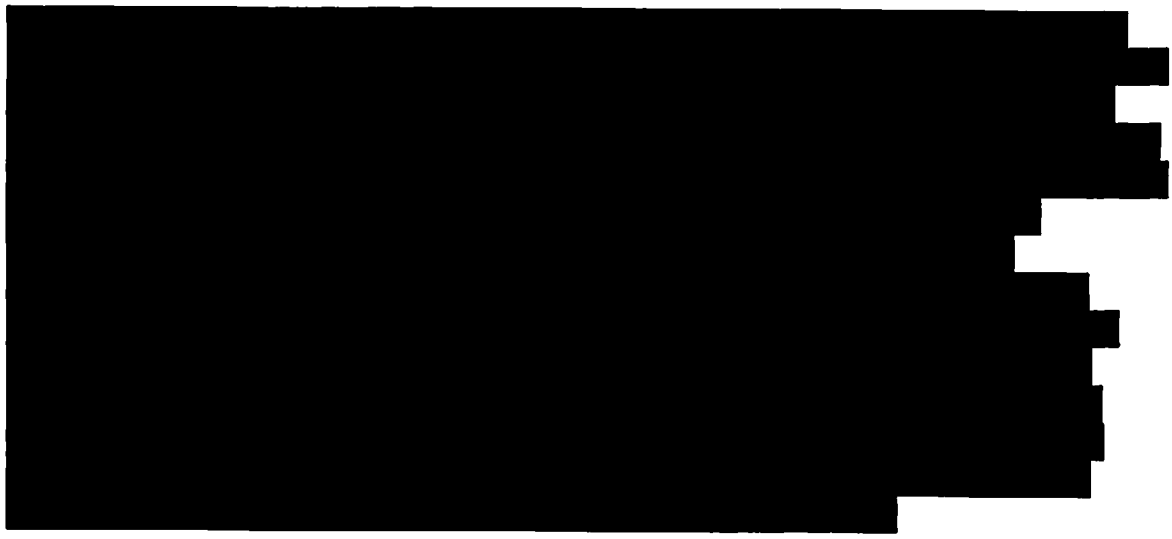
a. In From A, item IV c, the Committee requests that the PI indicate ALL the various cell lines with species' origins that will be used in the laboratory under THIS protocol (e.g., mouse, human, nonhuman primate). Please note that human and nonhuman primate cells require BLS2 and that the facilities listed are not adequate for BSL 2. A plumbed eyewash station is not available. If BSL requires 2, then this must be changed in Form A, item V c and Form A, item VI e must be answered.
b. If any of the cell lines listed above are of human or nonhuman primate origin, then all personnel using those cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. *Note: verification of* [redacted] *BBPT training qualifies.* If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.
c. Please contact Dr. Mary Bowman, Assistant Director for IBC, at 996-7427 with questions regarding the Committee's concerns.

I-03-062- AAV-Neurturin as a Treatment for Parkinson's Disease: Studies in [redacted]-

Following discussion that the BSL should be 2 due to [redacted] work, and that the PI had requested to add a second neurotrophic factor, NGF, in the same vector to the protocol, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item V c, please check BSL 2. Although the vector is RG1, packaging in human cell lines and work with nonhuman primates constitutes BSL2 work.
b. In Form A, item VI c, please check RG1 for adeno-associated virus.

03-030- Bacterial Virulence Testing of 5 Strains of Sphingomonas Elodea (*Modification 03-030-01*)



02-005- Interferon Signaling (*Modification 02-005-01*)

Following discussion that the PI was requesting to upgrade approval to BSL2 for the use of retroviral and lentiviral vectors, that the PI had one laboratory that was adequate for BSL2 procedure and needs to specify that the BSL2 work will be conducted in that laboratory, that the PI needs to clarify which vector will be used, that Appendix 1 should be provided and verification of BBPT and IATA training should be provided, a motion to approve this modification passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. The second page of the modification included a vector map and information on pLenti-hU6BX, but this vector was not listed in the modification request. Please clarify if this vector will also be used.
b. The PI should specify that BSL 2 work will be conducted in [redacted] as this lab meets all the criteria necessary for BSL2 work.
c. Please complete IBC Appendix 1 available on the IBC website at http://www.uic.edu/depts/ovcr/oprs/ibc/index.html for all personnel working under this IBC protocol.
d. All Personnel working with human cell lines (Phoenix Packaging Cells) need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.
e. Personnel in the laboratory that are responsible for shipping and receiving potentially infectious agents (lentiviral vectors and packaging cells) need to provide verification of shipping and receiving training. Training is required every two years. Contact [redacted] for training disc.
f. Caution: The Committee reminds the investigator and personnel to use caution in handling retroviral vectors with potential oncogenes inserted due to

the potential of infecting human cells when packaged using amphotropic, dualtropic, or pantropic packaging cell lines.

I-03-034- A Phase I Dose-Ranging Study of the Safety, Tolerability, and Immunogenicity of the [redacted] Trivalent Adenovirus Serotype 5 HIV-1 gag/pol/nef Vaccine in a Prime-Boost Regimen (*Modification I-03-034-01*)-

[redacted]

5. **Adverse Event Reports-**

[redacted]

6. **New Business-**

   a. **I-02-046- Biotransformation of Estrogens to Carcinogenic Quinoids (*Modification I- 02-046-01*)-**

Dr. Bowman informed the Committee that the PI was requesting to add an additional location for rDNA work and to upgrade the protocol to BSL2 for the use of human cell lines. The Committee discussed the laboratory needed to be inspected and that verification of BBPT needed to be provided.

a. In Form A, please list date of last lab inspection. Please contact [redacted] to schedule an inspection.
b. All Personnel working with human cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule. Please note that pending completion of inspection, final approval letter will restrict approval for use of human cell lines to those who have completed BBPT.

b. Certification of Biosafety Cabinets-

Mr. Lawrin informed the Committee that there are a number of companies that certify biosafety cabinets. He stated that a number of these companies hire certifiers who are not certified in accordance with the National Sanitarian Foundation (NSF) Standard 49. The *NIH Guidelines* default to NSF recommendations for biosafety cabinets. He recommended to the Committee that the IBC adopt a policy that only technicians who have undergone NSF Standard 49 certification be approved for certification of UIC biosafety cabinets. A motion to approve this policy was unanimously approved. The EHSO and the IBC office will coordinate providing information on approved vendors on their respective websites and to investigators.

The meeting was adjourned at 3: 30 PM

Institutional Biosafety Committee
Minutes of
January 8, 2004
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Aixa Alfonso (Chair-designee), Mr. Richard Anderson, Dr. Mary Bowman, Dr. Edward Cohen Dr. Jeffrey Fortman, Dr. William Hendrickson, Dr. Thomas Hope, Mr. Terrance Larwin, Ms. Geraldine Minley, Dr. Maria Rudisch and Ms. Sheila White

ABSENT: Dr. Alexander Neyfakh, Dr. Paul Goldspink, Dr. Randal Jaffe, and Dr. Lon Kaufman

1. **Announcements-**

Dr. Bowman informed the Committee that Dr. Neyfakh would not be attending today's meeting and Dr. Alfonso would be serving as chair-designee. Dr. Bowman also indicated that she was pursuing new Committee members to replace committee members who have asked to resign due to reassignment of duties. She announced that an update of modification 03-034-01 was added to the agenda under old business as item a.

2. **Minutes of December 11, 2003-**

The minutes of the December 11, 2003 meeting were approved pending minor editorial changes.

3. **Old Business-**

   a. **Update on Modification 03-034-01-**

[redacted]

4. **January Protocol Summary Reports-**

I-03-063- New Drug Discovery for Tuberculosis: Whole Cell and Target-Based Approaches-

Following discussion that this was a BSL3 project, and that although the PI had provided a detailed biosafety manual, the manual or an appendix to the manual needed to include how infected mice and exposed cages were transported to [redacted], how the cages were decontaminated and that infected mice were housed in [redacted] biohazard room, a motion to approve this protocol was unanimously passed by all those eligible to vote in accordance to UIC policies and procedures (1 abstention). Approval was with the understanding that it is pending the following clarifications.

a. In Form B, item III c, either in the ITR Biosafety Manual or in a separate appendix, please include information as to how infected mice and TB exposed cages are transported between the laboratory and the [redacted]. This should include the procedures(s) used by the investigator's laboratory for disinfecting the transport container.
b. In Form B, item III c, PI should indicate where in the [redacted] infected mice are maintained.

I-03-064- Regulation of Neurotransmitter Release in C. Elegans-

Following discussion that it was not clear if the PI was doing cell culture or injections of plasmid DNA into only whole worms, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item III, boxes for use of rDNA outside of living organisms for use in transient and stable transfection of cells in culture were checked. However, the work described in A IV c indicates that worms are used. If cell culture is used, please elaborate on which cells are used in Form A, IV c. If whole worms are injected, then these boxes should not be checked.
b. In Form A, item III, the box for natural exchangers was checked. Please refer to the list of natural exchangers shown in Appendix A of the NIH Guidelines. Please list which natural exchangers are being used in Form A, IV c.
c. In Form A, item IV c, please describe the vectors used. Are they all of plasmid origin? If not, please indicate the origin of the vectors and whether any are of microbial origin? If any of the vectors are of microbial origin, please describe vector and indicate if and how they are attenuated.
d. In Form A, item V a and item V b, please indicate the room and building in which work will be conducted and in which rDNA molecules will be stored, respectively.
e. In Form A, item V c, please list the highest biosafety level required for the project. If BSL2 is required, then section VI a-e must be completed.
f. Please complete Appendix 1 for personnel.

I-03-065- Studies on the Biology of Selenium-

Following discussion that the biosafety level for this protocol should be 2 due to the use of human cell lines, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item V c, biosafety level should be 2 for use of human cells.
b. In Form A, item VI e, complete this section for use of human cells.
c. All Personnel working with human cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.

I-03-066- Regulation of Metabolism and Gene Expression by Insulin and Growth Factors-

Following discussion that this project was being conducted at the [redacted] and that it had been approved by their research committee, that UIC should request verification that the laboratory at the [redacted] is appropriate for BSL2 work and a copy of the last inspection report if available for the file, and that ACC approval for animal aspects of this project would be required from both UIC and the [redacted], a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. Please provide a letter of verification from [redacted] safety office that laboratories listed on the protocol are approved for BSL2 work. Also, please include a copy of the last [redacted] laboratory inspection report.
b. All personnel working with human cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. If PI and personnel have completed bloodborne pathogen training within the last year at the [redacted], please include verification of that training. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.
c. Personnel in the laboratory that are responsible for shipping and receiving potentially infectious agents (adenoviral and retroviral vectors, and packaging cells) need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 996-3701 for training disc.
d. Please indicate if PI has submitted a modification to the [redacted] IACUC for this work. A condition for initiation of work involving animals will be approval of both the UIC and [redacted] IACUCs.

I-03-067- The Cytoskeleton in Signal Transduction

Following discussion the PI needed to elaborate on the type of adenoviral vector being used and IATA training was required for shipping and receiving, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

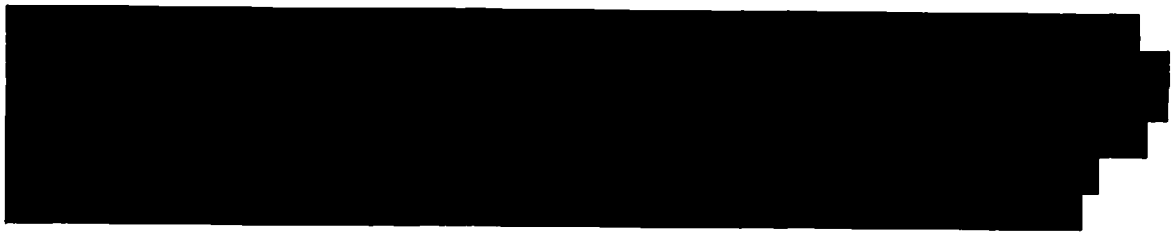
a. In Form A, item IV c, please provide a more detailed description of the adenoviral vectors being used. Which vectors? Are they attenuated and if so, how? In which cell type are they packaged?
b. Please provide a copy of the work order for the eye wash station installation.
c. Personnel in laboratory that are responsible for shipping and receiving potentially infectious agents (adenoviral vectors and packaging cells) need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 996-3701 for training disc.

I-03-068- Transient Receptor Potential Channels in Brain Neurons

Following discussion that the host organism for cloning needed to be indicated and that the protocol did involve human cells, but not other infectious agents, a motion to approve this protocol was unanimously passed by all those eligible to vote in accordance to UIC policies and procedures (1 abstention). Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IV c, please indicate which bacteria or other host is used for cloning.
b. In Form A, item V c, biosafety level should be 2 for use of human cells.
c. In Form A, item VI e, complete this section for use of human cells.
d. Appendix 1 for personnel needs to be completed.
e. All Personnel working with human cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.

I-03-069- [redacted]



I-03-070- Ultrastsructure and Function of Nerve and Muscle

Following discussion that the host organism for cloning needed to be indicated and whether any vectors other than plasmids were being used, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IV c, please indicate which bacteria or other host is used for cloning. Also, please clarify if only plasmid vectors are used. If vectors of microbial origin (e.g., adenoviral or retroviral vectors) are used, then these must be described in this section and clarification f would apply.
b. In Form A, item V c, biosafety level should be 2 for use of human cells.
c. In Form A, item VI e, complete this section for use of human cells.
d. Appendix 1 for personnel needs to be completed.
e. All Personnel working with human cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.
f. Personnel in laboratory that are responsible for shipping and receiving potentially infectious agents (e.g., adenoviral vectors) need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 996-3701 for training disc.

I-03-071- Pathophysiology of Early Events in Islet Transplantation

Following discussion that a description of how the adenoviral vector is attenuated needed to be provided and that personnel involved with animal portions of the project would need to undergo orientation to the [redacted] biohazard facility, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IV c, please indicate how adenoviral vector has been attenuated (e.g., what's missing?).
b. In Form A, item VI e, please indicate that mice will be housed in [redacted] biohazard room post-inoculation.
c. Personnel in laboratory that are responsible for shipping and receiving potentially infectious agents (adenoviral and lentiviral vectors and packaging cells) need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 996-3701 for training disc.
d. Condition: PI and laboratory personnel involved in animal work must undergo training/orientation to [redacted] biohazard room with Dr. [redacted] prior to initiation of animal work.

I-03-072- Structure Function Relation of Contractile Proteins

Following discussion that the species of origin for the cells used in cloning experiments needed to be identified, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IV c, please provide information as to species of origin and nature of BL21(DE3) and pLysS cells.

I-03-073- Antimicrobial Activity of Methotrexate in a Rabbit Model of Staphylococcus Epidermidis Induced-Endophthalmitis

Following discussion that appropriate safety precautions needed to be indicated in the protocol, and that the laboratory needed to be inspected, a motion to approve this protocol passed unanimously. Following discussion that Approval was with the understanding that it is pending the following clarifications.

a. In Form B, item III c, please address the following concerns:
    i. Please indicate that appropriate eyewear protection will be worn during handling and injection of staphylococcus epidermidis.
    ii. Please correct error regarding disposal of syringes into biohazard bag. All syringes, along with needles, must be disposed of into a sharp's waste container.
    iii. Please verify the location in which mice will be infected and the location at [redacted] in which mice will be housed.
    iv. Please provide ACC number that corresponds to this project.
b. Please contact biosafety officer, Terry Lawrin, at 413-3701, to arrange an inspection of laboratory.

c. All personnel working with potential infectious bloodborne pathogens need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.
d. Personnel in laboratory that are responsible for shipping and receiving potentially infectious agents need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 996-3701 for training disc.

5. Adverse Event Reports-

None to report

6. New Business-

None to report

The meeting was adjourned at 3:05 PM

Institutional Biosafety Committee
Minutes of
February 12, 2004
3:00 P.M. - Room 307 C AOB

PRESENT: Dr. Mary Bowman (Chair-designee), Mr. Richard Anderson, Dr. Edward Cohen, Dr. Jeffrey Fortman, Dr. Paul Goldspink, Dr. William Hendrickson, Dr. Thomas Hope, Dr. Randal Jaffe, Dr. Roberta Mason-Gamer, and Dr. Maria Rudisch

ABSENT: Dr. Aixa Alfonso, Mr. Terrance Larwin, Ms. Geraldine Minley, Dr. Alexander Neyfakh, and Ms. Sheila White

1. **Announcements-**

Dr. Bowman informed the Committee that Drs. Neyfakh and Alfonso were not able to attend today's meeting and that she would serve as the chair-designee. Dr. Bowman announced that human gene transfer renewal was added to the agenda, under new business as item c. She also indicated that the wrong version of protocol 03-056 had been distributed to the Committee and that the revised version was being distributed at the meeting.

Dr. Bowman announced to the Committee that Dr. Roberta Mason-Gamer was joining the Committee and would replace Dr. Lon Kaufman as the plant expert on the Committee. She asked the Committee members to introduce themselves.

2. **Minutes of January 8, 2004-**

The minutes of the January 8, 2004 meeting were approved pending minor editorial changes.

3. **Old Business-**

None this month

4. **February Protocol Summary Reports-**

03-056- Gene Regulation of Yersinia Enterocolitica-

The Committee discussed the following issues: 1) that the previous version of the protocol had been deferred because the room purposed for the work did not meet the qualifications for BSL2 work and that the PI had addressed this major concern by

switching rooms in which the work would be conducted, 2) that the biosafety cabinet in the new room needed to be recertified, and 3) that the transport of infectious material should be in a secondary container. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item VI e, flasks need to be transported in a secondary container that is sealed (e.g., Tupperware type container). Also, biosafety cabinet should be wiped with 10% bleach and then alcohol for decontamination.
b. For room identified for work, biosafety cabinet needs to be recertified. Certification is out of date. Certifier must be NSF 49 certified. Please contact IBC office at 996-7427 or Terry Lawrin, UIC biosafety officer at 413-3701 for list of certifiers that qualify.

I-04-001- Expression of Exogenous Genes in Mouse Skeletal Muscle Cells-

The Committee discussed the following issues: 1) that the PI was using AAV serotype 2, which is a RG1 agent according to NIH Guidelines, 2) that AAV vectors insert into the host genome and could potentially result in mutations depending on the insertion site, 3) that the packaging cell lines were human, 4) that the laboratory work should be conducted at BSL2, but the animals could be housed under BSL1 conditions, and 5) that BBP training was required. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. General Comment- Although AAV serotypes 1-4 are considered a risk group 1 virus. These vectors can insert into the host genome including humans; therefore, the possibility of insertional mutagenous exists. Moreover, the packaging cell lines used for AAV are human cell lines. Therefore, the laboratory aspects of this project should be conducted at BSL2. Once injected, animals may be housed under BSL1 conditions.
b. In Form A, item IV c, please address the following concerns:
    i. Please elaborate on the species of origin of the cell lines used for both stable and transient in vitro transfection studies. Also, elaborate on how AAV containing genes of interested are cloned. What packaging cell line is used for this purpose?
    ii. Please elaborate on the organism used for cloning of plasmid vectors (e.g. what strain of E. coli are you using?).
    iii. Please identify which serotype of AAV is being used.
    iv. Please indicate where animals will be housed and where they will be inoculated (In PI's lab or in animal facilities?).
c. In Form A, item V c, this section should be marked for BSL2.
d. In Form A, item IV e, this section should also be answered for BSL2 work.

e. All Personnel working with human/primate cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.
f. For questions regarding these clarifications, please contact Dr. Mary Bowman at 996-7427.

I-04-002- Eukaryotic Iron Metabolism and Regulation

Following discussion that Dr. Bowman had contacted the PI to clarify that the PI was only using cDNA from Sendai virus and not live virus and that this should be clarified in the protocol and that BBP training and BSL2 was required, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item IV c, please address the following concerns:
    i. Please identify the nature of the shuttle vectors used.
    ii. Please identify the species of origin of the cell lines used for both stable and transient in vitro transfection studies
    iii. Please indicate from where the cDNA clones for Sendai virus P/C mRNA were obtained. It should be made clear that PI is not working with live Sendai virus.
b. In Form A, item V c, this section should be marked for BSL2 for use of COS cells and potentially human cell lines.
c. In Form A, item IV e, this section should be addressed for BSL 2 work. COS cells must be handled under BSL2 conditions.
d. All Personnel working with human/primate cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.
e. Appendix 1 for personnel needs to be completed.

I-04-003- Nociceptive Response in Naked Mole-Rats

The Committee discussed the following issues: 1) the facilities identified in the protocol required installation of an eyewash station and 2) the biosafety cabinet required recertification. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item IV c, please indicate the source of attenuated replication incompetent vectors (e.g., from what company are they being obtained or is PI making vectors himself?). Is PI transporting vectors from collaborator's laboratory? If so, vials containing vector should be transported in sealed non-breakable containers (e.g., Tupperware type container).
b. In Form A, item VI c, bleaching for 1 hour is appropriate for decontamination of cages and vessels. If PI wishes to autoclave after bleaching, containers must be rinsed with water prior to autoclaving.
c. For room identified for work, biosafety cabinet needs to be recertified. Certification is out of date. Certifier must be NSF 49 certified. Please contact IBC office at 996-7427 or Terry Lawrin, UIC biosafety officer at 413-3701 for list of certifiers that qualify.
d. For room identified for work, a plumbed eyewash station needs to be available. Please contact Terry Lawrin for additional details on where station needs to be installed.

I-04-004- New Antibiotic Inhibitors of the B. Anthracis Ribosome

The Committee discussed the following issues: 1) that the PI had used the wrong title for this protocol and the correct title was "Interaction with Ribosomes", 2) that the PI needed to elaborate on the purpose and background for this protocol and 3) that the PI needed to provide a personnel appendix for this protocol. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, project title, please correct the project title to reflect the nature of the work being conducted.
b. In Form A, item IV a, please expand on the overall purpose of this research.. Please link the overall purpose to the title.
c. In Form A, item IV b, please elaborate on the scientific background and goals of the project.
d. In Form A, item IV c, please address the following concerns:
    i. Please elaborate on the origin of the reporter constructs. Will these only be developed from nonpathogenic E. Coli?
    ii. Please elaborate on the nature of the vectors used for the reporter constructs. Are these all plasmid vectors?
e. Appendix 1 for personnel must be completed.

I-04-005- New Antibiotic Inhibitors of the B. Anthracis Ribosome-

The Committee discussed the following issues: 1) that the PI needed to identify the source of the rRNA, 2) that the source of peptides needed to be identified, and 3) that the personnel appendix needed to be complete. Following discussion, a motion to approve

this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

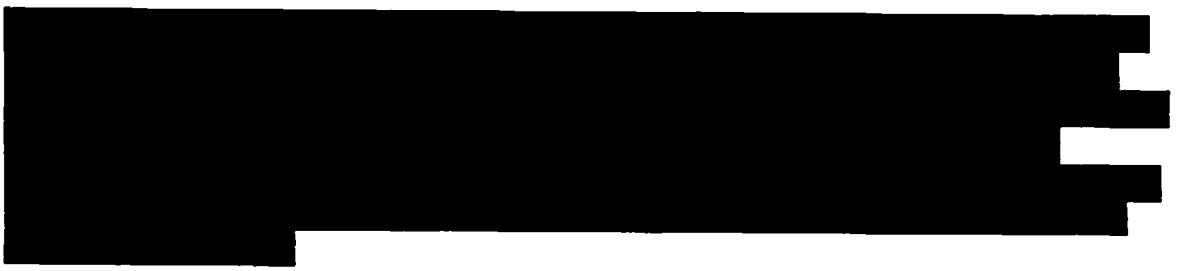
a. In Form A, item IV c, please address the following concerns:
    i. Please indicate that mutator E. Coli strain is nonpathogenic.
    ii. Please elaborate on how cell-free translation assays with B. Anthracis rRNA will be conducted once peptides that bind to synthetic nucleotide chains are identified. Will rRNA be isolated from B. Anthracis for this purpose or from a related bacterial strain? Be specific about which bacterial stains will be used. Also, be sure to indicate if any are virulent and/or attenuated and is so how.
    iii. Please elaborate on the source of the peptides to be used for testing. Are these new potential therapeutics? Known inhibitors of protein synthesis?
    iv. Please indicate which rRNA will be used to test organic compound interactions.
b. Appendix 1 for personnel needs to be completed.

I-04-006- Genomic Imprinting and the Regulation of Embryonic Growth

Following discussion that there were only minor concerns that needed to be addressed, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item II, do not mark box for whole animal use, this does not apply to transgenic animals.
b. In Form A, item IV c, indicate that transgenic or knockout animals are made by RRC upon receiving construct or embryonic stem cells from PI.

5. Adverse Event Reports-



6. New Business-

[redacted]

b. Sunshine Project Request-

Dr. Bowman informed the Committee that UIC along with approximately 400 other institutions registered with NIH OBA had received a request for IBC meetings from December and January meetings under Section IV b7 of the NIH Guidelines. She stated that the Sunshine Project was an organization concerned with biodefense issues. She also indicated that she had informed University Council and was awaiting their response.

c. Human Gene Transfer Protocol Renewal-

[redacted]

The meeting was adjourned at 3:45 PM

Institutional Biosafety Committee
Minutes of
March 11, 2004
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Aixa Alfonso (Chair-designee), Dr. Mary Bowman, Dr. Edward Cohen, Dr. Paul Goldspink, Dr. Randal Jaffe, Mr. Terrance Larwin, Dr. Roberta Mason-Gamer, Ms. Geraldine Minley, Dr. Maria Rudisch, and Ms. Sheila White

ABSENT: Mr. Richard Anderson, Dr. Jeffrey Fortman, Dr. William Hendrickson, Dr. Thomas Hope, and Dr. Alexander Neyfakh

1. **Announcements-**

Dr. Bowman informed the Committee that Dr. Neyfakh was unable to attend today's meeting, but was expected back next month. Dr. Alfonso would serve as the chair-designee. Dr. Bowman announced Ms. Geraldine Minley was resigning from the Committee and thanked her for her serve to the IBC.

Dr. Bowman also informed the Committee that University Council had approved the release of December and January minutes to the Sunshine project. Committee member's names, telephone information and proprietary information would be redacted from the minutes.

2. **Minutes of February 12, 2004-**

The minutes of the February 12, 2004 meeting were approved pending minor editorial changes.

3. **Old Business-**

None

4. **March Protocol Summary Reports-**

04-007- Analysis of Multiple Chimeric Transcripts in the t (3;21)-

Following discussion that this project involved ex vivo transplantation of various transcription factors involved in human leukemia using MSCV that is replication incompetent and ecotropic packaging into murine cells, that BBPT training and IATA training were needed, and that a brief description of the whole animal work should be

provided, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item II, please update ACC protocol number to 04-017.
b. In Form A, item IV c, please add a brief description of the whole animal work. For example, indicate the hematopoietic cells will be harvested from mice, stably transfected in vitro with ecotropic vectors, and cells injected into irradiated mice for grafting.
c. In Form A, item V c, biosafety level should be 2 for use of human (Phoenix) and primate (COS) cells.
d. In Form A, item VI e, please complete for BSL2 work.
e. All Personnel working with human/primate cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.
f. Personnel in laboratory that are responsible for shipping and receiving potentially infectious agents need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 413-3701 for training disc.

I-04-008- Aging and Molecular Response to Stress in the Immune System-

Following discussion that the work as described appears to BSL1 and that the PI should elaborate on why BSL2 was marked, that the source of samples for Northern blots should be specified, and if human, then BBP training would apply, and that the [redacted] biosafety Committee provide a letter indicating that the laboratory is appropriate for the biosafety level proposed, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item III, please check the following boxes:
    i. Use of rDNA outside living organism and check other and specify Northern blots.
    ii. Cloning of DNA from a eukaryotic source not known to be infected with a pathogenic agent and propagating it using plasmids in nonpathogenic prokaryotic source.
b. In Form A, item V c, work described only requires BSL1, please indicate why BSL2 was marked. Please elaborate on the source of rDNA and the source of samples used for Northern analysis. Use of samples from humans would constitute BSL 2.
c. In Form A, item VI c, JM 109 is considered RG1 and is not a plant pathogen. Please check correct boxes.
d. In Form A, item VI c, please indicate how biohazards are decontaminated (e.g., autoclaving).

e. Please provide a letter from [redacted] safety committee that laboratory facilities at [redacted] are appropriate for biosafety level proposed.
f. Appendix 1 for personnel needs to be provided.
g. If samples are isolated from human cells/tissue and PI or personnel in lab are doing the isolation, then all personnel working with human/primate cell lines, samples or tissues need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.

I-04-009- Gene Expression in Epithelial Tissues-

Following discussion that the biosafety level should be 2 and BBP training was required for human cells, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item V c, biosafety level should be 2 for use of human cell lines.
b. In Form A, item VI e, please complete for BSL2 work.
c. All Personnel working with human/primate cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.
d. Appendix 1 for personnel needs to be provided.

I-04-010- Molecular Mechanisms Regulating T Cell Function-

Following discussion that the description of the transgenic/knockout animals should be expanded and that the project should be conducted at BSL2 with BBPT, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IV c, please elaborate on which constructs, embryonic stem cells, etc. will be used for generation of transgenic/knockout mice. Also, please indicate that RRC will actually be generating the mice.
b. In Form A, item V c, biosafety level should be 2 for use of human cell lines.
c. In Form A, item VI e, please complete for BSL2 work.
d. All Personnel working with human/primate cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.
e. Appendix 1 for personnel needs to be provided.

I-04-011- Antimicrobial Studies of Clinical Pathogens

Following discussion that this protocol was well written and that a condition of approval should be that a letter of modification be submitted for addition of new microorganisms, a motion to approve this protocol with the following condition passed unanimously.

a. Condition: Please submit a letter of modification to this protocol when the laboratory obtains new microorganisms. Organisms that are of equal virulence, biosafety and security levels to what is currently approved will be eligible for administrative approval.

I-04-012- Cloning and Expression of Novel Human and Microbial Proteins

Following discussion that this protocol does not appear to use helper virus or whole animals for rDNA and that these boxes should not be checked, that plans for future experiments should be submitted as a modification, and that the work should be BSL2, a motion to approve this protocol was passed by all those eligible to vote in accordance with UIC policies and procedures (1 abstention). Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item II, it isn't clear why boxes 3 and 4 are marked. If helper virus is being used, this needs to be described in item IV c. If not, please do not check this box. Also, work that is described does not involve use of rDNA in whole animals, please do not mark this box. In addition, please remove ACC number, this protocol is expired.
b. In Form A, item IV c, last paragraph should be removed. Details of this project will need to be submitted at a future date in a modification letter.
c. In Form A, item V c, biosafety level should be 2 for use of human cell lines.
d. In Form A, item VI e, please complete for BSL2 work.
e. Please provide verification that all personnel listed have completed BBP training. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.

I-04-013- SIV Therapeutics (Assess BCG-Specific Gamma Delta T Cells for Anti-SIV Mucosal Immunity)

Following discussion that this protocol was submitted by a new investigator who had just moved to UIC and that the laboratory would be inspected on 3/14/04, that this protocol was requested for the laboratory analysis of samples from animal inoculated at [redacted] and not at UIC, that the PI needed to clarify decontamination procedures for infected waste, that the BBP training needed to be completed at UIC, that IATA training verification needed to be provided, and that a special subcommittee of Dr. Aixa Alfonso, Dr. Jeffrey Fortman, Dr. Paul Goldspink, and Mr. Terry Lawrin should review the

clarifications, a motion to approve this protocol was passed by all those eligible to vote in accordance with UIC policies and procedures (1 abstention). Approval was with the understanding that it is pending the following clarifications.

a. Condition: Laboratory for work and storage needs to be identified and inspected prior to the initiation of this work. Laboratory must meet BSL2 specifications.
b. In Form B, item g, please answer NO to this question.
c. In Form B, item II b, PI needs to clarify the all work involving inoculation of [redacted] will be done at [redacted] and that PI will be receiving samples (blood and bonchioalveolar lavage (BAL)) only. The nature of the samples as to what they are infected with should be indicated (e.g. BCG, SIV or co-infection with BCG/SIV). The stains of BCG and SIV should also be indicated. The procedures outline in Appendix 1 should be listed in this section. It should be clear which procedures are BSL2 in hood and which will be bench top.
d. In Form B, item III c, please describe how contaminated waste is decontaminated (e.g., 10% bleach, exposure time or autoclaving). Please provide a copy of laboratory specific biosafety manual. Manual should include exposure control plan and monitoring.
e. In Form B, item III c, please remove reference to reporting spills/accidents to NIH/OBA. It does not apply to this work. Spills should be reported to IBC and biosafety officer. Spill procedure should be posted in laboratory.
f. In Appendix 1, indicate the specific experience that personnel have undergone that qualifies them for this work.
g. Personnel will need to attend bloodborne pathogen training at UIC. Next training session is scheduled for April 13, 2004 from 3:30-4:30 PM in the School of Public Health East Auditorium (first floor), 2035 W. Taylor.
h. Personnel in laboratory that are responsible for shipping and receiving potentially infectious agents need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 413-3701 for training disc.

I-04-014- Characterization of the Role of Vγ2Vδ2 T Cells in Immunity to M. Bovis BCG Infection in [redacted]

Following discussion that this protocol was submitted by a new investigator who had just moved to UIC and that the laboratory would be inspected on 3/14/04, that this protocol was requested for the laboratory analysis of samples from animal inoculated at [redacted] and not at UIC, that the PI needed to clarify decontamination procedures for infected waste, that the BBP training needed to be completed at UIC, that IATA training verification needed to be provided, and that a special subcommittee of Dr. Aixa Alfonso, Dr. Jeffrey Fortman, Dr. Paul Goldspink, and Mr. Terry Lawrin should review the clarifications, a motion to approve this protocol was passed by all those eligible to vote in

accordance with UIC policies and procedures (1 abstention). Approval was with the understanding that it is pending the following clarifications.

a. Condition: Laboratory for work and storage needs to be identified and inspected prior to the initiation of this work. Laboratory must meet BSL2 specifications.
b. In Form B, item g, please answer NO to this question.
c. In Form B, item II b, PI needs to clarify the all work involving inoculation of [redacted] will be done at [redacted] and that PI will be receiving samples (blood and bonchioalveolar lavage (BAL)) only. The nature of the samples as to what they are infected with should be indicated (e.g. BCG, SIV or co-infection with BCG/SIV). The stains should also be indicated. The procedures outline in Appendix 1 should be listed in this section. It should be clear which procedures are BSL2 in hood and which will be bench top.
d. In Form B, item III c, please describe how contaminated waste is decontaminated (e.g., 10% bleach, exposure time or autoclaving). Please provide a copy of laboratory specific biosafety manual. Manual should include exposure control plan and monitoring.
e. In Form B, item III c, please remove reference to reporting spills/accidents to NIH/OBA. It does not apply to this work. Spills should be reported to IBC and biosafety officer. Spill procedure should be posted in laboratory.
f. In Appendix 1, indicate the specific experience that personnel have undergone that qualifies them for this work.
g. Personnel will need to attend bloodborne pathogen training at UIC. Next training session is scheduled for April 13, 2004 from 3:30-4:30 PM in the School of Public Health East Auditorium (first floor), 2035 W. Taylor.
h. Personnel in laboratory that are responsible for shipping and receiving potentially infectious agents need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 413-3701 for training disc.

I-04-015- Development of Gene Therapy Techniques for Congenital Adrenal Hyperplasia in an Animal Model

Following discussion that the ACC number was not current, that specific questions for sections IV a and b needed to be addressed on Form A, that the addendum identified a number of vectors, but did not specify which vector would be used for whole animal studies, that the description for the containment and PPE for the bombardment experiment should be elaborated on, and that both BBP and IATA training were required, a motion to approve this protocol was passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item II, please provide the current ACC number. The one listed is expired.

a. In Form A, item II, please provide the current ACC number. The one listed is expired.
b. In Form A, item IV a, please answer this specific question as to the overall purpose of the project in layperson's language or define scientific terms used.
c. In Form A, item IV b, please provide the scientific background of the research project and research goals. This was not addressed in the attached information.
d. In Form A, item IV c, please address the following concerns:
    i. Please indicate the nature of all cultured cells. Are they rabbit adrenal cells? NIH 3T3 cells? Or some other cells?
    ii. In the description of the in vivo rabbit studies the specific vectors that will be used need to be identified. Will all the vectors that are described on page 6 and 7 be used. If herpes simplex virus I vector will be used, PI needs to specify that rabbits will be housed in [redacted] Biosafety room after transfection.
    iii. In the description of expression vector for non-infectious use, PI states that these will be used for bombardment study. This is misleading as the intent of the procedure is to "infect" the animal with vector that will express SSC.
e. In Form A, item V c, only BSL2 should be marked.
f. In Form A, item IV a, mammal source should be identified as rabbits.
g. In Form A, item IV b, this question is applicable. Where was SSC originally cloned from?
h. In Form A, item IV c, this question is applicable as some of the vectors the PI is using are RG 2. Please check appropriate box.
i. In Form A, item VI e, please address the following concerns:
    i. Please identify the type of masks used by personnel during the bombardment procedure. N95 masks, which require a fit test by EHSO, are required for procedures that produce aerosols.
    ii. Please indicate specific decontamination procedures (e.g., bleaching or autoclaving).
    iii. Please indicate what steps are taken to minimize aerosols. Note: it is recommended to wait 30 minutes for potential aerosols to settle prior to cleaning room.
    iv. Please indicate what portions of the work take place in a biosafety cabinet.
j. Appendix 1 needs to be completed for all personnel working on this project and verification of bloodborne pathogen training needs to be provided. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.
k. Personnel in laboratory that are responsible for shipping and receiving potentially infectious agents need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 413-3701 for training disc.

5. Adverse Event Reports-

None to report

6. New Business-

a. IBC Calendar-

Dr. Bowman directed the Committee's attention to the IBC calendar outlining deadline dates for submission and preview, meeting dates, dates for notification of investigators for resubmission and outcomes of Committee meetings. A motion to approve the calendar was unanimously approved.

The meeting was adjourned at 3:10 PM

Institutional Biosafety Committee
Minutes of
April 8, 2004
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Alex Neyfakh, Dr. Aixa Alfonso, Mr. Richard Anderson, Dr. Mary Bowman, Ms. Anne Cousin, Dr. Jeffrey Fortman, Dr. Paul Goldspink, Dr. William Hendrickson, Dr. Thomas Hope, Dr. Randal Jaffe, Mr. Terrance Larwin, Dr. Roberta Mason-Gamer, Dr. Maria Rudisch, and Ms. Sheila White

ABSENT: Dr. Edward Cohen

1. **Announcements-**

Dr. Bowman welcomed Dr. Neyfakh back to the IBC on behalf of the Committee. She also introduced Ms. Anne Cousin as a new nonaffiliated member and asked the members of the Committee to introduce themselves.

Dr. Bowman informed the Committee that there were two handouts being distributed. The first handout corresponded to item ***ci*** under new business and the second handout was a modification request for protocol 03-035 and was added to the agenda as item d under new business.

2. **Minutes of March 11, 2004-**

The minutes of the March 11, 2004 meeting were approved pending minor editorial changes.

3. **Old Business-**

   a. **Update 04-013 and 04-014-**

Dr. Bowman informed the Committee that the PI of protocols 04-013 and 04-014 submitted revisions to these protocols [redacted] The work will only involve the processing of samples (blood or lavage samples) for in vitro analysis. All treatment of [redacted] will be done at another institution. The special subcommittee appointed for this protocol reviewed the revisions and approved the protocols.

4. **April Protocol Summary Reports-**

I-04-016- Transgenic Flies in Functional Genomics and Obesity Models

Following discussion that only appendix 1 for personnel needed to be completed on this BSL 1 protocol, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarification.

a. Appendix 1 for personnel needs to be completed.

I-04-017- Transgenic Drosophila in Neuropharmacological Research

Following discussion that only appendix 1 for personnel needed to be completed on this BSL 1 protocol, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarification.

a. Appendix 1 for personnel needs to be completed.

I-04-018- OmpR Regulation of Salmonella Virulence Determinants

Following discussion that a sink was being installed in the room in which the biosafety cabinet is housed and that approval should be with the condition that this protocol is for in vitro work only and that the PI would need to submit a modification or new protocol if animal studies will be conducted, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications and condition.

a. All Personnel working with human/primate cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule. Next training date is April 13, 2004 from 3:30-4:30 in the SPHE first floor auditorium, 2035 W. Taylor St.
b. Personnel in laboratory that are responsible for shipping and receiving potentially infectious agents need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 413-3701 for training disc.
c. Condition: This protocol is approved for in vitro experiments only. Should in vivo animal experiments need to be conducted, a modification of the existing protocol or a new protocol will need to be submitted and approved prior to initiation. Please consult with the IBC office prior to submission.

I-04-019- Gene Expression in Different Mammalian Cell Lines-

Following discussion that the biosafety level should be 2, that the PI needed to complete the appropriate sections for BSL2, that the PI needed to elaborate on the experiments involving siRNA technology, and that BBP and IATA training were both needed, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IV b, please identify the source of the liver cell lines.
b. In Form A, item IV c, please address the following concerns:
    i. Please provide a more elaborate description of which genes and in which cells/organisms siRNA technology will be used.
    ii. Please provide a map or description of the HCV RNA replicon. How much of the virus does this represent?
    iii. Please define ER.
c. In Form A, item V b, BSL2 should be marked.
d. In Form A, item VI, please complete this section for BSL2 work.
e. All Personnel working with human/primate cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.
f. Personnel in laboratory that are responsible for shipping and receiving potentially infectious agents need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 413-3701 for training disc.

I-04-022- Studies on the Mechanism of Cell Motility

Following discussion that only minor clarifications were requested, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form IV c, please indicate which vectors are prokaryotic vectors and which are eukaryotic vectors. Also, how will cells transfected with GFP-actin.
b. Appendix 1 for personnel should be completed.

I-04-023- Therapeutic Potential of Cdk4/6 siRNA in c-Myc Related Lymphoma

Following discussion that the whole animal studies needed to be described, that BBP and IATA training were required and a discussion on decontamination of biosafety cabinets, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IV c, please describe whole animal studies including containment procedures for animal work.

b. In Form A, item V a and V b, building should be MBRB.
c. In Form A, item VI b and c, please answer these sections.
d. All Personnel working with human/primate cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.
e. Personnel in laboratory that are responsible for shipping and receiving potentially infectious agents need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 413-3701 for training disc.

I-04-024- Analysis of G protein-mediated Signaling Pathways

Following discussion that the biosafety level should be 2, that the PI needed to complete the appropriate sections for BSL2, and that BBP training was required, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item V b, BSL2 should be marked.
b. In Form A, item VI, please complete this section for BSL2 work.
c. All Personnel working with human/primate cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.

I-04-025- Studies of Ribosomal Functions and Identification of New Antibiotic Sites in the Ribosome

Following discussion that the protocol was very similar to two other recently approved protocols submitted by this PI and that it was well written and there were no concerns, a motion to approve this protocol was approved by all those eligible to vote in accordance with UIC policies and procedures (1 abstention).

I-04-026- Adenoviral-Mediated Gene Transfer in Non-Ischemic Heart Failure

Following discussion that the protocol was well written, that the PI had all appropriate safety precautions outlined for delivery of adenoviral vectors to the heart, and that the Committee did not have any clarifications, a motion to approve this protocol passed unanimously.

I-04-027- Biochemical Studies of Bacillus Anthracis Protective Antigen

Following discussion that the PI was using a synthetic portion of the gene for protective antigen and would not be using any *Bacillus Anthracis* strain, that this was a BSL1 project, and that the PI needed to addition details on the procedures, a motion to approve this protocol was approved by all those eligible to vote in accordance with UIC policies and procedures (1 abstention). Approval was with the understanding that it is pending the following clarifications.

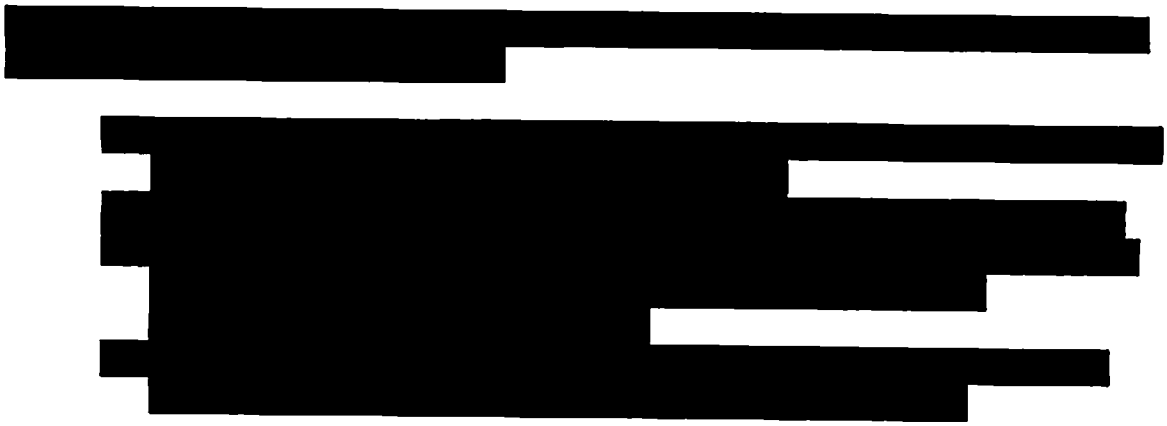
a. In Form A, item II, box 2 should be checked.
b. In From A, item IV c, please answer this section completely. Which vectors will be used? Will PA be expressed in any other cell lines?
c. Appendix 1 for personnel must be completed.

I-04-028 [redacted]

[redacted]

I-04-029- [redacted]

[redacted]



5. Adverse Event Reports-

None to report

6. New Business-

a. Establish Cell Lines-

Dr. Bowman informed the Committee that the IRB had inquired whether established cells that were initially transformed via recombinant technology required IBC approval. The Committee discussed that for stably transfected lines, there were no recombinant procedures being conducted and that this would fall outside of what the NIH Guidelines covered. The consensus is that IBC approval was not needed for these cell lines.

b. FAA Inspections-

Mr. Lawrin informed the Committee that the FAA was inspecting institutions that were shipping and receiving potential infectious material. The inspections appeared to be evaluating the process at the institution and whether appropriate procedures and training were in place. He reminded the Committee to request IATA training on all protocols that involve infectious material.

c. OBA Updates-

i. NIH Guidance on Informed Consent in Gene Transfer Research-

Dr. Bowman directed the Committee's attention to a summary of the contents of a new web site that OBA has posted for informed consent on human gene transfer research. She stated that the site gave instruction on the consent process and offer generic examples of language that could be used in different portions of the consent documents. She stated that the site could be useful to both investigators and the Committee.

ii. Genetic Modification Clinical Research Information System-

Dr. Bowman informed the Committee that OBA in conjunction with the FDA had launched a new comprehensive information system for tracking human gene transfer studies. The site was searchable by a number of methods including OBA protocol number, Principal Investigators, vectors used, disease treated, genetic element, ex vivo cell, and vector producer cell system. The site will also allow for adverse event reporting.

iii. National Science Advisory Board for Biosecurity-

Dr. Bowman informed the Committee that a new advisory board had been established to provide advice to federal departments and agencies on ways to minimize the possibility that knowledge and technologies emanating from biological research will be misused to threaten public health or national security. Although current responsibilities for IBCs have not changed, the board will be developing guidelines for case-by-case review and approval by IBCs of dual use research. Dr. Bowman indicated that she will keep the Committee informed of any recommendations or changes made by the advisory board.

d. Modification 03-035-

The meeting was adjourned at 3:35 PM

Institutional Biosafety Committee
Minutes of
May 13, 2004
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Alex Neyfakh, , Mr. Richard Anderson, Dr. Mary Bowman, Ms. Anne Cousin, Dr. Jeffrey Fortman, Dr. Paul Goldspink, Dr. William Hendrickson, Dr. Randal Jaffe, Mr. Terrance Larwin, Dr. Roberta Mason-Gamer, and Dr. Maria Rudisch

ABSENT: Dr. Aixa Alfonso, Dr. Edward Cohen, Dr. Thomas Hope, and Ms. Sheila White

1. **Announcements-**

Dr. Bowman informed the Committee that there were two new additions to the agenda. An update on the Sunshine Project was discussed as item b, under old business, and a SARS outbreak update was discussed as item a, under new business. Four handouts were distributed. The first two handouts pertained to the SARS outbreak, the third handout corresponded to the adverse event report, and the fourth handout was the BMBL table on BSL for animal activities for use in the discussion of protocol 04-033.

2. **Minutes of April 8, 2004-**

The minutes of the April 8, 2004 meeting were approved pending minor editorial changes.

3. **Old Business-**

   a. **Decontamination of Biosafety Cabinets-**

Dr. Bowman asked Mr. Lawrin to address this issue. Mr. Lawrin distributed an excerpt from Biological Safety Principles and Practices, 3rd Edition, edited by Diane Fleming and Debra Hunt regarding decontamination of biosafety cabinets. He also referred the Committee to the document from the Office of Health and Safety Information System (CDC) contained in their packages. Both documents referred to the risk of using flammables in high concentrations in biosafety cabinets. The Committee discussed that both documents referred to higher concentrations of flammable materials as being a concern and whether there was any level of flammable material that was acceptable (e.g., 70% ethanol used on towels to wipe down cabinet). The Committee asked Mr. Lawrin to continue to look into the matter and report back to the Committee next month.

b. Update on Sunshine Project-

Dr. Bowman directed the Committee's attention to the news release regarding the Sunshine project. She indicated that the Sunshine Project had filed a federal complaint against 9 institutions that according to the Sunshine Project had failed to comply with the request for public access to IBC minutes. The compliant was lodged with OBA and sought an immediate suspension of federal funding to these institutions with a 15-day deadline for compliance. Dr. Bowman stated that she would continue to monitor the issue and report back to the Committee on any news that was of concern to the UIC.

4. May Protocol Summary Reports-

I-04-030- Neuropharmacology of Arousal and Sleep Disorders

Following discussion that this project is similar to another project recently approved for this laboratory and that this one involves different genes, that some additional clarification was required on the use of natural exchangers and where the cDNA was derived from, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item III, it appears that the last two boxes in this section should not be checked. Please remove the check marks. If natural exchangers are used, please clarify in item IVc by listing the natural exchangers that are used.
b. In Form A, item IV c, please clarify the source and nature of the cDNAs used in transfection. From what mammalian species were they derived and identify the corresponding cDNAs if known.

I-04-031- Cytokine Regulation of Human Eosinophil Genes

Following discussion that this project needs to be conducted at BSL2 due to use of retroviral vectors and human cells, that PI needs to clarify the use of natural exchangers and propagation of DNA, and that laboratory personnel require BBP and IATA training, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item II, please check box 1, for use of retroviral vectors.
b. In Form A, item III, the last three boxes where marked in this section. Please clarify in Form A, item IV c, why these boxes were checked. Which DNA from prokaryotic sources or eukaryotic sources is being propagated only in that same source? Which natural exchangers are being used (see Appendix A of IBC guidelines)?
c. In Form A, item IV c, please provide addition information regarding vectors being used. For the retroviral vectors, which retroviral vectors are used? Are they attenuated and if so, how?

d. In Form A, item V b, BSL2 should be marked.
e. In Form A, item VI, please complete this section for BSL2 work.
f. All Personnel working with human/primate cells or cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see IBC web site for training schedule (http://www.research.uic.edu/protocolreview/ibc/education/index.shtml) of seminars offered by thee Office of Environmental Health and Safety.
g. Personnel in laboratory that are responsible for shipping and receiving potentially infectious agents need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 413-3701 for training disc.

I-04-032- Molecular Biology and Functions of Eosinophil Proteins

Following discussion that the PI needed to elaborate on the vectors used and the species of origin for cell lines so that BSL could be assigned and information provided indicated BSL2 that BBP and IATA training was required, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IV c, please provide additional information as to the vectors being used and the cells or cell lines needs to be provided. Indicate the nature of the vectors and the species of origin of the cells being used. If human cells or cell lines are used and/or viral vectors are used, the protocol should be conducted at BSL2 and clarifications b-e must be addressed.
b. In Form A, item V b, BSL2 should be marked.
c. In Form A, item VI, please complete this section for BSL2 work.
d. All Personnel working with human/primate cells or cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see IBC web site for training schedule (http://www.research.uic.edu/protocolreview/ibc/education/index.shtml) of seminars offered by thee Office of Environmental Health and Safety.
e. Personnel in laboratory that are responsible for shipping and receiving potentially infectious agents need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 413-3701 for training disc.

I-04-033- Therapeutic Interventions Against SARS-CoV: Care and Handling of SARS Infected Mice

Following discussion that this protocol addressed many of the concerns that were raised regarding this work when it was submitted as a modification to protocol 03-035, that many of the clarifications requested were to ensure that there was congruence between the protocol application and the biosafety manual and to clarify who would be notified in case of an exposure or accident, that the PI should contact EHSO regarding proper respirator mask and that PI needed to clarify the inactivation/decontamination section, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form B, PI needs to sign appropriate assurances.
b. In Appendix 1, please address the following concerns:
    i. Personnel appear to be receiving appropriate training and one of the co-investigators has worked at a BSL 3 level; however it is not clear from a description of the training if the PI has worked at BSL 3. The agents listed by the PI are BSL 2 agents under normal circumstances and only become BSL3 under circumstances of propagation and use of large amounts. This needs clarification as it relates to the PI's experience.
    ii. The Committee recommends that [redacted] also participate in the training of new personnel given her BSL3 experience. Please incorporate this into appendix 1.
    iii. Please indicate the level of experience all personnel have with handling mice.
    iv. PI needs to sign appropriate assurance.
c. In Addendum 1, Part A, please address the following concerns:
    i. Items 5 and 6 should refer to sections "3 and 4" above regarding the inoculation procedures with SARS.
    ii. Item 8, please correct temperature at which samples will exposed to heat shock. This should read 65^0C and not 650C. Also, refer the reader to section 3.11 of the biosafety manual for inactivation decontamination procedures.
d. In Addendum 1, Part C, item 2, please indicate who will be notified if a mouse is missing.
e. In BSL3 Manual, please address the following concerns:
    i. Section 2.1, in the last sentence PI indicates that "In the unlikely event that the member becomes sero-positive, proper medical care will be administered to the member". If someone becomes sero-positive, the PI should indicate who would be notified, e.g., Dr. Marder, CDC, etc.
    ii. Section 2.3, please address these concerns:
        1. First bullet – PI should include a statement as to how an eye exposure would be handled (e.g., flush with copious amounts of water). PI may also want to provide a minimum time that the site should be washed or flushed.
        2. Second bullet – This sentence seems disjointed. Is the exposed person suppose to contact UIC Emergency

Services or Employee Heath Services and in what order? When should the PI contact the UIC police? Per NIH Guidelines and UIC Policy, both the Biosafety Officer and the IBC office should be notified in writing of any potential exposures. Please list all those who will be notified and the order in which they will be notified.

3. Finally, the PI should not urge the exposed people to contact the appropriate health professional group, but should "require" them to contact the appropriate health professional group. Please change the wording of this statement.

iii. Section 3.3, please address the following concerns:
   1. In introductory paragraph, it appears that there will be two types of masks used in the suite, one that is appropriate for TB and one that is appropriate for SARS. Please contact Mr. Richard Anderson of the Office of Environmental Health and Safety Office (413-2140) to ensure that the appropriate respiratory mask is being used. Also, the PI needs to indicate what precautions will be in place to ensure that staff does not inadvertently use the "TB mask" when handling SARS.
   2. Part a, corridor should be "anteroom".
   3. Part c, the Committee recommends that the wraparound gowns not be reused and be disposed of after a single use and decontaminated via autoclaving. Please revise this section accordingly.
   4. Part h, the Committee recommend removing what is in parenthesis from the line "(i.e. that surgical masks protect from splash, "(Mycobacterium tuberculosis)"

iv. Sections 3.5 and 3.9, the PI refers to UV light as a means of decontaminating surfaces. It should be noted that dust can inhibit the effectiveness of UV light and that over time UV lights will lose effectiveness. Recommend that PI indicate lamps will be dusted prior to use and describe the frequency of UV light change. Finally, in section 3.9 PI should indicate the minimum time of UV light exposure fro decontamination.

v. Section 3.10, item a, it should be clear that contaminated waste will not be stored overnight, but will be autoclaved at the end of the day.

vi. Section 3.11, please address the following concerns:
   1. It would be clearer if this section was broken down into which type of samples will be treated by what method for inactivation/decontamination. Much of what is written here pertains to TB and not SARS. This section needs to be written appropriately so it is clear what is done for TB and what is done for SARS.

2. PI should clarify location of irradiator and if it is not in the facility he should indicate how materials will be safely transported to the irradiator. Section 3.11, 2nd paragraph, based upon the language in this section (2nd sentence) it would appear that the PI may do some work outside the hood. This is inconsistent with statements in addendum1 and should be clarified.
3. Remove "as described in 3 and 4" from paragraph 4.
4. Transport from the BSL3 into an intercampus lab of treated non-infectious specimens should be in a sealed plastic container (possibly one with handles) with pieces of foam inside. Prior to leaving the BSL3 laboratory this container and the specimen containers must be wiped down with an appropriate disinfectant. This needs to be incorporated into the protocol.

vii. Section 3.12, please address the following concerns:
1. Paragraph 2, there is a contradiction between this section of the manual and Addendum regarding where infection of mice will occur. It is indicated "on the bench" in the manual and "in the hood" in the addendum. Please correct the manual to the addendum version. In general, it should be indicated in the manual that infected mice DO NOT LEAVE THE BIOSAFETY CABINET since breathing infected mice are a potential source of aerosol infection.
2. Paragraph 3, add use of CO2 sedation prior to weighing and injection of anesthesia.
3. Paragraph 4, remove reference to "3 and 4" and indicate as described above.

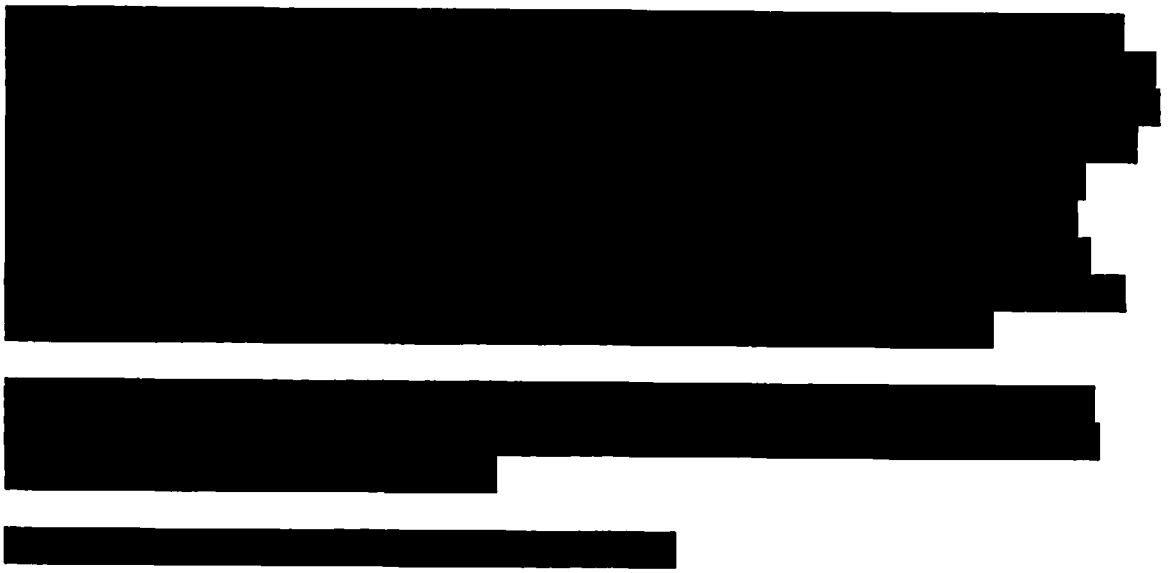
I-04-034- Hypertrophic Signaling and Cardiac Dysfunction

Following discussion that verification of BBP and IATA training was required for this protocol and that appropriate disinfection of work area needed to be included, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item VI e, alcohol alone is not sufficient to disinfect work area. Additional appropriate disinfectant should be used.
b. All Personnel working with human/primate cells or cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see IBC web site for training schedule (http://www.research.uic.edu/protocolreview/ibc/education/index.shtml) of seminars offered by thee Office of Environmental Health and Safety.

c. Personnel in laboratory that are responsible for shipping and receiving potentially infectious agents need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 413-3701 for training disc.

5. Adverse Event Reports-



6. New Business-

a. SARS Outbreak

Dr. Bowman referred the Committee to the handouts and news articles related to the most current SARS outbreak in China. She indicated that according to the WHO updates that the outbreak had been traced to two persons both of whom worked at the National Institute of Virology in Beijing, an institution conducting SARS research. Neither person is known to have been conducting research involving live SARS. The institute was closed on April 23rd and most of its staff were quarantined for medical observation. The WHO updated indicated that the ongoing investigation is likely to be complex, as no single infectious source or single procedural error appears to be the explanation for the outbreak. Strict adherence to BSL3 practices and procedures and use of a BSL3 facility are being strongly recommended by the WHO.

An additional article from the Wall Street Journal, indicating that there are members of the scientific community and others who feel that there should be additional regulations and oversight for laboratories working with SARS, was discussed. The article indicated that the CDC is discussing the possibility of designating SARS as a most-dangerous agent according to the chief of policy for the CDC's select agent program. Dr. Bowman stated that she will continue to monitor updates from the CDC and WHO regarding

SARS use in the laboratory and that she will forward this information to the PI at UIC who is working with SARS.

The meeting was adjourned at 3:10 PM

Institutional Biosafety Committee
Minutes of
June 10, 2004
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Alex Neyfakh, Mr. Richard Anderson, Dr. Mary Bowman, Ms. Anne Cousin, Dr. Jeffrey Fortman, Dr. Paul Goldspink, Dr. William Hendrickson, Dr. Randal Jaffe, Mr. Terrance Larwin, Dr. Roberta Mason-Gamer, and Dr. Maria Rudisch, and Ms Shelia White

ABSENT: Dr. Aixa Alfonso and Dr. Thomas Hope

1. **Announcements-**

Dr. Bowman directed the Committee to the handout that was included in their monthly packaging regarding a web cast presentation by the CDC on BSL3 lab safety practices and procedures and on the guidelines for working with SARS-CoV. She indicated that she had contacted the PIs on campus with approved BSL3 protocols and informed them of the presentation. All had indicated that they planned to watch. Dr. Bowman indicated that she would purchase the video for future use if the presentation provided information.

2. **Minutes of May 13, 2004-**

The minutes of the May 13, 2004 meeting were approved pending minor editorial changes.

3. **Old Business-**

   a. **Decontamination of Biosafety Cabinets-**

Mr. Lawrin informed the Committee that he had been informed by an engineer from the Baker Company that the limited amounts of alcohol used for wiping down biosafety cabinets did not pose an explosion hazards and could continue to be used safely.

4. **June Protocol Summary Reports-**

   A. **Expedited Approvals-**

Dr. Neyfakh informed the Committee of the following expedited approvals: 1) **I-04-011-01-** addition of personnel, 2) **I-04-029-01-** addition of a laboratory procedure for tissue homogenization which would take place in the biosafety cabinet in the BSL3 laboratory and cell culture, 3) **I-04-036- Restraint Alters Cutaneous Wound Repair-** a BSL1

project using plasmid vectors and GFP reporter constructs, 4) **I-04-039- Subcloning of Monkey MHC Genes Using Commercially Available Plasmids-** a BSL1 project using plasmid vectors for expression in E. coli, and 5) **I-04-040- Development of MHC Tetramer for Measuring BCG-Specific T Cells-** a BSL1 project using plasmid vectors for expression in E. coli and insect cells. The Committee accepted this portion of the report by consensus.

B. Protocols for Full Committee Review-

I-04-035- Adenoviral-Mediated Gene Transfer of Insulin-Like Growth Factor Splice Variants into Cardiac Myocytes

Following discussion that the PI had addressed the minor issues raised during prereview and provided the appropriate documentation to the Committee regarding bloodborne pathogen training and IATA training, a motion to approve this protocol was unanimously passed by all those eligible to vote in accordance with UIC policies and procedures (1 abstention).

I-04-037- Molecular Modification of Thin Filament Proteins and Calcium Regulation

Following discussion that the minor issue raised during prereview did not impact on safety and should be addressed administratively, a motion to approve this protocol passed unanimously.

I-04-038- Botanicals for Helicobacter Pylori Infections

Following discussion that the PI needed to indicate in the protocol that animals would be maintained in the biohazard room at [redacted], where tissue homogenization would take place and level of expertise in handling H. pylori, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form B, item III, please indicate that infected animals will be maintained in the [redacted] biohazard room. In addition, please indicate if tissue homogenization and work with open cultures will take place in a biosafety cabinet.
b. In Appendix 1, experience of PI with handling of H. pylori should be indicated. Also, all personnel that will be working with this organism should be included in this appendix.

I-04-041- Ribosomal RNA Processing and Cell Cycle Control

Following discussion that the PI needed to elaborate on the retrovirus from which vector was developed, that the project should be BSL2, and that the personnel on the protocol required bloodborne pathogen training, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IV, please indicate retrovirus from which pBABE was developed. Also, indicate if vector is attenuated and if so, how?
b. In Form A, item Vc, please indicate BSL2 for use of human BOSC cells.
c. In Form A, item VI, complete all items in this section for BSL2 work.
d. All Personnel working with human/primate cells or cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see Office of Environmental Health and Safety web site for seminar training schedule.

Note Dr. Edward Cohen arrived

I-04-042- [redacted]

[redacted]

5. Adverse Event Reports-

None to Report

6. New Business-

None to report

The meeting was adjourned at 2:25 PM

Institutional Biosafety Committee
Minutes of
July 8, 2004
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Alex Neyfakh, Dr. Aixa Alfonso, Dr. Mary Bowman, Ms. Anne Cousin, Dr. Jeffrey Fortman, Dr. Paul Goldspink, Mr. Terrance Larwin, Dr. Roberta Mason-Gamer, and Dr. Maria Rudisch, and Ms Shelia White

ABSENT: Mr. Richard Anderson, Dr. Edward Cohen, Dr. William Hendrickson, Dr. Thomas Hope, and Dr. Randal Jaffe

1. Announcements-

Dr. Neyfakh informed the Committee that he would be stepping down as chair of the IBC, but would remain as a member of the Committee. Dr. Bowman informed the Committee that Dr. Randal Jaffe had agreed to serve as chair of the IBC. A recommendation would be made to the Institutional Official to appoint Dr. Jaffe as chair of the IBC. Dr. Neyfakh was thanked for his service as chair of the Committee.

2. Minutes of June 10, 2004-

The minutes of the June 10, 2004 meeting were approved pending minor editorial changes.

3. Old Business-

None to report

4. July Protocol Summary Reports-

A. Protocols and Modifications for Expedited Approvals-

Dr. Neyfakh informed the Committee of the following expedited approvals: **03-061-01-** addition of personnel. The Committee accepted this portion of the report by consensus.

B. Protocols and Modifications for Full Committee Review-

I-03-070-02- Ultrastructure and Function of Nerve and Muscle-
I-04-030-01- Neuropharmacology of Arousal and Sleep Disorders-

Following discussion that the PI was requesting an upgrade of one of the PI's laboratories to BSL2, but that an eyewash station and recertification of the biosafety cabinet were needed, a motion to approve this modification passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. An eyewash station is not available within required 100 feet or 10 second limit. Please contact Terry Lawrin, UIC biosafety officer (413-3701), regarding installation of an eyewash station.
b. Biosafety cabinet needs to be recertified. Please see EHSO web site under biological safety for a list of approved certifiers (http://www.uic.edu/depts/envh/).

I-04-013- SIV Therapeutics (Assess BCG-Specific Gamma Delta T Cells for Anti-SIV Mucosal Immunity-

Following discussion that the PI was requesting to conduct the animal portions of the above titled project at UIC rather than at [redacted] as originally approved, that the protocol modification included the animal handling procedures of the study and a description of the safety precautions that would be used, and that the PI needed to expand on specific aspects of those safety precautions, a motion to approve this modification passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form B, item III c, please address the following concerns:
    i. Please indicate the PPE that will be used by staff that will be handling [redacted] during routine husbandry and sample collection. This includes glove, mask with splash protection, gown, head and shoe covers.
    ii. Please indicate that monkeys on this study will be segregated from the rest of the colony and access will be restricted to only those individuals authorized to work with the animals.
    [redacted] Please expand on spill procedures to take into account how BCG and SIV would be treated in the case of an accidental spill at the time of administration to [redacted]
    iv. Please indicate that N-95 respirator and safety glasses will be worn at the time of inoculation. All personnel using N-95 respirators must be fit tested and a respirator protocol must be established. Please provide a copy of the protocol. Please contact [redacted] for fit testing.
b. Assurances, PI needs to sign assurances on Form B for modification.

I-04-043- Membrane and Myofilament Control of Cardiac Dynamics-

Following discussion that this was a well written protocol involving rDNA work to understand the function of cardiac calcium regulatory proteins in cardiac disease, that work involved both in vitro transfection/expression studies and in vivo adenovirus use in mice, and that appropriate safety precautions were in place and that no clarifications were required, a motion to approve this modification passed unanimously.

I-04-044- Elucidation of Mechanisms Involved in Tissue Inflammation and Resolution

Following discussion that the protocol was well written, that work involved the use of human cells, both primary and cell lines and therefore required BSL2 precautions and bloodborne pathogen training, a motion to approve this modification passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item V c, BSL 2 should be marked for the use of human cells in culture.
b. In Form A, item VI e, please answer this section for BSL2 procedures.
c. All Personnel working with human/primate cells or cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. Please see IBC website under education and training for a list of seminar training dates (http://www.research.uic.edu/protocolreview/ibc/education/index.shtml).

I-04-045- The Role of Drosophila myb in Regulating Cell Division During Development

Following discussion that this is BSL1 level work and that it was clear that insect cells and E. coli were the only cells used, a motion to approve this protocol passed unanimously.

I-04-046- Regulation of Endothelial Permeability and Lung Injury

Following discussion that not all rooms listed qualified for BSL2 level, that the description of types of genes and animal procedures involving rDNA needed to be elaborated upon, that clarification regarding use of viral vectors in animals was required, that bloodborne pathogen and IATA training were required, and that revisions should be reviewed by a special subcommittee of Drs. Alfonso, Bowman and Fortman and Mr. Lawrin, a motion to approve this modification passed unanimously. Approval was with the understanding that it was pending the following clarifications.

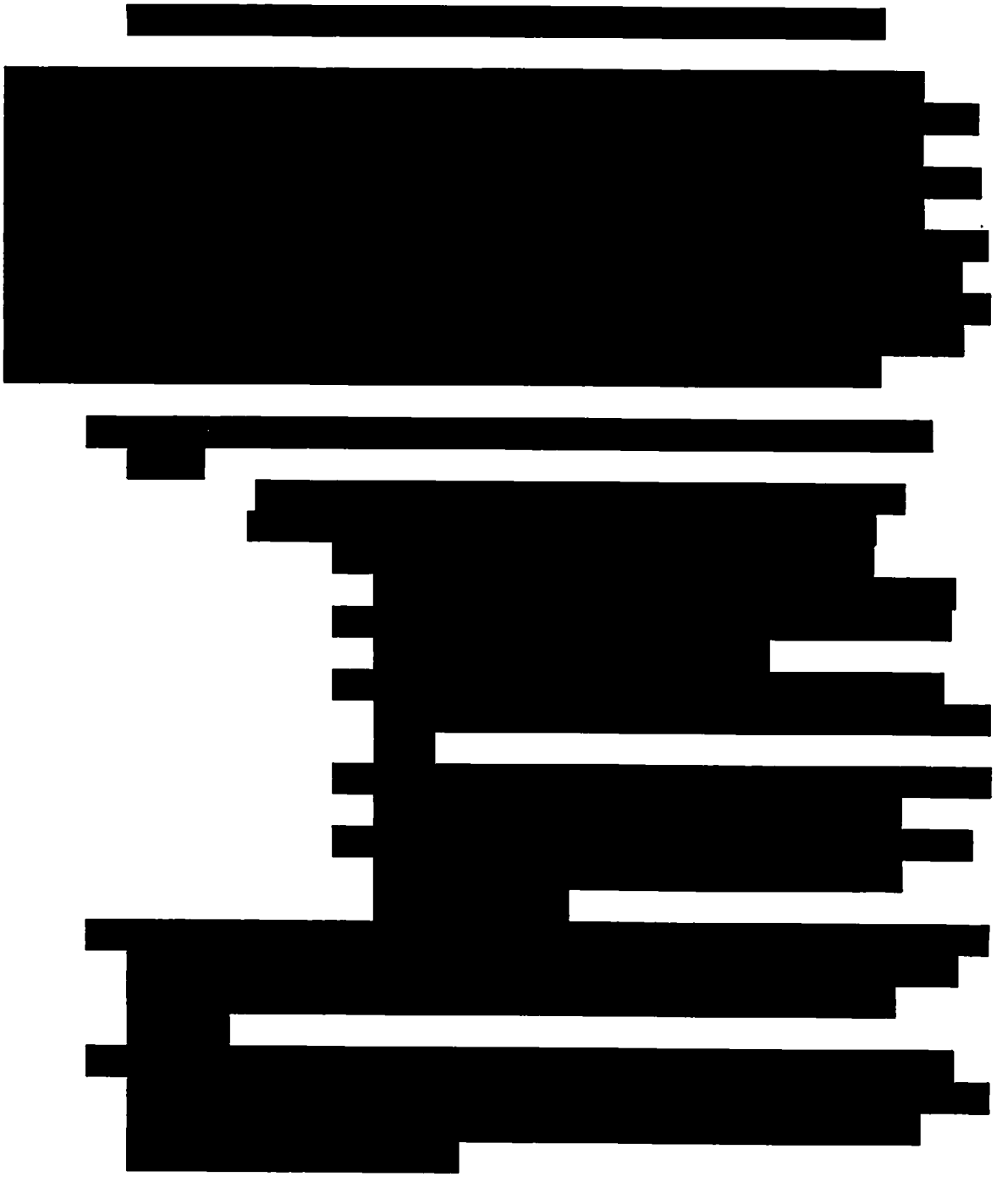
a. Rooms [redacted] do not have eyewash stations and therefore do not meet the BSL2 standard.

b. In Form A, item II, box 3 for whole animal studies is marked. Please provide the corresponding ACC number or numbers in which rDNA is administered to live animals.
c. In Form A, item III box 3, the wrong ACC number is listed here. The number should be 03-059.
d. In Form A, item IV c, please address the following concerns:
    i. Please describe the genes of interest in terms of known or potential functions (e.g., cytoskeletal proteins (actin, tubulin α and β).
    ii. Please describe the studies involving whole animals. Specifically indicate which vectors containing which genes will be administered to animals. Indicate route of administration, where administration will occur (BRL or specific room number of PI) and where animals will be housed post-infection. This should be done for all animal protocols that will use this IBC number. This does not include production of transgenic/knockout animals.
    iii. Please indicate if retroviral vectors will be packaged ecotropically or amphotrophically.
    iv. Please indicate which genes will be used with adenoviral and/or retroviral vectors.
    v. Vectors listed under Form B, item I a, should be listed in this section.
e. In Form A, item VI d, please clarify if CAV-1 is the only protein that will be expressed. There appear to be several other missing.
f. In Form A, item VI e, the first paragraph under Form B, item III should be added here.
g. Form B- this form is not needed. Please incorporate concerns addressed above.
h. All Personnel working with human/primate cells or cell lines need to complete Bloodborne pathogen training (BBPT) on a yearly basis. Please provide verification of training within last year for all lab personnel working on protocol. If training has not been completed, please see IBC web site for training schedule (http://www.research.uic.edu/protocolreview/ibc/education/index.shtml) of seminars offered by the Office of Environmental Health and Safety.
i. Personnel in laboratory that are responsible for shipping and receiving potentially infectious agents need to provide verification of shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 413-3701 for training disc.

5. Adverse Event Reports-

None to Report

6. **New Business-**



The meeting was adjourned at 2:50 PM

Institutional Biosafety Committee
Minutes of
August 12, 2004
3:00 P.M. - Room 307 C AOB

PRESENT: Dr. Randal Jaffe, Dr. Aixa Alfonso, Mr. Richard Anderson, Dr. Mary Bowman, Ms. Anne Cousin, Dr. Jeffrey Fortman, Mr. Terrance Larwin, Dr. Roberta Mason-Gamer, and Dr. Maria Rudisch, and Ms Shelia White

ABSENT: Dr. Edward Cohen, Dr. Paul Goldspink, Dr. William Hendrickson, Dr. Thomas Hope, and Dr. Alex Neyfakh

1. Announcements-

Dr. Randal Jaffe indicated to the Committee that he had been appointed as the new chair of the IBC and thanked the Committee for postponing the start of the meeting until 3 PM due to a conflict he had.

Dr. Bowman informed the Committee that a handout was being distributed for discussion under new business as item a.

2. Minutes of July 8, 2004-

The minutes of the July 8, 2004 meeting were approved pending minor editorial changes.

3. Old Business-

a. Update on MSP for SARS project-

Dr. Bowman informed the Committee that she, Terry Lawrin, and members of the laboratory working on SARS had met with Dr. Marder and UHS personnel to re-evaluate the Medical Surveillance Plan for SARS. She indicated that the plan was revised and approved. Dr. Bowman indicated that changes were also made in the biosafety manual for this work to reflect the changes in the MSP. Additional changes in the inactivation protocol had also been made. Mainly UV inactivation followed by neutralization assay would be used for monolayer cultures and gamma irradiation as previously described would be used for all other tissue sample with the exception of RNA/DNA samples. Dr. Bowman indicate that [redacted] of EHS had approved the respirator implementation manual for this lab and that all TB work would now be conducted in a separate BSL3 laboratory so that only those with working with live SARS would be in the BSL3 laboratory with live SARS.

4. **August Protocol Summary Reports-**

A. Protocols and Modifications for Expedited Approvals-

Dr. Jaffe informed the Committee of the following expedited approvals: **04-050-Evaluation of Transgenic Brassica Oleracca Plants**. The Committee accepted this portion of the report by consensus.

B. Protocols and Modifications for Full Committee Review-

I-04-047- Effect of MITF (Micropthalmia Trancription Factor) in Melanocyte Development and Differentiation in BALB/c Nude Mice-

Following discussion that the PI needed to be more specific regarding disposal and disinfection of biohazardous waste, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IVc, please identify that the species of origin for UISO-Mel6 is human.
b. In Form A, item VI e, please expand on disinfection and waste cleanup procedures. For example, hood should be biosafety cabinet, indicate whether all waste (liquid and solid) is bleached and then disposed of or whether dry, solid waste is autoclaved.

I-04-048- Streptococcus Pneumoniae Corneal Ulcers Treated with Linezolid-

Following discussion that the PI needed to discuss housing of animals post-infection with [redacted] and needed to be more specific regarding disinfection of biohazardous waste, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form B, item III, indicate where (room and building) injection will occur.
b. In Form B, item III, indicate where animals will be housed post-injection and where any special housing is required.
c. In Form B, item III, please indicate that biohazard bags will be autoclaved prior to disposal.

I-04-049- IG20 in Cancer Therapy-

Following discussion that clarification was requested regarding the experience of personnel with rDNA, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item VI d, please identify the protein that will be expressed in animals and the ACC number that corresponds to this project.
b. In Appendix 1, please elaborate on the experience and training of personnel on rDNA and in particular, the use of viral vectors.

I-04-051- Atopic Dermatitis and Vaccina Network: Animal Studies Consortium-

Following discussion that there were significant concerns regarding the occupational safety of those that would be working with Vaccinia or Vaccinia infected mice, that a separate biosafety manual was needed for this work indicating specifically the practices and procedures that would be followed, and that the PI needed to include specific details as outlined in the clarifications below, a motion to defer this protocol passed unanimously. Deferral was with the understanding that it is pending the following clarifications prior to re-review.

a. General Comment: A separate biosafety manual needs to be developed for this project. The PI should use the template established for BSL3 biosafety manual as a starting point and address all issues/questions raised in that manual. This manual is essentially the SOPs for all procedures that will involve Vaccinia both in vivo and in vitro, as well as spill/accident procedures, and the medical surveillance plan indicated below. The biosafety manual must be submitted with the revised protocol forms.
b. Medical Surveillance Plan- As part of the process of developing and completing the biosafety manual, a medical surveillance plan must be established, indicating who will require vaccination, where and by whom vaccination will be done, how those who received vaccination will be monitored post-vaccination, how vaccination will be verified, when personnel will require re-vaccination if needed and how training of all potential personnel requiring vaccination will occur prior to vaccination. This plan must be developed in coordination with PI, UHS, IBC office, and EHS.
c. In Form B, item II b, please address the following concerns:
    i. Please indicate where the inoculation procedure will occur. The Committee suggests that this occur in the [redacted] in a biosafety cabinet in the room in which mice will be housed.
    ii. Please indicate the duration or time mice will be maintained post immunization.
    iii. Please indicate the duration of time post-immunization in which mice could be shedding virus. Are mice capable of shedding vaccine from EV lesions and when are these expected to develop? Do humans who develop EV shed vaccine from their lesions? Please provide references addressing this question.
    iv. Please indicate if mice are expected to develop a scab-like lesion at the site of inoculation and the likely duration of time

for that lesions to appear and heal (e.g., describe the time course of events associated with inoculation of mice with Vaccinia).

v. Please indicate all routes by which Vaccinia can be shed by mouse secretions (e.g., blood, lymph nodes, scab or other skin lesions).

vi. Please indicate if flow cytometry will be used to analyze samples collected from infected mice. Will samples be from mice that are still shedding virus? If so, the safety precautions that prevent aerosolization of sample must be addressed in the protocol and where the flow cytometery will occur must be addressed.

d. In Form B, item III, please address the following concerns:

i. Please indicate where inoculation and sample collection will occur. Be specific about room and the use of a biosafety cabinet.

ii. Please indicate where sample processing will occur (room/biosafety cabinet) if samples are infectious.

iii. Please indicate how access to PI's laboratory will be restricted. Be specific about signage. Biohazard sign is not sufficient. How is key access to the room controlled? Only those who have been vaccinated should have key access to the room in which work with infected samples will occur. This includes any of the PI's other personnel, housekeeping, maintenance personnel, etc.

iv. Please include the animal care technicians and veterinarians who will provide support for this project in steps addressing personnel safety.

e. In Appendix 1, please address the following concerns:

i. There is no indication of the level of experience or expertise of personnel in working with infectious agents. If personnel have not been trained or do not have expertise, indicate how training will occur.

ii. In addition to the personnel listed here, any other additional laboratory personnel that will have exposure (work in laboratory where work is occurring) to infected samples must be listed here.

iii. Please add a statement the animal care technicians and veterinarians identified by [redacted] as supporting this project will participate in MSP.

f. All laboratory personnel involved in this project that will ship and receive any Vaccinia virus or infected samples must provide verification of IATA shipping and receiving training. Training is required every two years. Contact Terry Lawrin, UIC biosafety officer, at 413-3701 for training disc.

g. Please discuss the concerns raised above with Mary Bowman (996-7427).

5. Adverse Event Reports-

6. **New Business-**

   a. **Research with Conotoxin-**

Dr. Bowman informed the Committee that she had been requested by the IRB to review a protocol involving the use of a ω-conotoxin intrathecal delivery for pain relief. She indicated that this was a Phase III trial protocol and that the compound had already been tested for toxicity and used in over 1000 patients. She informed the Committee that this particular conotoxin was exempt from Select Agent registration due to the fact that the CDC had determined that it did not pose a danger. She also reminded that Committee that UIC IBC policy indicated that a protocol was to be submitted for use of all biological toxins. The consensus of the Committee was that submission of an IBC protocol for this work was not necessary as this was a phase III trial and review by the Committee would not add any additional protections that were not being addressed by the IRB. Dr. Bowman indicated that EHSO would monitor inventory of the conotoxin.

The meeting was adjourned at 3:30 PM

Institutional Biosafety Committee
Minutes of
September 9, 2004
3:00 P.M. - Room 307 C AOB

PRESENT: Dr. Randal Jaffe, Mr. Richard Anderson, Dr. Mary Bowman, Dr. Edward Cohen, Ms. Anne Cousin, Dr. Jeffrey Fortman, Dr. Paul Goldspink, Dr. William Hendrickson, Dr. Thomas Hope, Dr. Roberta Mason-Gamer, Dr. Alex Neyfakh, Dr. Maria Rudisch, and Ms Shelia White

ABSENT: Dr. Aixa Alfonso and Mr. Terrance Larwin

GUEST: [redacted]

1. **Announcements-**

Dr. Jaffe informed the Committee that there was an addition to the agenda under old business as item a (Update on [redacted] for BSL3 in [redacted]). He also informed the Committee that there were two additional items added to the agenda under new business as item c (Protocol I- 04-054), and item d (NRC Recommendations).

2. **Minutes of August 12, 2004-**

The minutes of the August 12, 2004 meeting were approved pending minor editorial changes.

3. **Old Business-**

   a. **Update on Animal Satellite Facilities for BSL3 in [redacted] for Use under Protocol I-04-033-**

Dr. Fortman informed the Committee that he, [redacted], and the PI's lead technician on this project had visited the BSL3 lab for the purposes of inspecting the facility for housing mice for this protocol. He indicated that two items of concern were noted. The first was the installation of a light timer and the second was the need for the CO_2 delivery system. He indicated that since that visit that the [redacted] machinist has made the CO_2 delivery system and a work order was submitted for the light timer. Dr. Fortman indicated that members of the [redacted] veterinary staff, [redacted] animal care staff and the PIs laboratory also met to discuss husbandry issues related to the delivery of mice to the building vivarium, transport to the laboratory, and decontamination/sterilization of cages, bedding and carcasses before leaving the laboratory for return to [redacted] vivarium and transport to [redacted]. He indicated that the time between inoculation and euthanasia was now 4 days; therefore, cages would not require changing during the study. Dr. Fortman indicated that as soon as the timer was installed the study could be initiated.

4. **September Protocol Summary Reports-**

A. Protocols and Modifications for Full Committee Review-

I-04-053- Regulation of Myosin Heavy Chain Gene Expression During Cardiac Hypertrophy and Heart Failure-

The Committee discussed that the purpose of this project was to transfect rats (normal or hypertrophic) with an adenoviral vector encoding one of two transcription factors for myosin heavy chain. The rats would be injected into the coronary artery during a surgical procedure and rats would be sacrificed at various time points (up to one week) post-transfection. The Committee discussed that the laboratory work involving preparation of the adenovirus was being conducted at a non-UIC facility and clarification as to transport of the vector to UIC was needed including the appropriate training. In addition, the Committee discussed that the work would be conducted in the [redacted] procedural room with only these investigators present, that N-95 masks would be used, but the investigators had to be fit tested for their use and that animals would need to be housed in biohazard room. Following this discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item II, please check first box, as wildtype for vector is RG 2.
b. In Form A, item V a, PI needs to specify [redacted] for housing post-injection of Adenoviral vector.
c. In Form A, item V b, PI needs to store the vector in a laboratory and not the general use small animal procedure room. If vector will be transported to UIC each time it is needed, please indicate this and then in AVIe indicate how it will be transported. This information should include how the vector will be packaged for transport and whether it is going via ground or air to UIC.
d. In Form A, item VI c, please check "2" as wildtype vector is a RG 2 agent.
e. In Form A, item VI f, please check "NO" and remove check mark from "YES' box. This agent will be handled at BSL 2, which is the appropriate level; therefore, this does not apply.
f. Appendix 1, please complete this appendix for the personnel that will be performing this work. These personnel will be required to have a respiratory fit test done by the UIC EHSO. Please contact [redacted] to schedule a fitting. Per OSHA requirements, personnel must have written clearance from a physician to wear a respirator.
g. Personnel listed in Appendix 1 must complete shipping and receiving training. **Hazardous Material Awareness** training is required by the Department of Transportation (DOT) for anyone preparing, shipping or receiving packages of hazardous materials (chemicals, infectious materials, chemical or diagnostic samples, etc.). This includes laboratory workers, office staff, and shipping and receiving personnel who handle packages and gas cylinders. The Hazardous Materials training must be repeated every three years. This

training is available online through the environmental health and safety office website (www.uic.edu/depts/envh/). A UIC net id is required for access to this site. Please note: If you are shipping materials by air you must meet the International Air Transportation Association (IATA) requirements. This training must be renewed every TWO years. Transportation (shipping and receiving) via air requires IATA training. This training is available via a CD disc supplied by Terry Lawrin, UIC biosafety officer. Please contact him at 312-413-3701.

I-04-052- Entry Mechanisms of Enveloped Viruses-

The Committee discussed that the PI was using a vector (pseudo-virus) for the viral entry studies and needed to provide a more detailed description and vector map, that the origin of the genes and DNA although in section IVc needed to be completed in section VI, and that the study did involve a vector system that was BSL2 and the BSL should not be lowered. A motion to approve this protocol passes unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item II, check second box, as DNA is cloned from RG 2, 3, or 4 agents.
b. In Form A, item III, check box pertaining to formation of rDNA molecules containing less than 2/3 of viral genome.
c. In Form A, item IV c, please provide a more detailed description of the vector(s) used for viral entry studies. If viral vectors (or pseudo viral vectors), please indicate the packaging cells used for amplification and whether vectors are attenuated and how they are attenuated.
d. In Form A, item VI a, please complete.
e. In Form A, item VI b, please complete.
f. In Form A, item VI c, please check RG 2, as some of these viruses would be pathogenic to humans.
g. In Form A, item VI f, please check "NO" and remove check mark from "Yes". This protocol will be conducted at BSL2, which is the appropriate level of containment/safety for this protocol for the vectors, cells and genes used. The IBC has determined that the BSL should not be lowered.
h. In Form A, item VII b and VII c, please sign these two assurances.

5. **Adverse Event Reports-**

[redacted]

[redacted]

6. **New Business-**

a. **BSL 3 Lab Practices and Procedures-**

Dr. Jaffe directed the Committee attention to the summary report of an incident of noncompliance involving the BSL3 practices of personnel working on IBC protocol I-04-029. The incident involved both the anteroom door and the laboratory door being propped open by laboratory personnel. Upon receiving the report, the IBC office immediately contacted the PI, the BSO, and the chair of the IBC. The PI informed the IBC office that the samples being handled at that time were from non-infectious [redacted]. The PI was informed that BSL3 practices were to be adhered to at all times in the laboratory regardless of the samples being processed and that retraining of all personnel involved in the project must occur immediately. The PI, with the BSO in attendance, held a retraining session for all personnel involved in the project. Via a letter from the Director of EHSO to the chair of the IBC, the BSO indicated that the training was comprehensive and complete and that all personnel demonstrated proficiency and passed a written test on safety practices in the BSL3. The Chair of the IBC approved the resumption of activity on this project. The PI also sent a letter of apology to the IBC indicating the steps being initiated to ensure that a similar incident does not reoccur.

The Committee discussed the summary report, the letters from the PI, and the Director of EHSO. They discussed what options the Committee had concerning this incident and any reoccurrence of noncompliance such as suspension of the IBC protocol. The Committee discussed why the incident might have occurred, whether the PI was appropriately supervising the project and the steps the PI had taken since the incident occurred to ensure compliance. The Committee also discussed whether the PI's department head had been informed and Dr. Bowman indicated that the department head had received a written summary of the incident. The consensus of the Committee was that a letter to the department head with copy to the PI be sent requesting that the department head meet with the PI regarding this incidence of noncompliance and that the department head respond to the IBC in writing ensuring that this issue of noncompliance will not occur again. In addition, the letter should indicate that reoccurrence of serious noncompliance on this protocol would be considered grounds for suspension of the protocol and termination of BSL3 laboratory privileges.

b. **BSL 3 Lab Policies and Certification-**

Dr. Bowman informed the Committee that the BSL3 task force submitted a final report to the Vice Chancellor for Research recommending that a formal BSL3 certification and quality assurance plan be developed. She informed the Committee that the Vice

Chancellor had asked that the EHSO and the IBC office work together to draft the policy for review and approval by the IBC. Dr. Bowman informed the Committee that additional information would be forthcoming as the policy documents were prepared.

c. Protocol I-04-054- Study of E2F Transcriptional Factor in Drosophila-

Dr. Bowman informed the Committee that a new investigator was in the process of transferring a grant to UIC and had requested for the purposes of facilitating that grant transfer to UIC, that his protocol be reviewed this month. She indicated that she, Dr. Jaffe and Mr. Lawrin had prereviewed the protocol. The Committee discussed that the PI was studying transcription factors that regulate cell cycle progression using both in vitro cell transfection experiments and transgenic fruit flies. The Committee discussed that the PI need to elaborate on the vectors used for the transfection studies, needed to have the facilities inspected as a condition of approval, and needed to complete the appropriate BBP and IATA training. Following this discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IV c, please address the following concerns:
    i. Please identify the types of vectors used for both the in vivo (transgenic) and in vitro transfection studies. If viral vectors will be used, please indicate specific type of vector and answer questions regarding attenuation. In addition, please see concern below regarding IATA training.
    ii. Please identify the species of origin for U2OS and Saos2 cells.
b. In Form A, item V a and V b, rooms as to where work will be conducted and rDNA molecules related to this protocol will be stored need to be identified. A condition of approval is that these room numbers must be provided to the IBC office and the rooms inspected by the EHSO prior to initiation of the work described in this protocol. Please contact Dr. Mary Bowman at 312-996-7427 regarding this concern.
c. In Form A, item IV d, please indicate what protein(s) will be expressed and answer the question for expression in plants.
d. In Form A, item VI e, please answer this question indicating what work will occur in a biosafety cabinet, what PPE will be used, and the decontamination/waste procedures that will be used.
e. In Form A, item VI f, please mark "No" to this question.
f. A condition for initiation of this work will be completion of blood borne pathogen training by personnel listed in Appendix 1. Please see IBC website for list of training seminar dates and times. Please forward copy of certificate of completion to IBC office once obtained. Please provide a copy of training certificate to the IBC office.
g. If viral vectors will be used, please contact Mr. Terrance Lawrin at 413-3701 to obtain a training disc for completion of IATA training for shipping and

receiving of infectious agents. Please forward copy of certificate of completion to IBC office once obtained.

d. NRC Recommendations-

Dr. Bowman reminded the Committee that the NRC had recommended and the NIH had formed the National Science Advisory Board for Biosecurity. (NSABB). The NSABB was established in response to concerns regarding dual use biodefense research. She indicated that while the responsibilities of the IBC have not changed, it appeared that they would be in terms of assessing research for its potential dual use. The Committee discussed the seven areas that were identified as "experiments of concern" and the recommendations of the NRC to develop a multi-tier review system for these types of research projects. Dr. Bowman indicated that she would continue to update the Committee as additional information became available.

The meeting was adjourned at 3:30 PM

Institutional Biosafety Committee
Minutes of
October 14, 2004
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Randal Jaffe, Mr. Richard Anderson, Dr. Mary Bowman, Dr. Edward Cohen, Ms. Anne Cousin, Dr. Jeffrey Fortman, Dr. Paul Goldspink, Dr. William Hendrickson, Dr. Thomas Hope, Dr. Roberta Mason-Gamer, Dr. Alex Neyfakh, Dr. Maria Rudisch, and Ms Shelia White

ABSENT: Dr. Aixa Alfonso and Mr. Terrance Larwin

1. **Announcements-**

Dr. Jaffe informed the Committee that there was an addition to the agenda under new business as item a (Final Report from Sunshine Project on IBCs).

2. **Minutes of September 9, 2004-**

The minutes of the September 9, 2004 meeting were approved pending minor editorial changes.

3. **Old Business-**

   a. **BSL 3 Policy**

Dr. Bowman directed the Committee to the second draft of the BSL3 Policy for Certification/Recertification and Quality Assurance. She reminded the Committee that this was joint effort between EHSO, which had drafted the policy, and the IBC at the request of the Vice Chancellor for Research. Dr. Bowman asked the Committee to review the policy and provide feedback. She indicated that in addition to the policy several appendices outlining the criteria for BSL3 would be forthcoming. The committee discussed the policy and indicated that there were the following concerns listed below. Dr. Bowman requested that the Committee have final comments to her within two weeks.

1. Formatting and typographical errors needed to be corrected.
2. Regulations and references needed to be listed in separate sections, as they were different.
3. Concerns were raised as to whether there were any potential inconsistencies between the different regulations and references and which should be followed and how that would be determined.

4. Concerns were raised as to lack of expertise on the Committee to evaluate all criteria for HVAC and equipment and the need for outside consultation from an expert.
5. Concerns were raised as to how outsourced certification would be paid. Would the PI be responsible, department, college or a combination? Can we approve a policy requiring this without knowing this since it will be an expensive process? In addition, if certification determines that maintenance/repair must be done, concerns were raised as to who would be responsible for payment.
6. The Committee raised the question as to what exactly a certification company would provide the UIC and whether or not the facilities and equipment could be certified separate from the practices and procedures. In addition, the Committee questioned the number of companies that provided this type of service and the references for those companies.
7. The Committee questioned whether decontamination of laboratory was required prior to certification/testing process, who would conduct this and who would pay.
8. Specific comments on language in policy:
    a. Section 5.1
        i. After first prior insert "to"
        ii. As written statement implies that certification process must be conducted twice. Please clarify.
    b. Section 5.1.2- Define multidisciplinary professionals
    c. Section 5.4- Include BRL in notification if the facility certification is related to animal facility.
    d. Section 5.5.1
        i. Add (DDD) after Head
        ii. Change cease to cessation and delete when necessary.
    e. Section 6.2
        i. Nonconformity should be designated as minor or major.

b. Update on BSL 3 Practices and Procedures related to IBC Protocol 04-029-

Dr. Jaffe directed the Committee's attention to the letter from the Department Head of the PI to protocol 04-029. The letter indicated that the PI and the Department Head had met to discuss the seriousness of the lapse in procedure and the steps that had been taken to ensure that it would not occur again. The Committee discussed whether the alarm had sounded and the need to have the alarm tested. Dr. Bowman indicated that she would pursue having the alarm tested. In addition, the Committee discussed whether an alarm could be installed that would sound if both the anteroom door and the containment laboratory door were opened at the same time. Mr. Anderson indicated that he would look into this request.

4. October Protocol Summary Reports-

a. Protocols and Modifications for Expedited Approvals-

I-04-029-03- Change in title to reflect additional grant using the same procedures.

I-04-029-04- Addition of personnel. Approved by Chair, BSO, and Associate Director-ACC/IBC

I-04-055- Genetic Studies of the Membrane Skeleton-

The purpose of the BSL1 project is to study the role of spectrin and related genes during development. A number of Drosophila genes, alpha and beta spectrin, ankyrin, neuroglian, and anion exchanger, have been cloned and recombinant fruit flies with normal or mutant genes are being developed to study their function in development. These proteins (or fragments) are also being cloned and expressed in vitro using pBluescript and pGEX.

A. Protocols and Modifications for Full Committee Review-

I-04-056- Role of Nectin-1 in Corneal HSV Infection-

The Committee discussed that the purpose of the project was to infect mouse cornea with Herpes Simplex virus-1 (HSV-1) to determine the role of nectin-1, a primary mediator of HSV-1 entry into cells. Corneas of anesthetized mice would be infected with wild type and mutant strains of HSV (viral load- max 1 X 10^7 CFU). Mutant strains are deficient in the viral thymidine kinase gene and can replicate in ocular tissue, but not in nervous tissue. Mice will be euthanatized within 7 days of inoculation and ocular and nervous tissues would be collected for plaque assays, PCR, and β-gal expression in cells. Dr. Bowman informed the Committee that the PI had addressed the concerns raised during prereview. The recombinant strains were being obtained from a PI at [redacted]. If necessary, the virus would be propagated in the laboratory in Vero cells under the BSL2 conditions outlined in the protocol. Work with open cultures would occur in a [redacted]. Dr. Bowman indicated that the PI had informed her that they anticipated receiving sufficient amounts such that propagation at UIC would not be necessary and only dilution for injection and aliquoting in the [redacted] would be needed. In addition, she indicated that the appropriate shipping and receiving documentation had been completed. A motion to approve this protocol passed unanimously.

I-04-051- Atopic Dermatitis and Vaccina Network: Animal Studies Consortium-

Following discussion that although the PI had revised his previous protocol there were still numerous clarifications that needed to be addressed, that the MSP was not finalized as to who would administer vaccine to personnel, that it was unclear as to whether only

flow cytometry was being conducted, the amount of potential aerosol that would be generated and whether this could be conducted on an inactivated sample, and that training of personnel needed to be elaborated on, a motion to defer this protocol passed unanimously. Deferral was with the understanding that it is pending the following clarifications prior to rereview.

a. In Form B, item Ie, in addition to [redacted], please list PI's laboratory, as sample processing and culture will occur in this room.
b. In Form B, item III, please address the following concerns:
    i. Number 1, please change statement to read "All laboratory personnel, [redacted] veterinarians, and [redacted] animal care personnel who have...Dryvax. The project will not be initiated until *at least three weeks post-immunization of all appropriate personnel.*"
    ii. Number 2, please add the following statement to this section: "Access to this biohazard room will be restricted to only those personnel (laboratory, vets, and animal care) that are vaccinated and participating in this project. No other animals will be housed in this room during the experiment and mice will be housed in microisolator cages.
    iii. Number 3, please indicate the specific room in which sample processing will occur. This should be the PI's laboratory. In addition, please clarify the statement "to be assigned by UIC authority". What authority will be assigning space for sample processing? This room must be inspected by the BSO.
    iv. Number 5, sign should also indicate that only those personnel vaccinated with vaccinia may enter.
    v. Number 6 and 8, appropriate eye protection should also be included.
    vi. Number 7, please change statement to read "After initiation of project, all personnel (laboratory, veterinary and animal care) will be instructed to perform a daily check for the following signs and symptoms, (*complete with appropriate signs and symptoms*), associated with vaccinia infection while working with vaccinia. If positive findings are observed, the affected individuals will be instructed to contact UHS and report to the emergency room for further evaluation per the instructions in the Medical Surveillance Plan for this protocol." PI needs to fill in the signs and symptoms.
c. In Appendix 1, please address the following concerns:
    i. For [redacted], please indicate how [redacted] will be trained on the specifics of this protocol and vaccinia.
    ii. For [redacted] please indicate what training [redacted] will receive on working with pathogens and specifically with vaccinia.
    iii. Please state specifically if PI will be participating in the project and whether PI will be vaccinated. If PI is participating in the

project, please include relevant information as to PI's experience and/or training.

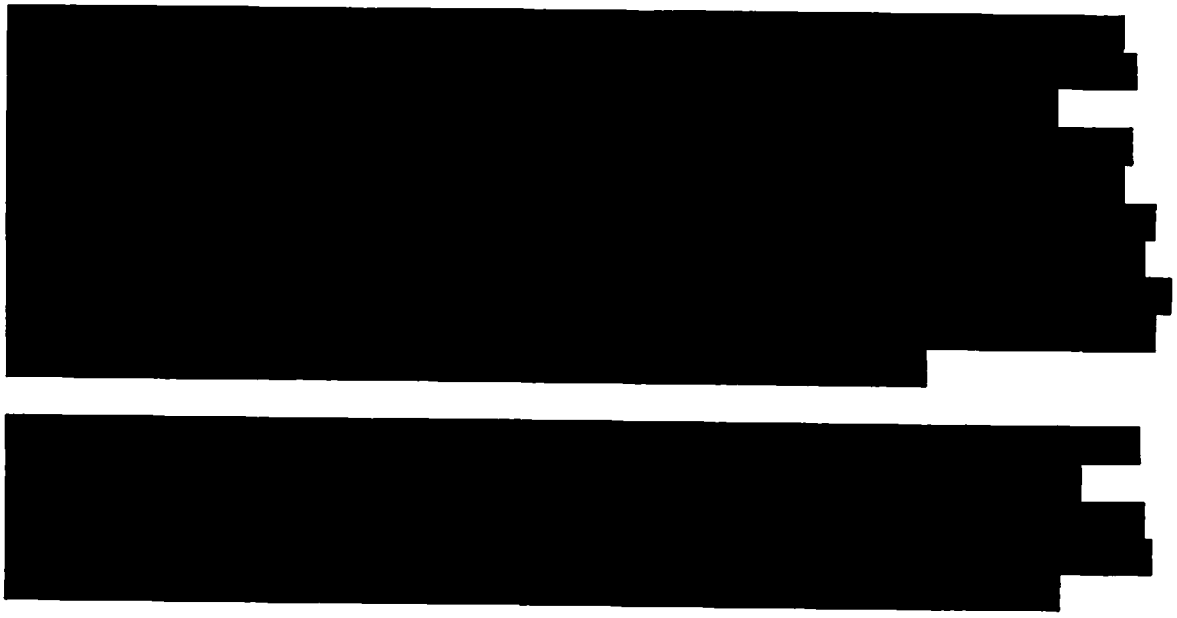
d. In Biosafety Manual, please address the following concerns:
   i. Under Medical Surveillance Plan:
      1. Add [redacted] and PI's before staff.
      2. Change 3rd sentence to read. All staff will be vaccinated according to the attached Medical Surveillance Plan.
      3. It is suggested that that last two sentences be removed from the biosafety manual and that they be addressed in the attached MSP.
   ii. Under Personnel and Training:
      1. In addition to signature of trainee, PI needs to provide other supporting documentation that personnel understand the appropriate procedures (e.g., written test).
   iii. Under PPE:
      1. Please include the appropriate eye protection.
      2. Please define conditions under which N-95 masks will be used.
      3. Please indicate that all personnel will undergo medical clearance for N-95 use and will undergo yearly fit testing. Documentation of fit testing must accompany this IBC protocol.
   iv. Under biosafety cabinet:
      1. Please divide this section into two parts referring to [redacted] biosafety cabinet and laboratory biosafety cabinet.
      2. For each indicate what procedures will occur in biosafety cabinet.
      3. Please provide documentation of biosafety cabinet certification within the last year.
      4. Please indicate how biosafety cabinet will be decontaminated after each use.
   v. Under Spill/Accident Procedures:
      1. Please review the details of the UIC Biosafety manual regarding spills and types of spills. Additional details based on the recommendations of the biosafety manual need to be included in this section.
      2. Please refer to the MSP for contact information on exposures. Also, according to protocol, personnel working with vaccinia will monitor themselves daily for potential infections, this section suggests that this would only occur in the case of a known accidental exposure.
      3. Please indicate that both BSO and IBC office will be informed of any accidents regarding vaccinia use.
   vi. Under Waste Disposal Procedures:
      1. Please indicate that all solid waste will be autoclaved on the day it is created.

2. Please indicate how waste will be transported to the autoclave.
3. Please indicate minimum contact time for exposure of liquid waste to bleach before disposal.

vii. Under Flow Cytometry Studies:

1. Please indicate where vortexing of samples will occur (BSC?).
2. Please be specific as to room in which flow cytometer will be housed, the amount of aerosol that will be produced and whether cell sorting will also be conducted.
3. Please indicate whether samples could be inactivated (e.g., fixed?) prior to flow cytometry to eliminate potential aerosol of infected samples.
4. Please contact Terry Lawrin (413-3701), UIC BSO, to discuss this concern.

5. Adverse Event Reports-



6. New Business-

a. Final Report from Sunshine Project on IBCs-

Dr. Bowman informed the Committee that the final report from the Sunshine Project on IBCs had been released. The report indicated that UIC's minutes had failed. Dr. Bowman informed the Committee that UIC's minutes were in accordance with the recommendations recently published by OBA in a series of FAQs.

The meeting was adjourned at 3:20 PM

Institutional Biosafety Committee
Minutes of
November 11, 2004
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Randal Jaffe, Mr. Richard Anderson, Dr. Mary Bowman, Dr. Edward Cohen, Dr. Jeffrey Fortman, Dr. Paul Goldspink Dr. Thomas Hope, Mr. Terrance Lawrin, Dr. Roberta Mason-Gamer, Dr. Maria Rudisch, and Ms Shelia White

ABSENT: Dr. Aixa Alfonso, Ms. Anne Cousin, Dr. William Hendrickson and Dr. Alex Neyfakh

1. **Announcements-**

There were no announcements to report.

2. **Minutes-**

The minutes of the October 10, 2004 meeting were approved pending minor editorial changes.

3. **Old Business-**

   a. **BSL 3 Policy and Certification**

Dr. Bowman informed the Committee that the Committee's concerns and comments regarding the BSL3 policy and certification process were forwarded to the EHSO. She indicated that the EHSO was pursuing information on consultants for the facilities aspects of the policy.

   b. **Update on BSL 3 Practices and Procedures related to IBC Protocol 04-029-**

Dr. Bowman informed the Committee that Mr. Lawrin had conducted a test of the audible alarm system for the BSL3 laboratory in [redacted] as requested by the Committee. The test consisted of opening the containment door to one of the BSL3 labs about 12 inches for approximately one minute. During the test the alarm did not sound; however, Mr. Lawrin also indicated that he did not observe a change in pressure as indicated on the pressure monitor. Dr. Bowman indicated that she had consulted with the engineer involved in the design of the facility. She indicated that the engineer stated that without a significant change in pressure, which was not observed, that the alarm would not sound. The Committee discussed that the test failed because it did not challenge the system

sufficiently. Mr. Lawrin indicated that the room is highly negative to the anteroom. Dr. Bowman indicated that the other method of testing involved closing the bubble dampers, which would involve needing to decontaminate the lab. The Committee discussed that this would be done when the lab completed the certification process and did not need to be done at this time, but that the pressure difference on the intake HEPA filters should be checked to determine if the filters should be changed.

Dr. Bowman asked Mr. Anderson if he had determined whether the alarm system could be configured to sound if both doors (anteroom and containment) were opened at the same time. He indicated that this could be done. The Committee discussed that this criteria would be discussed for the facility appendix to the BSL3 policy.

4. **October Protocol Summary Reports-**

a. Protocols and Modifications for Expedited Approvals-

Dr. Jaffe referred to the Committee to the modifications and protocol that were eligible for expedited approval.

I- 02-054-01- Addition of personnel.

I- 03-070-03- Addition of personnel and upgrade of a laboratory to BSL2.

I- 04-030-02- Addition of personnel and upgrade of a laboratory to BSL2.

I-04-057- Organization of the Early Secretory Pathway in Yeast-

The purpose of the protocol is to understand what mechanisms are involved in targeting and transport of proteins within the cell and to the extracellular environment. Baker's yeast is the model organism. Portions of the yeast genome will be cloned into yeast shuttle vectors and site directed mutagenesis will be used to determine the function of various proteins or protein domains. Plasmids will be propagated in laboratory strains of E. coli. Cell free assays using GST and 6XHis-tagged fusion proteins from yeast or E. coli cultures will also be performed. This project will be conducted at BSL2.

b. Protocols and Modifications for Full Committee Review-

I-03-055-01- Role of Forkhead Box (Fox) and Hepatocyte Nuclear Factor 6 (HNF-6) Transcription Factors in Mouse Liver Regeneration, Differentiation and Cancer

The Committee discussed the modification request for the ex vivo administration of lentiviral vector expressing siRNA or a mutant siRNA to FoxM1b transcription factor to

athymic nude mice, that the vector was a replication deficient lentivirus also expressing GFP and inducible via doxycycline administration, and that it would be transfected ex vivo in U2OS clone 3 cells. Following discussion, a motion to approve this modification was unanimously passed.

5. Adverse Event Reports-

There were no Adverse Events reported.

6. New Business-

There was no New Business to report.

The meeting was adjourned at 2:20 PM

Institutional Biosafety Committee
Minutes of
December 9, 2004
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Randal Jaffe, Mr. Richard Anderson, Dr. Mary Bowman, Ms. Anne Cousin, Dr. Jeffrey Fortman, Dr. Paul Goldspink, Mr. Terrance Lawrin, Dr. Alex Neyfakh, Dr. Maria Rudisch, and Ms Shelia White

ABSENT: Dr. Aixa Alfonso, Dr. Edward Cohen, Dr. William Hendrickson, Dr. Thomas Hope, and Dr. Roberta Mason-Gamer

1. **Announcements-**

Dr. Bowman informed the Committee that a request to train personnel for protocol 04-029 was added to the agenda as item a under new business. In addition, she informed the Committee that OBA had announced to the research community that it would soon begin site visits to select institutions to obtain further information on IBC compliance with the *NIH Guidelines* and to educate institutions more directly about compliance.

2. **Minutes-**

It was determined that the approved October minutes were inadvertently sent to the Committee for review and not the November minutes. A few minor editorial corrections in the October minutes were made. Dr. Bowman informed the Committee that the November minutes would be presented to the Committee in January.

3. **Old Business-**

None

4. **October Protocol Summary Reports-**

   a. **Protocols and Modifications for Expedited Approvals-**

None to report.

   b. **Protocols and Modifications for Full Committee Review-**

I-03-034- A Phase I Dose-Ranging Study of the Safety, Tolerability, and Immunogenicity of the [redacted] Trivalent Adenovirus Serotype5 NIV-

1gag/pol/nef Vaccine (MRKAD5HIV-1gag/pol/nef) in a Prime-Boost Regimen in Healthy Adults- (*Modification 03-034-02*)

[redacted]

I-04-058- Roles of Checkpoint Proteins and Chromatin Modifications in Genome Stability, DNA Repair, and Telomere Maintenance

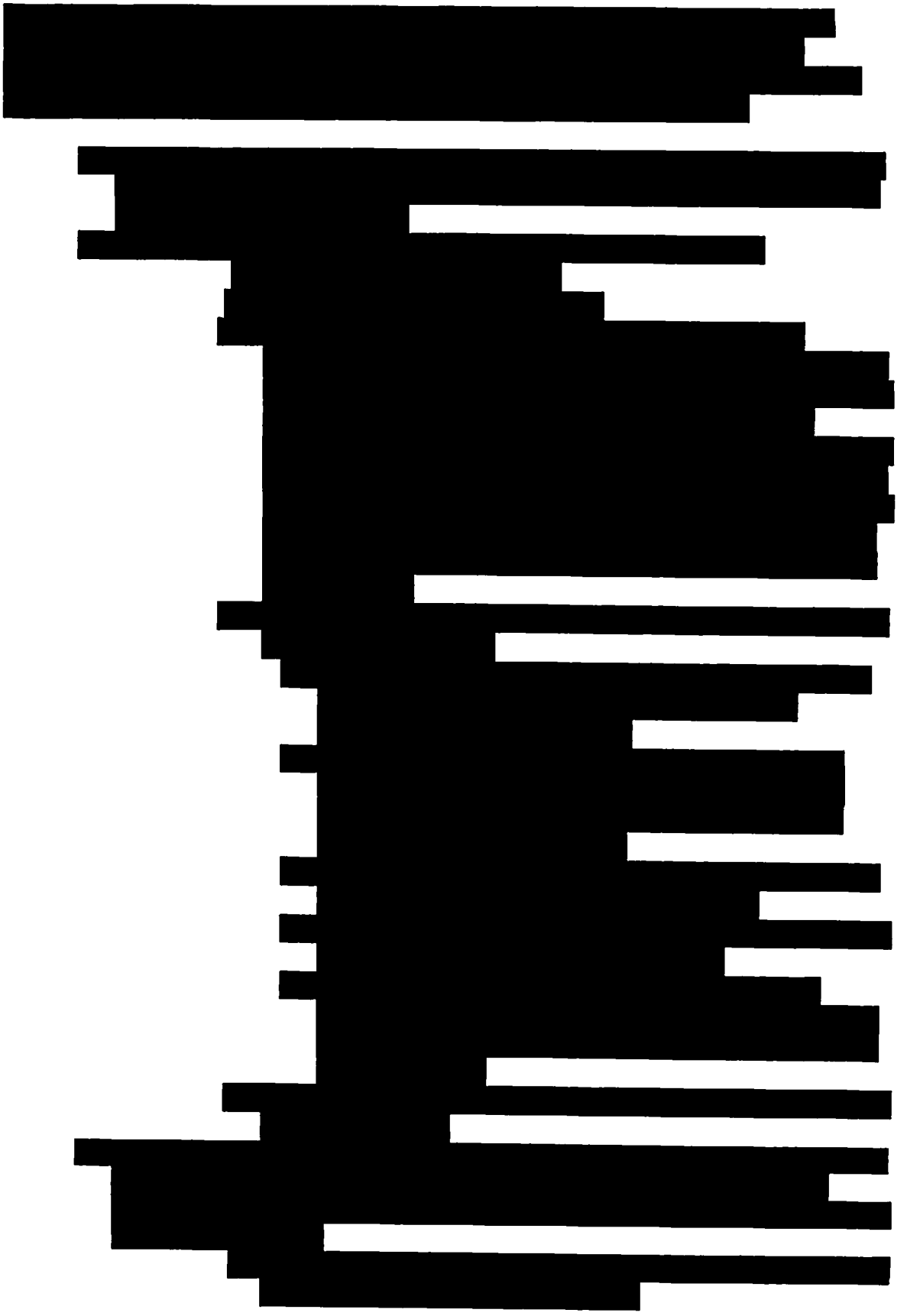
The Committee discussed that the goals of this study are to understand how cells regulate DNA repair, cell division after DNA damage has occurred, and maintenance of telomeres, that the primary model system will be fission yeast, Schizosaccharomyces pombe, and that a large number of DNA repair proteins, DNA damage checkpoint proteins, DNA replicase proteins, telomere related proteins, histones, and histones modifying enzymes would be tested. The Committee also discussed clarification as to the other model organisms mentioned was needed to determine if human cells would be used. A motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

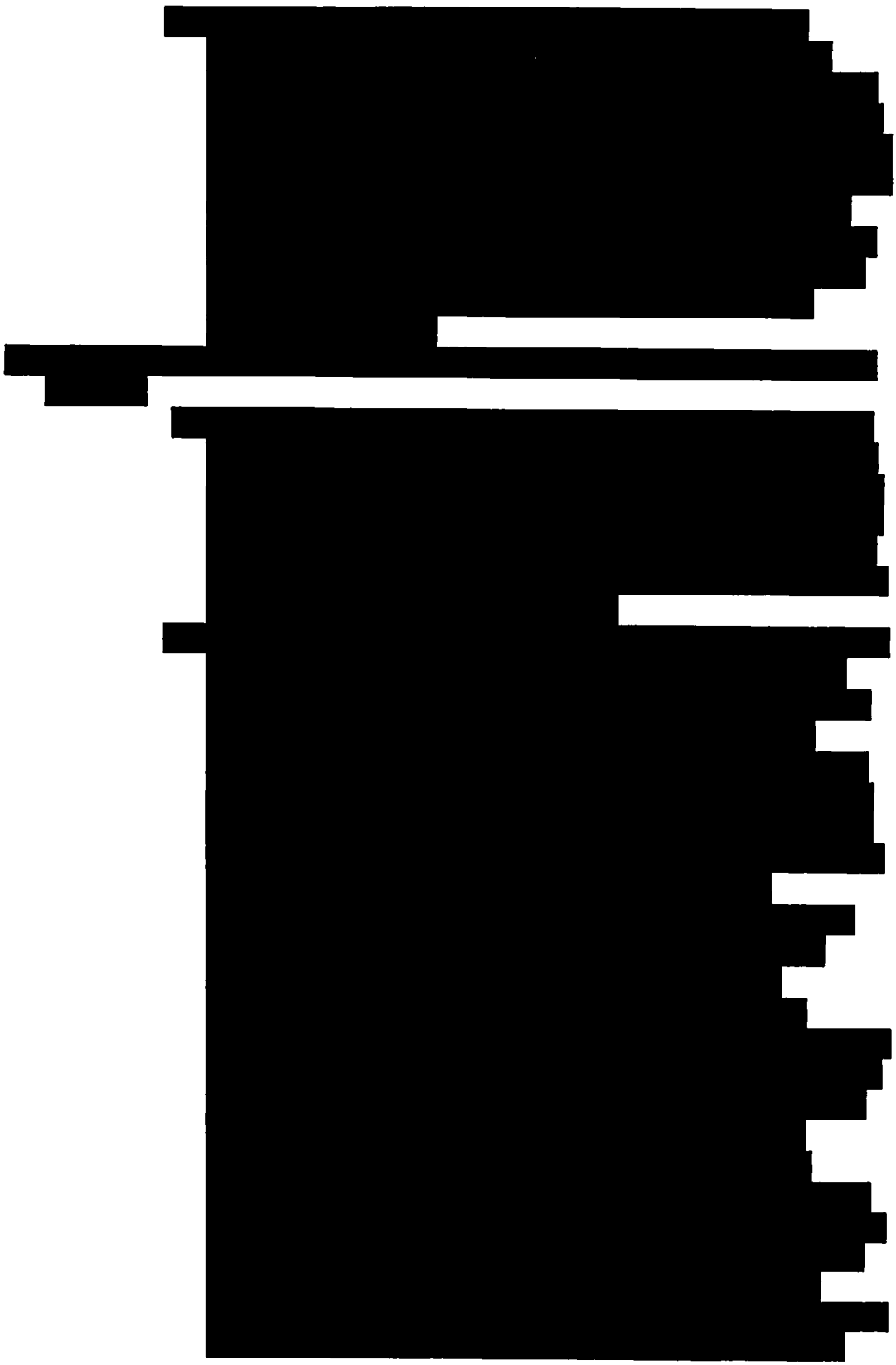
Clarifications:

a. In Form A, item IV c, please address the following concerns:
   i. PI suggests using human model as comparison. PI needs to clarify if this means expression in human cell lines or expression of human genes only. If project will involve use of human cell lines for either expression or to do initial isolation of genes, then project should be conducted at BSL2. See comments below.
   ii. Please indicate the types of vectors to be used for expression in vitro. If using viral vectors, please provide information as to how vectors are attenuated and the nature of the packaging cell lines to be used. Use of viral-based vectors will require BSL2. Viral vectors also require IATA training for shipping and receiving. Please contact Mr. Terry Lawrin (413-3701) for a training CD. A copy of the IATA training certificate will need to be sent to the IBC office prior to approval.

b. In Form A, item V c, change BSL to 2 for use of human cell lines.
c. In Form A, items VI a-e, complete for BSL 2.
d. All personnel working with human cell lines must complete bloodborne pathogen training. Please see IBC web site for a list of training seminar dates. Once completed, please send copy of training certificate to IBC office. This is required prior to approval.

I-04-059- A Phase III Randomized, Open-Label Study of CG1940 and CG8711 Versus Docetaxel and Prednisone in Patients with Metastatic Hormone-Refractory Prostate Cancer who are Chemotherapy-Naïve-





[redacted]

I-04-060- Study of Fusobacterium nucleatum Expression of Relevant Genes Implicated in the Development of Halitosis (Malodor)-

The Committee discussed that this organism was classified as BSL1 by ATCC, that it was not clear if this was really a risk group (RG) 2 organism known to cause disease in healthy adult humans, that the description of the study was not in lay language, and that disinfection procedures needed to be described. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item II, box 2, it is unclear if this should be marked. Please see comments below related to RG.
b. In Form A, item IV a, please describe the project using layman's language. Description is too scientific.
c. In Form A, item IV c, please address the following concerns:
    i. Please define MIC and MBC.
    ii. Please clarify if the plasmid being obtained from [redacted] contains the gene for I-cysteine desulfydrase or is this just the empty plasmid.
d. In Form A, item VI c, please clarify the risk group for this project. Does Fusobacterium nucleatum **cause** disease in healthy adults? This would classify it as RG2 and BSL2. If not, then RG should be 1.
e. In Form A, item VI e, please indicate what disinfection procedures will be used (e.g., 10% bleach followed by 70% ethanol).
f. In Form A, item VI f, it is not clear why PI is requesting that BSL be lowered. Please call Dr. Mary Bowman (996-7427) to discuss this item.

5. Adverse Event Reports-

[redacted]

6. New Business-

a. New personnel on Protocol I-04-029-

Dr. Bowman informed the Committee that the PI had requested that a new member of his laboratory who is currently trained on BSL2 activities be allowed to observe procedures conducted under this protocol in the BSL3 laboratory as part of the training process. Dr. Bowman indicated that the PI had stated that personnel would complete entry into the medical surveillance program prior to entering the lab. The Committee agreed that this was an appropriate request for training and that in addition to the MSP, personnel had to be fit tested for an N-95 mask prior to entering the BSL 3 lab. Dr. Bowman stated she would inform the PI.

The meeting was adjourned at 3:10 PM

Institutional Biosafety Committee
Minutes of
January 13, 2005
3:00 P.M. - Room 307 C AOB

PRESENT: Dr. Randal Jaffe, Mr. Richard Anderson, Dr. Aixa Alfonso, Dr. Mary Bowman, Dr. Edward Cohen, Ms. Anne Cousin, Dr. Paul Goldspink, Dr. Thomas Hope, Dr. Roberta Mason-Gamer, Dr. Alex Neyfakh, and Ms Shelia White

ABSENT: Dr. Jeffrey Fortman, Dr. William Hendrickson, Mr. Terrance Lawrin and Dr. Maria Rudisch

1. **Announcements-**

None

2. **Minutes-**

The minutes of both the November 11, 2004 and the December 9, 2004 IBC meetings were approved pending a minor editorial clarification.

3. **Old Business-**

   a. **MOU with Jesse Brown VAMC**

Dr. Bowman provided an overview to the Committee of the Agreement between the University Of Illinois Board Of Trustees and the Jesse Brown VA Medical Center for IBC review and approval of rDNA research projects using monies administered by UIC, but conducted at the VA. She indicated that the applicability would be for all rDNA research using UIC monies and for all research involving testing in humans of materials containing rDNA that is conducted at the Jesse Brown VA Medical Center involving University-affiliated employees. The agreement indicates that the UIC biosafety officer will have the authority to inspect the facilities in which the rDNA research will be conducted, that portions of minutes that pertain to VA projects will be provided to the VA and that the UIC will receive copies of the VA Safety Subcommittee minutes as part of the VA R&D minutes. Dr. Bowman also indicated that the agreement had been reviewed by University Counsel and was awaiting signatures by members of the Board of Trustees prior to review and approval by the Jesse Brown VA Medical Center R & D Committee.

4. **January Protocol Summary Reports-**

a. Protocols and Modifications for Expedited Approvals-

I-03-012-01- Development and Testing of siRNA-Based Therapeutic Agents-

The modification requested the addition of 3rd generation lenti-viral based vectors for *in vitro* transfection studies (stable and transient) of various human cancer cell lines. Goal is to conditionally express siRNA to suppress endogenous drug transporters associated with multi-drug resistance.

b. Protocols and Modifications for Full Committee Review-

I-04-011-Antimicrobial Studies of Clinical Pathogens (*Modification 04-011-01*)-

The Committee discussed that the PI requested a change in PI to another UIC investigator who will take over as director of the laboratory due to the PI is moving to another institution. PI will maintain adjunct appointment at UIC and will remain as Co-PI of the protocol. Additionally, the modification requested the addition of new personnel who will be trained by the original PI. The Committee discussed that verification of bloodborne pathogen training was required for new personnel. Following discussion, a motion to approve this modification passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. Please provide verification of bloodborne pathogen training to IBC office for new personnel working on project.

I-04-003- Nociceptive Response in Naked Mole-Rats (*Modification 04-003-01*)-

The Committee discussed that the PI is requesting to use 2 fully replication competent HSV vectors as these vectors are only available in this form. The first expresses substance P. The proposed use is the same as that originally proposed in the protocol. The second expresses TRPV2 receptor antisense RNA. These receptors are the main receptors on A-delta type pain fibers. The purpose is to block these pain fibers to determine the role of the abnormal C pain fibers in naked mole rats. Original protocol was approved at BSL2 and work with replication competent vectors will still be BSL2. The Committee also discussed whether a medical surveillance plan (MSP) was required for use of replication competent vectors, but it was the consensus of the Committee that the PI was using appropriate safety precautions, that MSP would not add to those precautions, that and the surveillance for a ubiquitous virus in which 30-80% of the population is already seropositive would be difficult.

a. Condition: Work cannot be initiated until approval of the ACC is granted to conduct proposed study in naked mole rats.

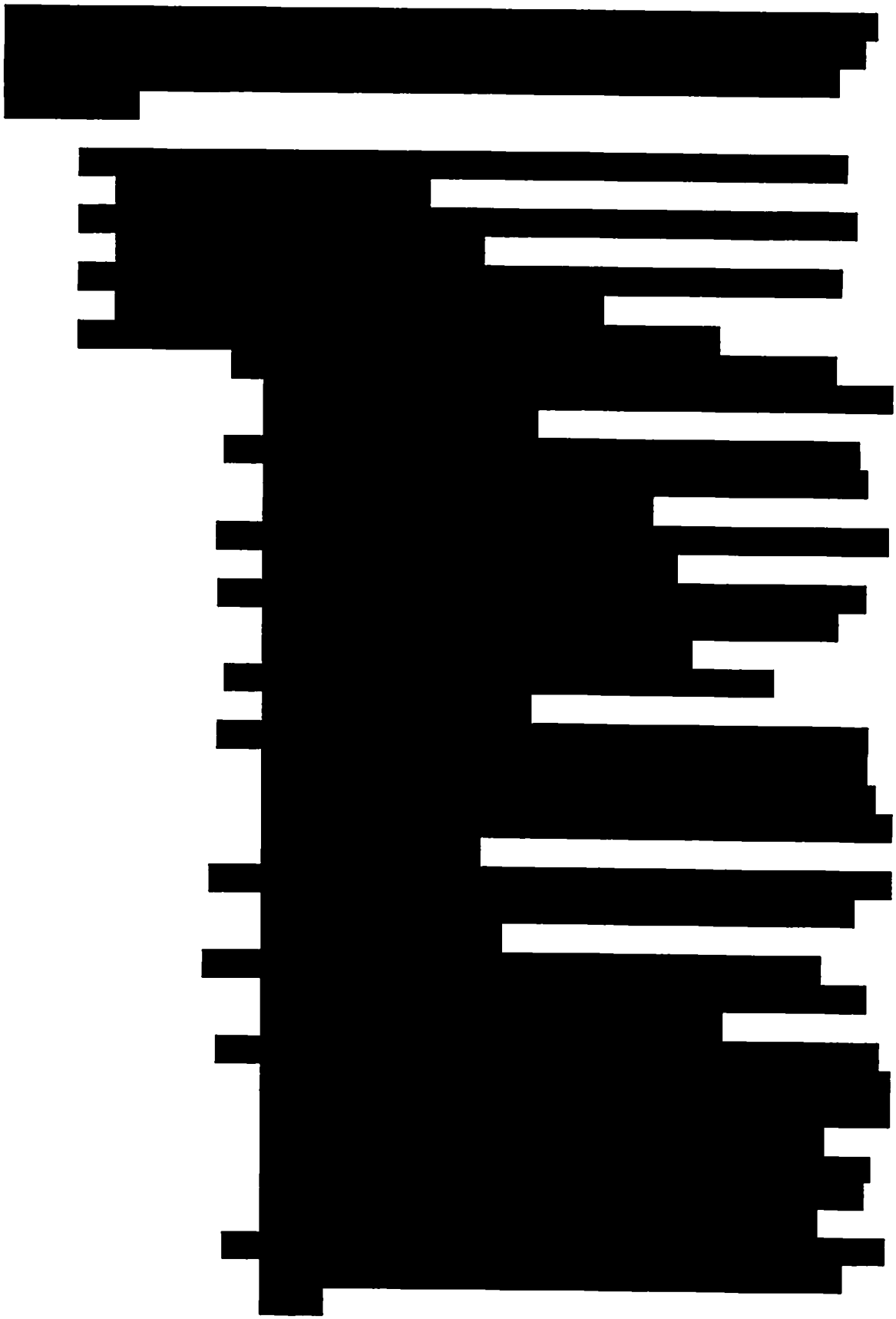
I-04-061- Cancer Therapy with Fibroblasts Tranfected with Genomic DNA from Autologous Cancer-

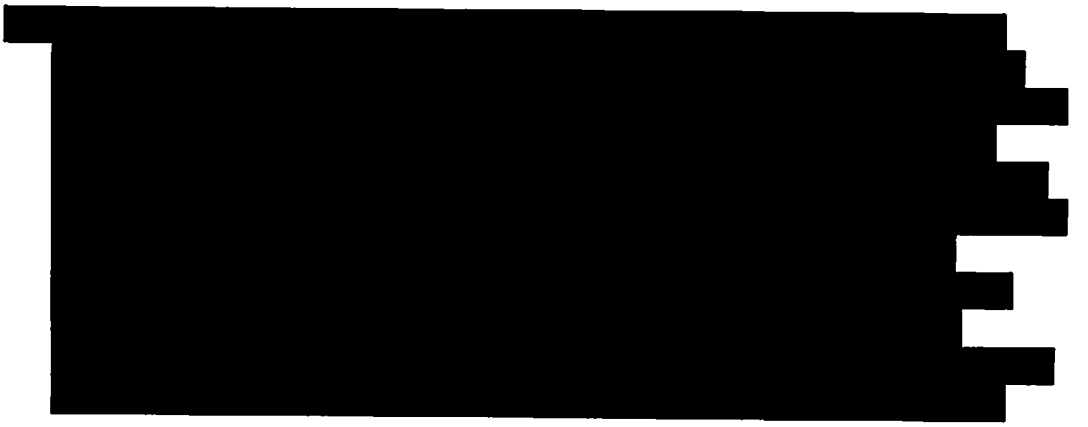
The committee discussed that the purpose of the project was to develop a vaccine based strategy to treat cancer patients with minimal residual disease remaining after conventional therapy. Murine fibroblast cell lines would be transfected with plasmids containing genes from the cancer cells. Tumor bearing mice would then be inoculated with the transfected cells to determine efficacy. The committee discussed that the PI was moving laboratories and the room in which the study would be conducted needed clarification. A motion to approve this protocol passed unanimously. Approval was with the following clarifications.

a. In Form A, item II, please mark box regarding use in whole animals.
b. In Form A, item Va and Vb, please clarify whether room [redacted] is the correct room for lab location and storage of rDNA. In addition, please note that if laboratory location changes during the course of this study, PI must notify IBC office and laboratory must be inspected by EHSO.

I-04-062- [redacted] V520-023; HVTN 502: A Study to Compare a 3-Dose Treatment with the [redacted] HIV Vaccine (MRKAd5 HIV-1 gag/pop/nef) to Placebo in Adults at High Risk of HIV Infection -

[redacted]





I-04-063- Role of Protein Kinase C in Tamoxifen-Resistant Breast Cancer

The Committee discussed that the purpose of the study was to develop tamoxifen-resistant human breast cancer cell lines by transfection with plasmids containing PKC and aromatase. These cells would be propagated in athymic nude mice and used to test the effect of various treatments. Verification of bloodborne pathogen training was required. A motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. Please provide verification of bloodborne pathogen training to IBC office.

5. Adverse Event Reports-

None to report

6. New Business-

None to report

The meeting was adjourned at 4:12 PM

Institutional Biosafety Committee
Minutes of
February 10, 2005
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Randal Jaffe, Dr. Aixa Alfonso, Dr. Mary Bowman, Ms. Anne Cousin, Dr. Jeffrey Fortman, Dr. William Hendrickson, Mr. Terrance Lawrin, Dr. Maria Rudisch, Dr. Roberta Mason-Gamer, and Ms Shelia White

ABSENT: Mr. Richard Anderson, Dr. Edward Cohen, Dr. Paul Goldspink, Dr. Thomas Hope, and Dr. Alex Neyfakh

GUEST: Ms. Marilyn Hau

1. **Announcements-**

Dr. Bowman informed the Committee that Marilyn Hau, Director of the Environmental Health and Safety Office was attending the meeting to participate in the discussion regarding the BSL 3 policy and certification process. Members of the Committee introduced themselves.

2. **Minutes-**

The minutes of January 11, 2005 IBC meetings were approved pending a minor editorial clarification.

3. **Old Business-**

   a. **BSL3 Policy and Certification**

Dr. Bowman directed the Committee's attention to the revised BSL3 policy and appendices. She reminded the Committee that the Vice Chancellor for Research had asked the IBC to coordinate approval of a policy for BSL3 certification with EHSO. The Committee discussed the following issues related to the policy: 1) editorial comments related to the regulations and references section and formatting problems were discussed, 2) that prion should be included in the list of agents and energy should be removed under definitions, 3) that [redacted] should be added to the list of notifications regarding results of certifications and nonconformities when appropriate, 4) in section 5.3, that applicable should be added to qualify federal and state regulations, 5) in section 5.9 that it should simply indicate that a database will be maintained, 6) in section 5.9 that the last sentence should be a separate section and that it was the institution's responsibility to notify the PI in an appropriate timeframe for recertification and that the language should be changed to indicate that the PI was requested to contact EHSO should prior notification not be done, 7) that approval and implementation of this policy would require rereview of all IBC

protocols to ensure that they are in compliance with the policy and new approval dates that are synchronized with the date of certification should be issued to aid both the investigator and the tracking process, 8) that subcommittees should be established to review each item on the appendices to ensure that they are accurate and that the appendices are complete, 9) that the subcommittee for appendices A and E for practices, procedures and training would consist of Dr. Alfonso, Mr. Anderson, Dr. Bowman, Dr. Fortman, Dr. Jaffe, Mr. Lawrin, and a member of one of the current BSL3 laboratories on campus, and 10) that the subcommittee for appendices B, C, and D for ventilation, laboratory design, engineering and biosafety cabinets would consist of Mr. Anderson, Dr. Bowman, Dr. Fortman, Dr. Jaffe, Mr. Lawrin, and an engineer from physical plant who was involved in the renovation of current BSL3 laboratories on campus.

The Committee also discussed that certification could involve one company certifying all aspects of the program or two companies one certifying the facilities and the other the practices and procedures. Dr. Bowman indicated that she had met with Capital Programs to discuss certification of the new BSL3 laboratories in [redacted] as part of the commissioning process for this building and that the IBC had been invited to participate in the process of selecting a company for certification.

Following the discussion documented above, a motion to approve the BSL3 policy pending the revisions that were discussed, and to establish special subcommittees for review and approval of the BSL 3 appendices passed unanimously. Approval was with the understanding that the IBC special subcommittee would review and approve the final draft of the BSL3 policy.

b. MOU with Jesse Brown VAMC

Dr. Bowman informed the Committee that the Agreement between the UIC Board of Trustee's and the Jesse Brown VA Medical Center (JBVAMC) regarding the IBC had been signed by both the UIC and the JBVAMC. She indicated that the UIC policy for Use of rDNA and Infectious Agents in Research would be revised to incorporate this agreement. In addition, she indicated that she would work with the VA to coordinate notification of UIC/VA employees.

4. February Protocol Summary Reports-

a. Protocols and Modifications for Expedited Approvals-

The Committee was directed to the modifications eligible for expedited approvals.

I-03-035-01- Addition of Personnel- approved

I-03-070-04- Addition of Personnel- approved

I-03-071-01- Addition of Personnel and new genes for ex vivo transfection. Approved pending- Verification of bloodborne pathogen training needs to be provided.

I-04-030-03- Addition of Personnel

I-04-033-01- Addition of Personnel

b. Protocols and Modifications for Full Committee Review-

I-05-001- In Vitro Gene Transduction of Hematopoietic Stem Cells Treated with 5-azaD-2'-Deoxyctidine and Trichostatin A

Following discussion that the project involved ex vivo gene transfer of genes related to hematopoiesis into hematopoietic stem cells and then into NOD/SCID mice to study in vitro expansion and stem cell engraftment, that the project would use attenuated retroviruses, that although the PI needed to complete Form A, most of the required information had been provided in Form B, and the BBPT and IATA training were required, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. General comment: Wrong form is submitted. This project does involve rDNA and requires completion of Form A. In addition to completion of these items in Form A (items II, III, IV all, V all, VI all, and VII all and sign appropriate assurances), please be sure to address the specific clarifications listed below.
b. In Form A, item IV c, please clarify the following concerns:
    i. Please clarify if ACC approval for this project has been obtained.
    ii. Please specifically identify the gene or genes that will be inserted into vectors and identify the function of the genes.
    iii. Please indicate the retrovirus origin and indicate how virus was made replication incompetent (e.g., what's been removed from the virus).
c. In Form A, item VII e, please indicate the disinfectant used (e.g., 10% bleach).
d. All personnel working with human cells must complete bloodborne pathogen training on an annual basis. Please see IBC web site for a list of training seminar dates. Once completed, please send copy of training certificate to IBC office. This is required prior to approval. Please note, if training was completed via the UIC Hospital, please send verification of completion of OSHA bloodborne pathogen training within the last year.
e. Please indicate in Appendix 1, personnel who will be responsible for the shipping and receiving of potentially infectious material (blood samples or retroviral vectors). These personnel must complete IATA shipping/receiving

training. Please contact Terry Lawrin (413-3701) to obtain a copy of training CD. Please send copy of completion of training to IBC office. This is required prior to approval.

I-05-002- Transcription Factor Function in Determining Mammalian Cell Fate Decisions

Following discussion that the PI was studying transcription factors using transgenic and knockout mouse models, that the PI needed to submit an ACC protocol for the production and use of mice, and that the project should be BSL2 with the use of COS cells, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item III, check box for production of transgenic animals and provide ACC number as Form A, item IVc suggests that transgenic/knockout animals will produced. If PI does not have a current ACC protocol, indicate "to be submitted" for the ACC number.
b. In Form A, item IV f, PI has marked that he is requesting a decrease in BSL. It is not clear why this have been requested. This protocol is BSL2 for the use of COS cells. Please rectify this section.
c. Please provide copies of IATA training certificates to the IBC office.

I-05-003- Nociceptor-Selective Analgesia

Following discussion that the PI had not provided a description of the whole animal work being conducted, that it was not clear where the reagents (HSV) would be stored, and that the PI had not provided specific practices and procedures for use of the reagents safely, a motion to defer this protocol passed unanimously. Deferral was with the understanding that it is pending clarifications prior to rereview.

a. In Form A, item II, please address the following concerns:
    i. Please indicate ACC number.
    ii. Do not check box #3, but do check box #1.
b. In Form A, item IV c, please address the following concerns:
    i. Remove reference to HIV and BSL3, does not apply to this project and should be removed.
    ii. If PI will only be receiving HSV-proenkephalin from a collaborator at another institution and not producing or propagating in her laboratory this should be clearly stated in this section.
    iii. Please provide a description of the whole animal inoculation process.

iv. Please indicate where animals are inoculated (e.g., PI's laboratory or [redacted]) and whether inoculations take place in a biosafety cabinet.

c. In Form A, item V a and b, please clarify the rooms in which the PI will use and store the virus (e.g., make sure the room numbers and buildings are correct). If work with the virus or infected samples will take place both at the [redacted] and the PI's laboratory, then both need to be listed.
d. In Form A, item VII a, please answer this section.
e. In Form A, item VII c, please answer that HSV is both a human and animal pathogen.
f. In Form A, item VII e, please indicate the specific practices and procedures that are used in your laboratory for conduction of this project. In addition, indicate that animals are housed in the [redacted] biohazard room in microisolator cages and handled via [redacted] SOP for this room. In addition, please describe the procedures for transporting either the infected material to [redacted] or the infected animals back to [redacted]. The Committee suggests discussing this with the biosafety officer, Terry Lawrin.
g. Please indicate in Appendix 1, personnel who will be responsible for the shipping and receiving of potentially infectious material (HSV). These personnel must complete IATA shipping/receiving training. Please contact Terry Lawrin (413-3701) to obtain a copy of training CD. Please send copy of completion of training to IBC office. This is required prior to approval.

I-05-004- Serpin Structure and Function

Following discussion that the research involves standard cloning and in vitro transfection studies of serpins, proteins functioning as proteinase inhibitors, using plasmid vectors and possibly other vectors, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item III, box for rDNA outside of living organisms should be checked for cell culture work with BHK cells lines. Also, check all appropriate subboxes in this section. In addition, box for propagation in nonpathogenic prokaryotic source should be checked for E. coli work.
b. In Form A, item III, from the work described, box for natural exchangers should not be marked. Appendix A of the NIH Guidelines lists the groups of natural exchangers..
c. In Form A, item IVc, please indicate whether all rDNA is packaged in plasmid and if not what other types of vectors are used.

I-05-005- Structure and Function of Alpha-2-Macroglobulin and its Receptor LRP

Following discussion that the research involves standard cloning and in vitro transfection studies of alpha2-macroglobulin and its receptor, LRP, using plasmid vectors and

possibly other vectors, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item III, box for rDNA outside of living organisms should be checked for cell culture work with BHK cells lines. Also, check all appropriate subboxes in this section. In addition, box for propagation in nonpathogenic prokaryotic source should be checked for E. coli work.
b. In Form A, item III, from the work described, box for natural exchangers should not be marked. Appendix A of the NIH Guidelines lists the groups of natural exchangers..
c. In Form A, item IVc, please indicate whether all rDNA is packaged in plasmid and if not what other types of vectors are used.

I-05-006- Functional Analysis of Herpes Virus Genes

Following discussion that the PI was studying HSV proteins, ICP34.5 and viral interferon regulatory factors (HSV 1, 2, and 8), that these genes or portions would be cloned into recombinant HSV to study function, and that mammalian cells in culture would be infected with HSV to study the interaction between HSV and cellular pathways involving double-stranded RNA, that all work will be conducted at BSL2 and safety practices were appropriately described, a motion to approve this protocol passed unanimously.

I-05-007- Interferon Signaling

The Committee discussed that the research involved elucidating how interferons and a downstream regulatory protein, BARA, regulate cell cycle progression in normal and cancer cells, that a large list of cell regulatory proteins, BARA, cyclins, cyclin dependent kinases (cdks), Cdc25, Cdk inhibitors and p53 would be transfected in vitro using retroviruses of murine Moloney leukemia virus or murine stem cell virus origin or lentivirus based, that all vectors were replication incompetent, and that the investigator should be cautioned regarding the use of retroviruses and cell regulatory proteins. Following discussion a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IV c, please list the human cells or human cell lines that will be used.
b. All personnel working with human cell must complete bloodborne pathogen training on an annual basis. Please see IBC web site for a list of training seminar dates. Once completed, please send copy of training certificate to IBC office. This is required prior to approval.
c. Please indicate in Appendix 1, personnel who will be responsible for the shipping and receiving of potentially infectious material (retroviral vectors). These personnel must complete IATA shipping/receiving training. Please contact Terry Lawrin (413-3701) to obtain a copy of training CD. Please send

copy of completion of training to IBC office. This is required prior to approval.

Caution: The Committee reminds the investigator and personnel to use caution in handling retroviral vectors with potential oncogenes or cell cycle genes inserted due to the potential of infecting human cells when packaged using amphotropic, dualtropic, or pantropic packaging cell lines.

I-05-008- Integrin-Mediated Cell Signaling and Gene Expression

The Committee discussed that work involved in vitro site-directed mutagenesis studies of platelet integrin, GPIIb-IIIa, talin and transfection studies, as well as, transgenic mouse studies with a novel class of integrin ligands, CCN proteins, and the structural domains important for integrin binding, and that all work described was BSL1. Following discussion a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item II, do not mark box #3 for production of transgenic mice and remove ACC number. If work in whole animal is proposed, please elaborate on this in AIVc. In addition, ACC protocol 02-027 is only approved for transgenic animals.
b. In Form A, item IV c, please list the natural exchangers from Appendix A of the NIH Guidelines that are being used. If this was inadvertently marked in Form A III, please remove check mark.

I-05-009- Restoring Hematopoiesis Following Radiation Injury

Following discussion that this project involved infection of irradiated mice with Klebsiella pneumoniae to determine if mesenchymal stem cells added to bone marrow transplant would attenuated the course of infection by enhancing engraftment, that the safety precautions were well described, that although the PI or personnel had not worked directly with an infectious agent before, the laboratory has extensive cell culture experience with hematopoietic cells and the handling of these cultures is very similar to that of an infectious agent, and that laboratory personnel would require IATA training, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item III, PI should indicate that work surfaces will be cleaned and wiped with chlorine dioxide or bleach solution.
b. In Appendix 1, no experience with infectious agents is listed; however, PI and laboratory personnel do have experience with cell culture work. Please expand on experience (years, procedures, decontamination procedures, etc.) that all personnel have with cell culture work. This is important for the Committee to assess expertise for handling infectious agents.

c. In Appendix 1, please indicate the personnel who will be responsible for the shipping and receiving of potentially infectious material (Klebsiella pneumonia). These personnel must complete IATA shipping/receiving training. Please contact Terry Lawrin (413-3701) to obtain a copy of training CD. Please send copy of completion of training to IBC office. This is required prior to approval.

I-05-010- Functional Role of the Cytoskeleton in Cell Adhesion and Motility

Following discussion that the purpose of the research is to determine the role of a number of cytoskeletal proteins in cell adhesion and motility pathways especially in hematopoietic cells, that genes of interest will be cloned and expressed in E. coli strains or transfected into various mammalian cell lines for expression studies, and that transgenic and knockout mice would be developed to study function of various proteins or protein domains, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IV c, please list the natural exchangers from Appendix A of the NIH Guidelines that are being used as this box was checked in item III. If this was inadvertently marked in Form A, item III, please remove check mark.
b. In Form A, item VI, please complete items a-d.
c. In Form A, item VI e, please indicate the disinfectant used, the method used for decontamination of biohazard waste (e.g., autoclave), and whether work with vectors and cells is conducted in a biosafety cabinet.
d. Per OHSA requirements, personnel must complete bloodborne pathogen training on an annual basis. Please provide verification of training for this year for personnel who completed training on 1/13/04 or 2/10/04.

5. Adverse Event Reports-

None to report

6. New Business-

None to report

The meeting was adjourned at 3:25 PM

Institutional Biosafety Committee
Minutes of
March 10, 2005
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Randal Jaffe, Dr. Aixa Alfonso, Mr. Richard Anderson, Dr. Mary Bowman, Ms. Anne Cousin, Dr. Jeffrey Fortman, Dr. Paul Goldspink, Mr. Terrance Lawrin, Dr. Roberta Mason-Gamer, Dr. Alex Neyfakh, Dr. Maria Rudisch, and Ms Shelia White

ABSENT: Dr. Edward Cohen, Dr. William Hendrickson, and Dr. Thomas Hope

GUEST: Dr. R. Brooks Robey

1. **Announcements-**

Dr. Bowman informed the Committee that Dr. Brooks Robey was attending the meeting as the ad hoc member from the Jesse Brown VA Medical Center per the Agreement between the Jesse Brown VAMC and the UIC. Members of the Committee introduced themselves.

Dr. Bowman indicated that there were two changes to the agenda. The first was to remove the IBC Policy as item b under new business and the second was to add the BSL3 laboratory in [redacted] to the agenda as item b under new business.

2. **Minutes-**

The minutes of February 10, 2005 IBC meetings were approved pending a minor editorial clarification.

3. **Old Business-**

   a. **BSL3 Policy and Certification**

Dr. Bowman informed the Committee that the subcommittees formed to review the criteria in the appendices to the BSL3 policies had met to discuss and revise the appendices. Progress was being made toward finalizing the criteria for practices, procedures, training, ventilation, facilities, and biosafety cabinets.

4. **March Protocol Summary Reports-**

   a. **Protocols and Modifications for Expedited Approvals-**

The following protocols and modifications eligible for expedited approvals were summarized for the Committee.

I-04-013- SIV Therapeutics (*Modification 04-13-01*)-

Due to change in species from Rhesus macaques to Cynomolgus macaques, a different strain of SIV, SHIV89.6P, must be used for this study. Strain is BSL2 as was originally strain and will be handled under identical conditions.

I-05-017- Pathogenesis of Atopic Dermatitis-

The purpose of the research is to cross various different transgenic/knockout mice to determine the role of interleukin-4 in the development and maintenance of atopic dermatitis. IL-4 transgenic mice will be crossed with different immune gene-Knockouts (T cell receptor, B cell, mast cell, antigen presenting cell) and studied for the development of atopic dermatitis. The transgenic and knockout strains already exist. Project is BSL1.

I-05-018- B. Subtilis Pho Regulon Signal Transduction Network-

The purpose of the research is to study signal transduction in bacteria, particularly, two component regulatory systems of Bacillus subtilis. Genes or portions of genes in the Pho response will be cloned into E. coli or B. subtilis using plasmid vectors. Project is BSL1.

b. Protocols and Modifications for Full Committee Review-

I-05-011- Modulation of Cardiac Filament Activity

The Committee reviewed that the following: 1) that the purpose of the research was to study troponin genes and to determine the mechanism as to how troponin proteins function as "on switches" for molecular motors in heart muscle cells and that these motors control the movement of filaments responsible for the shortening of heart muscle cells, 2) that the genes for troponin, myofilament proteins, or kinases that phosphorylate troponin, both normal and mutant forms (mutations, deletions or chimeras), would be cloned and expressed in E. coli using plasmids, 3) that PKC would be expressed in insect cells using baculoviruses and 4) that adenoviral vectors (Ad5, attenuated by E1 and E3 deletion) would be used for transient transfection in isolated rodent cells. Following review, the committee discussed that the personnel listed in the protocol as being involved with adenoviruses required bloodborne pathogen training and IATA shipping and receiving training. A motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarification.

a. In Appendix 1, PI has identified 3 personnel that work with adenoviruses under this protocol. These personnel are required to have bloodborne pathogen training (BBPT) and at least one of these personnel must completed IATA shipping and receiving training. BBPT is a yearly requirement and IATA training is required every 2 years. If personnel have not complete training, please see ACC web site for list of seminar training dates for BBPT. CD training discs for IATA are available from the biosafety officer, Terry Lawrin (413-3701). Please submit copies of BBPT and IATA training verification to the IBC office.

I-05-012- Studies on the Biology of Selenium

The Committee reviewed the following: 1) that the goal of the research was to gain a better understanding of the mechanism of selenoprotein synthesis and to determine the role of these proteins in cancer risk and development, 2) that the structure/function relationship of various selenoprotein polymorphisms would be evaluated to determine their role in cancer risk, 3) that the tRNA responsible for selenocysteine would be either overexpressed or attenuated using dominant-negative mutant gene manipulations in cell culture, 4) that the transcription factor genes that regulate selenocysteine insertion would also be transfected into cells in culture, 5) that expression of proteins would be in E. coli or mammalian cell lines (both human and rodent), and that the genes of interest included those that function as anti-oxidants, are involved in protein folding, and or function as reductases. Following review, the Committee discussed that the project used human cells and therefore require BSL2 and Bloodborne pathogen training. A motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item V c, BSL2 should be marked for use of human cells.
b. In Form A, item VI a-f, complete for BSL2 work.
c. Please submit copies of bloodborne pathogen training (BBPT) verification to the IBC office. BBPT is a yearly requirement

I-05-013- Estrogen Regulation of Social Behavior

The Committee reviewed the following: 1) that the goal of this research was to understand the effects of estrogen in regulating social behavior via the estrogen receptor alpha in prairie voles, 2) that male prairie voles will be transfected via stereotaxic injection into the brain with adeno-associated viral vectors expressing estrogen receptor alpha, 3) that the vectors do not contain viral DNA, are nonreplicating and are supplied by a collaborator at another institution and are BSL1. Following review, the committee discussed that it would be better for the PI to store vector in PI's laboratory and not in the [redacted]. Dr. Bowman indicated that she would inform the PI of this suggestion. A motion to approve this protocol passed unanimously.

I-05-014- Botanicals for Chlamydia Pneumonia Infections

The Committee reviewed the following: 1) that the purpose of the project was to determine the safety and efficacy of botanical extracts in mice infected with Chlamydia pneumonia (CP), and 2) that mice (C57Bl/6 or ApoE) would be inoculated 3 times with and following the last inoculation, the mice would be treated with various botanical extracts up to 60 days to determine if extracts eradicate CP infection. Following review, the Committee discussed that the purpose of the study as described does not indicate a link to artherosclerosis, that there was incongruence between the animal protocol and the IBC protocol regarding apoE mice, that clarification is required regarding where preparation of the inoculum will occur and where animal procedures (inoculation and tissue harvest) will occur, that transport of infectious samples needs to be clarified and expertise of personnel with BSL2 needs to be clarified. A motion to defer this protocol passed unanimously. Deferral was with the understanding that it is pending the following clarifications prior to rereview.

a. In Form B, item I e, both PI's laboratory and [redacted] biohazard room should be listed here.
b. In Form B, item II a, the purpose of the study needs to be expanded to cover the role of CP and various botanical extracts on the development of artherosclerosis.
c. In Form B, item II b, please address the following concerns:
    i. Please indicate that these procedures will be performed under ACC protocol 04-277.
    ii. Currently the ACC protocol only lists C57Bl/6 mice and not apoE mice. If apoE mice will be used, then PI must modify the ACC protocol appropriately to include apoE mice. In addition, if these mice will be bred at UIC, breeding appendices will also need to be completed for the ACC protocol.
    iii. In paragraph 1, protocol indicates that animals will be anesthetized with isoflurane. This should be changed to CO2.
    iv. In paragraph 1, inoculation should be with a blunted needle or a cannula.
    v. In paragraph 2, protocol indicates that animals will be euthanatized at 60 days; however, in last paragraph, protocol indicates that animals will be euthanatized before, 30 and 60 days after botanical treatment. Please reconcile.
    vi. Please provide a table of animal groups including age, treatment and tissue harvest time point. This should be congruent with the ACC protocol that covers this work.
d. In Form B, item III, please address the following concerns:
    i. Please indicate that all inoculations and tissue harvest will take place in the biosafety cabinet in the [redacted] biohazard room.
    ii. Please indicate that work with open cultures will take place in the biosafety cabinet in the PI's laboratory.
    iii. Please indicate that mice will be housed in the biohazard room.

iv. Please indicate the type and concentration of disinfectant used.
v. Please indicate that CP or infected samples will be transported in sealed nonbreakable containers between the laboratory and [redacted]

e. In Appendix 1, please complete for this protocol. List all personnel involved with this study and their experience with BSL2 level agents.
f. Personnel are required to have bloodborne pathogen training (BBPT) and at least one of these personnel must complete IATA shipping and receiving training. BBPT is a yearly requirement and IATA training is required every 2 years. If personnel have not completed training, please see ACC web site for list of seminar training dates for BBPT. CD training discs for IATA are available from the biosafety officer, Terry Lawrin (413-3701). Please submit copies of BBPT and IATA training verification to the IBC office.

I-05-016- Structure & Function of 105-kD Basement Membrane Protein

The Committee reviewed the following: 1) that the purpose of the research is to elucidate the function of a human skin basement protein, designated 105-kD protein, 2) that both the human or mouse cDNA for the 105-kD protein would be cloned in nonpathogenic vectors and transfected into human cells for expression of recombinant protein, and 3) that non-prokaryotic cells will also be transfected for recombinant protein expression. Following review, the Committee discussed that the PI needed to elaborate on the specific vectors being used as well as the cell lines, that the project was BSL2 and required bloodborne pathogen training for the use of human cell lines. An initial motion to defer this protocol was defeated by a vote of 3 in favor and 9 opposed. Following further discussion a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IV c, please address the following concerns:
   i. Please indicate the vectors that will be used for both cloning for eukaryotic and prokaryotic recombinant protein/
   ii. Please indicate the human, mouse and prokaryotic cell lines that will be used for transfection and expression.
b. In Form A, item V c, please check BSL2 and remove check mark from BSL1. All work with human cell line is BSL2.
c. In Form A, item VI, item a-f, complete for BSL2 level project.
d. Personnel are required to have bloodborne pathogen training (BBPT). BBPT is a yearly requirement. If personnel have not completed training, please see ACC web site for list of seminar training dates for BBPT. Please submit copies of BBPT training verification to the IBC office.

I-05-019- Metabolic Regulation of Somatotrope Function-

The Committee reviewed the following: 1) that the purpose of the research was to elucidate the mechanisms by which changes in metabolism result in changes circulating

GH levels, and to study the impact of metabolic changes on the expression of neuropeptides involved in GH synthesis and release, 2) that transgenic mice for human rGH utilizing the LoxP, cre recombinase , and tetracycline inducible system to create a tissue specific inducible knockout mouse would be used, 3) that mice with GH knocked out will also be produced, 4) that transient transfection studies would be conducted with primary pituitary cell cultures using baboon and mouse cells to determine the intracellular signaling pathways, and 5) that modifications for specific genes and vectors would be submitted as genes of interest are identified. Following review, the Committee discussed that the project should be BSL2 and required bloodborne pathogen training for use of primary baboon cells, that the PI's laboratory was at the Jesse Brown VAMC and needed to be inspected. Dr. Robey indicated that a coordinated inspection of all laboratories at the Jesse Brown VAMC that will require inspection by the UIC biosafety officer would be helpful to the investigators at the VA. The consensus was that UIC and the VA would work together to coordinate the inspection process at the VA. Following this discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item V c, BSL should be 2 for use of nonhuman primate cells.
b. In Form A, item VI e, please complete for BSL2 work.
c. Please contact UIC biosafety officer, Terry Lawrin (413-3701) to discuss BBPT for use of primary cells from nonhuman primates. If BBPT training has been completed at the Jesse Brown VA within the last year, please inform the biosafety officer of this and please provide verification to the IBC office.
d. Laboratory must be inspected by UIC biosafety Officer. Please contact IBC office (996-7427).

I-05-020- Gene Regulation in Streptococcus Pneumoniae

The Committee reviewed the following: 1) that the purpose of the research was to study the regulation of gene activity in Streptococcus pneumoniae. In particular, the mechanisms involved in horizontal transfer of genes between natural exchangers will be studied, 2) that genes or portions of genes from S. pneumoniae or its natural exchangers would be cloned in S. pneumoniae or in E. coli using standard expression plasmid vectors, 3) that reporter gene constructs would be cloned in S. pneumoniae to study gene expression, and 4) that the S. pneumoniae strains used are nonvirulent derivatives of the laboratory strain, Rx. Following discussion, a motion to approve this protocol was unanimously approved.

5. Adverse Event Reports-

None to report

6. New Business-

a. IATA notification

Mr. Lawrin reminded the Committee that the IATA and DOT regulations require that when hazardous materials are shipped, the shipper must provide 24/7 coverage until the package has been received. He distributed information on Chemtrec, a company that provides such coverage to institutions at a fee. The Committee discussed how this compliance regulation was currently being conducted at the University, whether the institution should assume the responsibility for all biohazardous shipments, and which department/unit was responsible for assuming this responsibility. Dr. Bowman indicated that she would like to review the material and contact the Chemtrec directly to discuss exactly how coverage would be accomplished, before the Committee voted on a recommendation. The consensus of the Committee was to table the discussion until additional information could be obtained.

b. [redacted] BSL3

Mr. Anderson reported to the Committee that the EHSO had received a report from an occupant in [redacted] that the anteroom door to the BSL3 laboratory had been seen propped open this morning. The report was received approximately an hour prior to the start of the IBC meeting. Mr. Lawrin indicated he went to [redacted] to investigate. At the time he arrived, the door was not open. He indicated that he talked with the building manager. It appears that one of the users of the laboratory had called for service of the autoclave. Mr. Lawrin spoke with the autoclave service repairman and he indicated that had propped the door open in order to get back into the anteroom. He left the room to open the autoclaves other door, which was in the adjacent clean side room. During discussion, it was not clear whether any work was ongoing in the laboratory at the time, who had given the repairmen access to the room, and how long the door was left open. The Committee was concerned about the security of the facility and access to the BSL3 laboratory. The consensus of the Committee was that a thorough investigation needed to be done to determine all the facts and once completed that a letter should be sent to the users of the facility indicating that additional training of all personnel on entry procedures, maintenance/repair procedures, and use of the autoclave should be sent from the IBC. The letter should indicate that the IBC considers this to be a serious issue and that the PIs involved must take an active role in ensuring that all personnel are following appropriate procedures and practices at all times.

The meeting was adjourned at 3:17 PM

Institutional Biosafety Committee
Minutes of
April 14, 2005
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Randal Jaffe, Dr. Aixa Alfonso, Mr. Richard Anderson, Dr. Mary Bowman, Dr. Jeffrey Fortman, Mr. Terrance Lawrin, Dr. Roberta Mason-Gamer, and Dr. Alex Neyfakh

ABSENT: Dr. Edward Cohen, Ms. Anne Cousin, Dr. Paul Goldspink, Dr. William Hendrickson, Dr. Thomas Hope, and Dr. Maria Rudisch

GUEST: Dr. R. Brooks Robey

1. **Announcements-**

Dr. Bowman informed the Committee that Ms. Sheila White had resigned from the Committee due to obligations related to a new job. She indicated that she was in the process of recruiting a third unaffiliated member. The Committee acknowledged Ms. White's contribution to the Committee and the university.

Mr. Lawrin informed the Committee that this would be his last meeting as he was leaving the university to accept a position at another institution. The Committee expressed its appreciation to Mr. Lawrin for his service to the Committee and the university.

Dr. Bowman informed the Committee that there were three additions to the agenda. Protocol 05-003 was added as item c under old business, protocol 05-014 was added as item d under old business, and modification to protocol 04-062-01 was added as item b under new business.

2. **Minutes-**

The minutes of March 10, 2005 IBC meetings were approved pending a minor editorial clarification.

3. **Old Business-**

   a. [redacted] **BSL3-**

Dr. Bowman reminded the Committee that last month an incident was reported in which the autoclave maintenance personnel had propped the anteroom door of the BSL3 open to remove material from the clean side of the autoclave in the next room and at that time all the details of the incident were not known. She indicated that the BSO had further

investigated the incident. Personnel from one of the two labs using this autoclave went to the anteroom on 3/11/05 and found that the autoclave was malfunctioning. This was reported to the building manager. The manager contacted the autoclave maintenance personnel, who happen to be in the building at the time, and informed him of the malfunction. The maintenance personnel reported to the BSL3 anteroom to fix the problem. The autoclave had finished its cycle and the material inside was decontaminated. The autoclave was repaired and the repairmen informed the laboratory personnel that it was now working. The personnel gowned up and proceeded into the lab. The repairmen temporarily propped the door open to retrieve the contents from the clean side located in the next room. The repairmen then returned to the anteroom removed his tools and left the facility with the door shut. At the time the incident was first reported, the Committee had concerns as to who contacted the maintenance personnel, that EHSO had not been informed and supervision of maintenance personnel.

Dr. Bowman indicated that she had discussed the incident with the PI of the laboratory who was at the facility at the time the autoclave repairmen arrived. The PI indicated that it was not clear whether the repairman was responding to an earlier request for service or the recent request by this lab. The PI had also indicated that on more then one occasion, personnel from the laboratory had arrived to find service personnel in the anteroom working alone and that they had not been informed of this issue. She indicated that the PI specifically requested information as to how maintenance issues should be handled and that he felt that it was an institutional issue. The Committee discussed that it was the responsibility of the Safety office and the Committee to educate PIs as to the proper protocol for maintenance and that a template was needed with the proper procedures. The Committee requested that EHSO prepare this template and Mr. Anderson indicated that he would do so.

b. IATA Notification-

Dr. Bowman reminded the Committee that when shipping biohazardous material that the shipper is required to provided 24/7 availability via phone during the shipping process incase of an incident and that last month it had discussed contracting with a service for this coverage. She indicated that she had spoken with Chemtrec, one of the companies providing this service and discussed what would be required by each shipper and the institution to obtain the service. She indicated that it would be essential that all investigators with IATA training would need to be contacted and given a protocol to follow to ensure that shipping paperwork contained the necessary contract information and that the Company was provided with the necessary information on the material being shipped. The motion to recommend to the institutional official that the institution adopt this service was unanimously approved.

c. IBC Protocol 05-003-

The Committee discussed the following issues: 1) that this protocol had been previously deferred and involved the transfection of mice with HSV-proenkephapin, 2) that the PI had provided a complete description of the inoculation of animals with HSV and where the procedures will be performed and the virus would be stored, 3) that the safety precautions were appropriately described, 4) that the PI had provided verification of IATA training, and 5) that the PI had not indicated in the protocol that she was not developing the construct or propagating in the laboratory at UIC. Dr. Bowman indicated that she had talked with the PI and she indicated that this was the case and would ask the PI to send an email confirming this for the file. Following discussion, a motion to approve this protocol passed unanimously.

d. IBC Protocol 05-014-

The Committee discussed the following issues: 1) that this protocol had been previously deferred and involved the inoculation of mice with Chlamydia pneumonia and treatment with various botanical extracts, 2) that the PI had clarified the issues related to incongruence with the corresponding ACC protocol, 3) that the PI had clarified locations where preparation of inoculum and injection of animals would occur and endpoints of study, and safety practices, and 4) that the PI still needed to verify BBP and IATA training. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarification.

a. Please provide copies of Bloodborne training and IATA shipping receiving training certification to the IBC office.

4. April Protocol Summary Reports-

a. Protocols and Modifications for Expedited Approvals-

No protocols or modifications were submitted this month that were eligible for expedited approvals were summarized for the Committee.

b. Protocols and Modifications for Full Committee Review-

I-05-021- Membrane Transport Mechanisms in the Human Intestine-

The Committee discussed the following issues: 1) that the purpose of this study was to determine genes involved in the regulation of sodium ion absorption by the gastrointestinal tract and focused on elucidating the roles of the Na+/H+ exchanger gene family members NHE2 and NHE3, 2) that genes would be cloned in plasmid vectors and expressed in E. coli (laboratory strains) or tissue culture cells and reporter constructs would also be used, 3) that the effects of enteropathogenic E. coli (EPEC) on the activity of the NHE isoforms will be studied by infecting monolayers of Caco-2 cells with EPEC

or nonpathogenic E. coli and that this would be done in collaboration with the PI of protocol 02-054, and 4) that the PI needed to address the clarifications listed below. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. Only one PI should be listed on protocol, other personnel should be listed as Co-PI.
b. In Form A, item IV c, biosafety cabinet level 1 should be a biosafety cabinet.
c. Please provide copies of Bloodborne training certification to the IBC office.

I-05-022- Expression of cDNA Clones in E. Coli and Eukaryotic Cells

The Committee discussed the following issues: 1) that the purpose this research was to study genes that regulate brain function in adult mice and in particular, small RNA pathway genes (dicer, drosha, elf2c, fmrp, microRNA precursors, BC1, etc.) and genes involved in synaptic plasticity (CAMKII, PSD-95, glutamate receptor, etc.), 2) that the genes would be cloned in plasmid-based cDNAs and transfected into human and mouse cells, 3) that siRNAs would be used to down-regulate gene activity to determine function, and 4) that the PI needed to elaborate on the brain functions being studied, the vectors for the constructs listed and the safety precautions used. Following discussion, a motion to defer this protocol passed unanimously. Deferral was with the understanding that it is pending the following clarifications prior to rereview.

a. In Form A, item IV a and b, please elaborate as to which brain functions the investigator will be studying.
b. In Form A, item IV c, please address the following concerns:
    i. Please clarify if PI is constructing all of the constructs listed. If not, from where will they be obtained?
    ii. Please indicate the vectors for each construct.
c. In Form A, item V c, please change BSL to BSL2. All work with human cell lines must be conducted at BSL2.
d. In Form A, items VI a-e, complete this section for BSL2 work.
e. All personnel listed on Appendix 1 who work with human cell lines must complete Bloodborne pathogen training. Please see IBC web site for a list of seminar training dates (http://www.research.uic.edu/protocolreview/ibc/education/index.shtml). This is a yearly requirement of OSHA. Please provide copies of BBPT verification to the IBC office.

I-05-023- Botanicals for Chlamydia Pneumonia Infections

The Committee discussed the following issues: 1) that the purpose of the research was two fold and involved studying the function of molecular chaperones in protein secretion and tumor progression including BiP, members of the J-domain family (MtJ1, HtJ1, PD1,

Dnak, DnaJ, and GrpE), the HSP70 family, 2) that genes would be in various plasmid expression vectors and transfected in numerous cancer cell lines to determine function and ability of various drugs to inhibit function and that siRNA technology will also be employed, 3) that the second purpose was to identify novel inhibitors of glycogen synthase kinase (GSK-3) and that genes of interest included GSK-3 and Akt1, 4) that the genes would be cloned in various expression vectors and transfected into cancer cell lines, 5) that it would be helpful if the PI clarified that genes and vectors by project purpose in the description, 6) that the PI needed to elaborate on the procedures for waste disposal and decontamination, and 7) that personnel required BBP and potentially IATA training. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item VI c, please address the following concerns:
    i. Please clarify the Tet on/off system. Please list the specific vector. If using a viral vector system, please elaborate how the vector is attenuated. In addition, please clarify which genes will be expressed using this vector system.
    ii. Please separate the genes of interest, plasmids and vectors, and cell lines used by the project under which they will be used to help clarify the nature of the work.
b. In Form A, item V c, please change BSL to BSL2. All work with human cell lines must be conducted at BSL2.
c. In Form A, items VI e, please list the specific PPE that are used by personnel during the conduct of the work. Please indicate if that work is conducted in a biosafety cabinet, and the procedures used for disposal of infected waste and for disinfection.
d. All personnel listed on Appendix 1 who work with human cell lines must complete Bloodborne pathogen training. Please see IBC web site for a list of seminar training dates (http://www.research.uic.edu/protocolreview/ibc/education/index.shtml). This is a yearly requirement of OSHA. In addition, bloodborne pathogen training for the PI needs to be updated. Please provide copies of BBPT verification to the IBC office.
e. If PI is using viral vectors, then personnel in the laboratory responsible for the shipping and receiving of these vectors must complete IATA shipping and receiving training. Please contact the EHSO (996-7429) to obtain a training disc. Please provide a copy of the training certification to the IBC office. This training is required every two years. Also, depending on the nature of the viral vectors used, review category II, box 1 should be checked.
f. Biosafety cabinet certification is out of date. Cabinets should be certified on an annual basis. Please have cabinet recertified and provide a copy of the updated certification to the IBC.

I-05-024- Biotransformation of Estrogens to Carcinogenic Quinoids

The Committee discussed the following issues: 1) that the purpose of the research was to determine the mechanism of toxic effects of horse estrogens as it is believed that formation of quinoids is an important mechanism of carcinogenesis and cytotoxicity of some estrogens and equine estrogens are metabolized to catechol estrogen and quinoids, 2) that estrogen response elements (ERE) from human genes would be cloned into a luciferase reporter plasmid and expressed in E. coli to assess estrogenic potential of compounds, 3) that the pRL-TK plasmid would be used in luciferase assays in E. coli, 4) that recombinant proteins for GST P1-1, an enzyme used to study the effects of reactive estrogen intermediates, and COMT, an enzyme that is involved with catechol estrogens, would be expressed in E. coli, 4) that the PI needed to correct some of the categories of research identified on the form, and 5) that the PI needed to indicate that work was occurring in biosafety cabinet. Following discussion a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item II, boxes 1 and 2, these boxes do not apply as the PI is not using any microbial organisms that are RG 2 or higher. Please remove check marks.
b. In Form A, item III, please remove check mark from 9. PI is not exchanging DNA between microbial organisms listed in Appendix A.
c. In Form A, item VI c, please check RG1 here. As the strains of E. coli used are a laboratory strains.
d. In Form A, item VI e, please list the specific PPE used by personnel when handling rDNA. Please indicate if work takes place in a biosafety cabinet.

I-05-025- Characterization of the TXA2 Receptor

The Committee discussed the following issues: 1) that the purpose of the research was to study the function of the thromboxane A2 receptor in hemeostasis and thrombosis and to determine how drugs bind to the receptor (both normal and mutant forms) to help develop drugs for use in cardiovascular disease, 2) that WT and mutant forms of human thromboxane A2 receptor, using site-directed mutagenesis, would be used to express thromboxane A2 receptor in various cell lines and expressed receptors would be evaluated for structure, ligand-receptor binding and coupling to G-protein to determine the regions that constitute the ligand binding pocket and that could be used as potential targets for antagonists, and 3) that the PI needed to correct the categories of research being conducted, clarify safety procedures, and provide verification of bloodborne pathogen training. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item I, box 1, this does not apply to this project as the acquisition of the plasmids containing the drug resistant trait in laboratory strains of E. coli, does not apply here.

b. In Form A, item II, boxes 1-3, it is unclear from the description provided in IV c why these boxes are marked. If the PI is using viral vectors then box 1 should be marked and IV c should be expanded to include the use of viral vectors. If not, then this box and box III should not be marked. PI is not cloning DNA from a RG2 or higher source, therefore this box should not be checked.
c. In Form A, item III, box 9 should not be marked. PI is not exchanging DNA between one microbial organism and another listed in Appendix A.
d. In Form A, item IV c, please address the following concerns:
    i. Please see comments above relate to review category II.
    ii. Please elaborate on the other plasmids or vectors used.
    iii. Please list the cell lines used and the species of origin of these cell lines.
    iv. Please elaborate on the production of the transgenic animals. Which constructs are being developed for the transgenic mice? Please indicate if mice are already produced and you are just maintaining them and breeding for experiments. In not, please indicate who will produce transgenics (e.g., PI? RRC?).
e. In Form A, item VI e, please indicate how waste is decontaminated. In addition, please indicate what PPE is used when handling materials (e.g., gloves, lab coats, etc.). Please elaborate on what medical evaluation or surveillance is being conducted for this project and how. Is this just in the case of an accident? Routine medical evaluation and surveillance are not normally required for this type of project.
f. All personnel listed on Appendix 1 who work with human cell lines must complete Bloodborne pathogen training. Please see IBC web site for a list of seminar training dates (http://www.research.uic.edu/protocolreview/ibc/education/index.shtml). This is a yearly requirement of OSHA. In addition, bloodborne pathogen training for the PI needs to be updated. Please provide copies of BBPT verification to the IBC office.

I-05-026- Proposed Role for Neuronal Serotonin N-Acetyltransferase; Aging and Epigenetic Regulation of Brain 5-Lipoxygenase

The Committee discussed the following issues: 1) that the purpose of the research was two fold and involved studying the role of N-acetylserotonin and the melatonin system in psychiatric disorders and the role of inflammatory products in aging-associated brain cell damage, 2) that synthetic DNA pieces of the following genes, LTRs, AANAT, MT1, MT2, 5-LOX, FLAP and GABA receptors, would be cloned and inserted into plasmids for expression in E. coli, and that the cloned DNA would be used for DNA sequencing, competitive RT-PCR, in-situ hybridization, TUNEL/Nissel straining, and transfection/expression studies, 3) that the PI needed to elaborate on the transfection/expression studies, the use of rDNA in animals, and the use of RG2 vectors

or hosts, and 4) that the PI needed to provide BBP training verification and potentially IATA training. Following discussion, a motion to defer this protocol passed unanimously. Deferral was with the understanding that it is pending the following clarifications prior to rereview.

a. In Form A, item II, both box 1 and 4 are marked, but the research described in item IV c, does not agree. If PI is not using RG2 hosts or vectors box 1 should not be marked. If PI is not transfecting animals with rDNA then box 4 should not be marked. Please clarify.
b. In Form A, item III, box 6 should be checked for expression and cloning in laboratory strains of E. coli. In addition, from description provided in IV c, it appears that PI is doing transfection studies in vitro. If so, then box 4 should be marked and the appropriate subboxes marked.
c. In Form A, item IV b, please define LTR, MT1, MT2, FLAP and GABA and indicate how these genes fit into the purpose of the research.
d. In Form A, item IV c, please address the following concerns:
    i. Please elaborate on the transfection/expression experiments involving 5-LOX gene promoter sequence (e.g., which cell lines are transfected?, which plasmids and or vectors are used?).
    ii. Please elaborate on the use of RG2 vector or hosts if being used.
    iii. Please elaborate on the use of rDNA in whole animals. ACC protocol 02-084 is not approved for rDNA use in animals. If this will be done, then ACC protocol must be modified appropriately.
e. In Form A, item V c, if PI is using viral vectors or human cell lines then project is BSL2. If not, then based on current description, project is BSL1. Please mark only one box.
f. In Form A, item VI e, please address the following concerns:
    i. Please indicate that work takes place in a biosafety cabinet and not a hood.
    ii. Please indicate how all infected wasted is decontaminated and disposed
    iii. Please indicate how decontamination is accomplished. 10% bleach should be used followed by alcohol. Alcohol alone is not sufficient for decontamination.
g. All personnel listed on Appendix 1 who work with human cell lines must complete Bloodborne pathogen training. Please see IBC web site for a list of seminar training dates (http://www.research.uic.edu/protocolreview/ibc/education/index.shtml). This is a yearly requirement of OSHA. Please provide copies of BBPT verification to the IBC office.
h. If PI is using viral vectors, then personnel in the laboratory responsible for the shipping and receiving of these vectors must complete IATA shipping and receiving training. Please contact the EHSO (996-7429) to obtain a training disc. Please provide a copy of the training certification to the IBC office. This training is required every two years.

I-05-027- 5-HT N-Acetyltransferase and Cocaine-Induced Behaviors; Circadian Mechanisms in Cocaine Addiction

The Committee discussed the following issues: 1) that the purpose of the research was to determine the role and mechanism of action of melatonin and its receptors, MT1 and MT2, in the development of addictive behaviors, specifically addition to cocaine, 2) that synthetic DNA pieces of the following genes, AANAT, MT1, MT2, and clock gene period 1, would be cloned and inserted into plasmids for expression in E. coli and used for DNA sequencing, competitive RT-PCR, and in-situ hybridization, that siRNAs for MT1 and MT2 would be expressed using pSilencer adenoviral vectors and used to inhibit expression of MT1 and MT2, 3) that the mouse period 1 gene promoter would be inserted into a luciferase construct for use in transfection/expression studies, and 4) that the PI needed to elaborate on the transfection/expression studies, the use of rDNA in animals, and the use of RG2 vectors or hosts, and 5) that the PI needed to provide BBP training verification and potentially IATA training. Following discussion, a motion to defer this protocol passed unanimously. Deferral was with the understanding that it is pending the following clarifications prior to rereview.

a. In Form A, item II, box 4 is marked, but the research described in item IV c, does not agree. If PI is not transfecting animals with rDNA then box 4 should not be marked. Please clarify.
b. In Form A, item III, box 6 should be checked for expression and cloning in laboratory strains of E. coli. In addition, from description provided in IV c, it appears that PI is doing transfection studies in vitro. If so, then box 4 should be marked and the appropriate subboxes marked.
c. In Form A, item IV b, please define AANAT and indicate how this gene fits into the purpose of the research.
d. In Form A, item IV c, please address the following concerns:
    i. Please elaborate on the transfection/expression experiments involving mouse period 1 gene promoter sequence (e.g., which cell lines are transfected?, which plasmids and or vectors are used?).
    ii. Please elaborate on the pSilencer adenoviral vector being used and indicate if it is an attenuated vector and is so, indicate how it is attenuated.
    iii. Please elaborate on the use of rDNA in whole animals. What is being done and how? ACC protocol 04-142 is only approved for the oligos (antisense and scramble), if PI is using rDNA either in a plasmid or in an adenoviral vector then the ACC protocol must be modified to include the details of this experiment. Use of adenoviral vectors in mice will require housing the mice under BSL2 conditions.
e. In Form A, item VI e, please address the following concerns:
    i. Please indicate that work takes place in a biosafety cabinet and not a hood.

ii. Please indicate how all infected wasted is decontaminated and disposed.
iii. Please indicate how decontamination is accomplished. 10% bleach should be used followed by alcohol. Alcohol alone is not sufficient for decontamination.

f. All personnel listed on Appendix 1 who work with human cell lines must complete Bloodborne pathogen training. Please see IBC web site for a list of seminar training dates (http://www.research.uic.edu/protocolreview/ibc/education/index.shtml). This is a yearly requirement of OSHA. Please provide copies of BBPT verification to the IBC office.
g. Personnel in the laboratory responsible for the shipping and receiving of these vectors must complete IATA shipping and receiving training. Please contact the EHSO (996-7429) to obtain a training disc. Please provide a copy of the training certification to the IBC office. This training is required every two years.

I-05-028- Molecular Basis of Glutamate Receptor Field Formation

The Committee discussed the following issues: 1) that the purpose of the research was to elucidate the mechanism by which glutamate receptor expression and location is controlled in neuronal synapses, 2) that mutant drosophilia would be identified with defects in glutamate receptor clustering, the mutant genes would be isolated and cloned in E. coli using standard plasmid vectors, and that some genes would be labeled with GFP, PFR or FLAG, 3) that clones would be modified to identify potentially important biologically active sites and both normal and mutant clones would be expressed in drosophilia, E. coli or yeast, and 4) that the PI needed to provide Appendix 1. Following discussion a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. Appendix 1 was not provided.

I-05-029- Regulation of Hemoglobin Synthesis

The Committee discussed the following issues: 1) that the purpose of the research was to determine the pattern of DNA methylation and chromatin structure of the beta-globulin gene locus in baboon bone marrow cells following treatment of baboons with inducers of fetal hemoglobin expression, 2) that the DNA would be isolated from baboon bone marrow cells, amplified via PCR and PCR products would be cloned in plasmid vectors and expressed in E. coli, 3) that clones would be examined for patterns of methylation, 4) that various regions of the baboon beta-globulin locus would be amplified via PCR, cloned as above, and sequenced to provide information for primer generation for chromatin immunoprecipitation studies, and 5) that the PI needed to provide verification of bloodborne pathogen training and the laboratory needed to be inspected. Following

discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. Please provide verification to UIC IBC office of Bloodborne pathogen training within the last year from Jesse Brown VA. This training is required annually for use of nonhuman primate cells.
b. Laboratory must be inspected by UIC biosafety Officer. Please contact IBC office (996-7427).
c. In Appendix 1, please elaborate on the training and expertise that each of the personnel has with rDNA and BSL2.

I-05-030- Site-Directed Mutagenesis Studies of Enzymes Involved in Biological Detoxification and Disease

The Committee discussed the following issues:1) that the purpose of the research was to clone and express enzymes from various bacteria and from humans to study their structure and function, 2) that the bacterial DNA would be obtained from ATCC as genomic clones and the human DNA will be obtained as cDNA from ATCC, 3) that the enzymes of interest for bacteria include phosphodiesterases, and those involved in fatty acid biosynthesis, NAD biosynthesis, menaquinone biosynthesis, and isoprenoid biosynthesis and the enzymes of interest from human genome include pyruvate kinase, Keap1, Nrf2, neh2, Cul3, Roc1, and Situins (SIRT1-7), 4) that all genes would be cloned in prokaryotic expression plasmids in laboratory strains of E. coli, and 5) that the PI needed to elaborate on the function of the enzymes and whether site directed mutagenesis would be conducted. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item II, box 2, this box should be checked if any of the bacteria from which the genomic clones were isolated fall into this category (e.g., if the DNA was isolated from a pathogenic bacteria, then this box needs to be checked).
b. In Form A, item IV a, please indicate what types of enzymes or proteins will be expressed and what the potential physiological role of these proteins is. The first sentence is too vague.
c. In Form A, item IV c, please indicate from which bacteria(s) the genomic clones were isolated.
d. In Appendix 1, PI indicates that all personnel are experienced with site-directed mutagenesis, but in A IV b, PI indicated that this will not be done. Please reconcile.

I-05-031- Reduction of Amyloid Burden by Antisense APP

The Committee discussed the following issues: 1) that the purpose of the research was to study the expression level of various neurotrophic and signaling molecules in the

presence or absence of brain pathology and the neurotrophic and signaling molecules of interest were NGF, BDNF, CREB, PKA, PKC and SNAP25, 2) that PCR products for the above genes would be cloned in pGEM4Z vector and probes for in situ hybridization would be generated to study the expression level of the various genes in the brain, and 3) that this investigator was at the VA and an inspection of the laboratory by EHSO needed to be conducted. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. Laboratory must be inspected by UIC Environmental Health and Safety Office. A member of the EHSO will contact you to schedule an inspection.

5. **Adverse Event Reports-**

[redacted]

6. **New Business-**

a. IBC Policy

The Committee discussed the language adding applicability of the policy to all UIC investigators using monies administered by the UIC at the Jesse Brown VA Medical Center for rDNA research. A motion to approve the addition to the policy passed unanimously with minor editorial clarifications.

b. Modification of protocol I-04-062 (*04-062-01*)-

[redacted]

The meeting was adjourned at 3:50 PM

Institutional Biosafety Committee
Minutes of
May 12, 2005
3:00 P.M. - Room 307 C AOB

PRESENT: Dr. Randal Jaffe, Dr. Aixa Alfonso, Mr. Richard Anderson, Dr. Mary Bowman, Ms. Anne Cousin, Dr. Jeffrey Fortman, Dr. Paul Goldspink, Ms. Mariyln Hau, Dr. William Hendrickson, Dr. Roberta Mason-Gamer, and Dr. Alex Neyfakh, and Dr. Maria Rudisch

ABSENT: Dr. Edward Cohen and Dr. Thomas Hope

1. **Announcements-**

Dr. Bowman informed the Committee that there were two additions to the agenda. Under new business, protocol 05-044 was added as item a, and [redacted] ventilation was added as item b. In addition, she informed the Committee that Marilyn Hau was appointed to the Committee as the interim biosafety officer. She asked the members of the Committee to introduce themselves.

Ms. Hau asked to add an additional item to the agenda as item c under new business regarding a CDC announcement on H2N2 virus.

Dr. Bowman informed the Committee that thank you cards for Terry Lawrin and Shelia White were being circulated for signature.

2. **Minutes-**

The minutes of April 12, 2005 IBC meetings were approved pending a minor editorial clarification.

3. **Old Business-**

   a. **BSL3 Certification**

Dr. Bowman informed the Committee that a company had been selected to certify the BSL3 laboratories in the [redacted]. She indicated that the Company was reviewing design documents and documents from the commissioning process and that she would keep them informed as to the progress of the certification.

   b. **Maintenance Template**

Dr. Bowman reminded the Committee that last month the Committee had requested that a template be prepared for use by the PIs in handling maintenance issues related to the BSL3 and that Mr. Anderson indicated that he would prepare the template. Mr. Anderson indicated that Appendix E of the biosafety manual indicated that the safety office should be called for maintenance and that a template was not needed. The Committee discussed that this was not sufficient and that the PIs had requested additional guidance related to routine, urgent or emergency maintenance issues. Ms. Hau stated that she would work on a document, which the Committee could review next month. In the interim, PIs would be informed that they should contact the on call safety personnel for all maintenance issues.

4. May Protocol Summary Reports-

a. Protocols and Modifications for Expedited Approvals-

No protocols or modifications were submitted this month that were eligible for expedited approvals.

b. Protocols and Modifications for Full Committee Review-

I-05-032- Genes in Painful Conditions and Their Influence by Treatment

The Committee discussed the following issues: 1) that the purpose of the research was to study genes involved in pain control, drug addiction, Alzheimer's disease and other disease states, 2) that genes of interest included opioid receptors, dopamine receptors, 5HT receptors, uptake transporters, GABA receptors, NDMA receptors, and kinase genes, 3) that the genes would be cloned into a variety of plasmid vectors and transfected in vitro in a number of established cell lines to examine their effects in these cells, 4) that the project used human cell lines and was a BSL2 level project, 5) that Appendix 1 for personnel needed to be completed and appropriate training and safety precautions needed to be listed, and 6) that the biosafety cabinet needed to be certified. Following discussion, a motion to defer this protocol passed unanimously. Deferral was with the understanding that it was pending the following clarifications prior to rereview.

a. Please correct typographical errors in protocol.
b. In Form A, item IV a-c, please clarify the goal of the experiments. What is being sought by expressing genes in these established cell lines?
c. In Form A, item Vc, please check BSL2 not BSL1. All human cell lines should be used at BSL2.
d. In Form A, item VI, complete this entire section for BSL2 and specifically address all items requested in item e.
e. Appendix 1, this must be completed for all protocols. Please list all personnel who will be working under this protocol and specifically address all items requested in this appendix.

f. All personnel listed on Appendix 1 who work with human cell lines must complete Bloodborne pathogen training. Please see IBC web site for a list of seminar training dates (http://www.research.uic.edu/protocolreview/ibc/education/index.shtml). This is a yearly requirement of OSHA. In addition, bloodborne pathogen training for the PI needs to be updated. Please provide copies of BBPT verification to the IBC office.
g. Please ensure the biosafety cabinet has been certified within the last year. UIC requires that certifiers be NSF49 certified. Two approved certifiers are Clean Air ([redacted]) and Salus ([redacted]). Please provide a copy of the certification certificate to IBC office.
h. Please indicate whether or not potentially infectious material (e.g. human cell lines) will be shipped from your lab off-campus. If yes, the personnel in the laboratory responsible for the packaging and shipping of potential infectious biologicals must complete IATA shipping and receiving training for air shipments or DOT training for ground shipments. Please contact the EHSO (996-7429) to obtain an IATA training disc (via air) or access EHSO web site for on line DOT (ground) training. Please provide a copy of the training certification to the IBC office.

I-05-033- Study of E2F-RB Pathway

The Committee discussed the following issues: 1) that the purpose of the study was to elucidate the mechanisms of eukaryotic gene expression and to determine how chromatin modifying activities are used during development, 2) that Drosophilia and mammalian E2f RB and DP genes, which play a role in cell cycle progression, would be used in transgenic drosophila, subcloning in E. coli, and transient transfection studies in insect cells, 3) that studies would also be conducted to study RB-interacting proteins, 4) that this was a relatively new investigator and EHSO needed to inspect the laboratory and ensure that the biosafety cabinet was certified within the last year, 5) whether IATA training was required for receiving as well as shipping, and 6) that chemical safety issues should be handled by EHSO. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. Please contact the EHSO (996-7429) to arrange an inspection of the laboratory.
b. Please ensure that appropriate biohazard signs are posted for entry into the laboratory and the PPE regarded for handling biohazard is posted.
c. Please ensure the biosafety cabinet has been certified within the last year. UIC requires that certifiers be NSF49 certified. Two approved certifiers are Clean Air ([redacted]) and Salus ([redacted]). Certification date will be checked at the time of inspection.
d. In Form A, item VIe, please address the following concerns:

i. Please clarify that work with human cell lines is taking place in a biosafety cabinet.
ii. Please clarify the PPE clothing. Is PI referring to lab coats?
iii. Please clarify specifically how work surfaces and biosafety cabinet are decontaminated and how spills are handled.
iv. Please clarify reference to work with viruses. Viral work is not proposed in this protocol.

e. Please indicate whether or not any potentially infectious material (e.g. any human cell lines, viral vectors) will be shipped from your lab off campus. If yes, the personnel in the laboratory responsible for the packaging and shipping of potential infectious biologicals must complete IATA shipping and receiving training for air shipments or DOT training for ground shipments. Please contact the EHSO (996-7429) to obtain an IATA training disc (via air) or access EHSO web site for on line DOT (ground) training. Please provide a copy of the training certification to the IBC office.

I-05-034- Molecular Mechanisms of Leukocyte Activation

The Committee discussed the following issues: 1) that the purpose of the protocol is to understand how white blood cells are activated during inflammation and during infection and how this activation can be regulated to reduce activity during inflammation or enhance immunity during infection, 2) that human leukocytes would be used for function assays testing role of activation factors, 3) that various chemoattractant receptors genes or related signaling proteins would be expressed in E. coli on cell lines using plasmid, retroviral and adenoviral vectors to study structure/function relationship with activation, leukocyte gene expression, superoxide formation, and lipid mediated leukocyte activation/inactivation, and 4) that the PI needed to clarify shipping/receiving questions, clarify the genes of interest and provide verification of bloodborne pathogen training. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item IV c, please address the following concerns:
   i. Please expand description of genes of interest.
   ii. Please indicate the plasmid vectors used.
   iii. Please indicate which retroviral vector is used (e.g., MMTV), how it is attenuated and packaging cell line used.
   iv. Please indicate which adenoviral vector is used, how it is attenuated and packaging cell line used.
b. Please provide copies of bloodborne pathogen training certificates to the IBC office. Please note that two personnel listed on appendix I do not have bloodborne pathogen training dates. Only those personnel with current dates and verification will be approved to work with BBP under this protocol.
c. Please indicate whether or not any cell lines will be shipped from your lab off campus. If yes, the personnel in the laboratory responsible for the packaging and shipping of potential infectious biologicals must complete IATA shipping

and receiving training for air shipments or DOT training for ground shipments. Please contact the EHSO (996-7429) to obtain a IATA training disc (via air) or access EHSO web site for on line DOT (ground) training. Please provide a copy of the training certification to the IBC office.

I-05-035- Chemoattractant-Induced Gene Expression in Leukocytes

The Committee discussed that the purpose of this protocol was almost identical to the previous protocol, but that both were submitted for grant purposes, and the clarifications needed were the same as the previous protocol. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item IV c, please address the following concerns:
    i. Please expand description of genes of interest.
    ii. Please indicate the plasmid vectors used.
    iii. Please indicate which retroviral vector is used (e.g., MMTV), how it is attenuated and packaging cell line used.
    iv. Please indicate which adenoviral vector is used, how it is attenuated and packaging cell line used.
b. Please provide copies of bloodborne pathogen training certificates to the IBC office. Please note that two personnel listed on appendix 1 do not have bloodborne pathogen training dates. Only those personnel with current dates and verification will be approved to work with BBP under this protocol.
c. Please indicate whether or not any potentially infectious material (e.g. any human cell lines, viral vectors) will be shipped from your lab off campus. If yes, the personnel in the laboratory responsible for the packaging and shipping of potential infectious biologicals must complete IATA shipping and receiving training for air shipments or DOT training for ground shipments. Please contact the EHSO (996-7429) to obtain an IATA training disc (via air) or access EHSO web site for on line DOT (ground) training. Please provide a copy of the training certification to the IBC office.

I-05-036- Regulation of the Reelin Gene

The committee discussed the following issues: 1) that the purpose of the protocol was to determine which portions of the reelin gene promoter are important for controlling gene expression, 2) that the promoter would be cloned using a luciferase reporter construct and transfected into NT2 cells and that similar constructs would be introduced into mice to measure biologically accurate promoter function, 3) that transcription factors would also be studied in culture, 4) that the project needed to be conducted at BSL2, 5) that the biosafety cabinet needed to be recertified, 6) that personnel needed to provide verification of bloodborne pathogen training, and 7) that the PI needed to clarify shipping and

receiving question. Following discussion, a motion to defer this protocol passed unanimously. Deferral was with the understanding that it is pending the following clarifications.

a. In Form A, item IV c, please clarify the constructs that will be used to generate transgenic mice. List construct and reporter gene.
b. In Form A, item Vc, please check BSL2 not BSL1. All human cell lines should be used at BSL2.
c. In Form A, item VI e, please complete this section for BSL2. Please address all questions asked. Protective devices include biosafety cabinet and personnel protective equipment such as gloves, lab coats, etc.
d. All personnel listed on Appendix 1 who work with human cell lines must complete Bloodborne pathogen training. Please see IBC web site for a list of seminar training dates (http://www.research.uic.edu/protocolreview/ibc/education/index.shtml). This is a yearly requirement of OSHA. In addition, bloodborne pathogen training for the PI needs to be updated. Please provide copies of BBPT verification to the IBC office.
e. Please ensure the biosafety cabinet has been certified within the last year. UIC requires that certifiers be NSF49 certified. Two approved certifiers are Clean Air ([redacted]) and Salus ([redacted]). Please provide copy of updated certification to IBC.
f. Please indicate whether or not any potentially infectious material (e.g. any human cell lines, viral vectors, etc.) will be shipped from your lab off campus. If yes, the personnel in the laboratory responsible for the packaging and shipping of potential infectious biologicals must complete IATA shipping and receiving training for air shipments or DOT training for ground shipments. Please contact the EHSO (996-7429) to obtain an IATA training disc (via air) or access EHSO web site for on line DOT (ground) training. Please provide a copy of the training certification to the IBC office.

I-05-037- Pharyngeal Development in C. Elegans

The Committee discussed the following issues: 1) that the purpose of this protocol was to study the genes controlling muscle differentiation and organogenesis in the nematode, 2) that the genes of interest included various transcription factors (ceh-22, ceh-28, tbx-2, and peb-1) or signal transduction molecules (daf-4, daf-3, sma-1, dbl-4), 3) that the genes would be expressed in E. coli using standard plasmids and lambda phage vector systems, 4) that transgenic C. elegans would be used for promoter-reporter gene constructs, and 5) that the PI needed to clarify the transient transfection studies and the strain of E. coli used. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IVc, please address the following concerns:

i. PI checked box 4 under category III. Please clarify the transient transfection studies that will be conducted. What cell lines will be used? What vectors will be used? Please uncheck box if this is not being done.
ii. Please clarify the strain or strains of E. coli being used.

I-05-038- Immune-Endocrine Control of Reproductive Functions

The Committee discussed the following issues: 1) The purpose of this research was to study the role of the immune and endocrine systems in the development of reproductive pathologies and in particular, changes in gene expression in response to inflammation and oxidative stress, that total RNA would be extracted from rodent or avian tissue, cDNA prepared and probes prepared using standard plasmids and expression in E. coli for northern plot analysis, 3) that recombinant proteins would also be expressed in mouse Leydig cell culture using retroviral and adenoviral vectors, 4) that the PI needed to provide verification of biosafety cabinet certification, 5) that personnel needed to provide verification of bloodborne pathogen training, and 6) that the PI needed to clarify shipping and receiving question. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. Please provide copies of bloodborne pathogen training certificate to the IBC office.
b. Please indicate whether or not any potentially infectious material (e.g. any human cell lines, viral vectors) will be shipped from your lab off campus. If yes, the personnel in the laboratory responsible for the packaging and shipping of potential infectious biologicals must complete IATA shipping and receiving training for air shipments or DOT training for ground shipments. Please contact the EHSO (996-7429) to obtain a IATA training disc (via air) or access EHSO web site for on line DOT (ground) training. Please provide a copy of the training certification to the IBC office.
c. Please ensure the Biosafety cabinet has been certified within the last year. UIC requires that certifiers be NSF49 certified. Two approved certifiers are Clean Air ([redacted]) and Salus ([redacted]). Please provide copy of updated certification to IBC office.

I-05-039- Entry of Alpha Herpes Viruses into Mammalian Cells

The Committee discussed the following issues: 1) that the purpose of the research was to gain a better understanding of the mechanisms involved in receptor-mediated Herpes Simplex viral entry and cell-to-cell viral spread, 2) that the role of cellular receptors (HVEN, nectin, and 3-O-sulfated heparan sulfate) and viral envelope glycoproteins (gB, gC, gD, gH and gL) in viral entry would be examined, 3) that established cell lines would be transfected with expression plasmids expressing wild type or mutant entry receptors,

receptor generating enzymes, envelope glycoproteins, and fluorescent reporter constructs, 4) that recombinant, mutant and wildtype forms of HSV1 and HSV2 would be used along with animal alpha herpes viruses, 5) that the PI had indicated the use in whole animals, but had not described the work, 6) that verification of biosafety cabinet certification needed to be provided, 7) that the laboratory required a plumbed eyewash station, and 8) that the PI needed to clarify shipping/receiving questions. Following discussion, a motion to defer this protocol passed unanimously. Deferral was with the understanding that it is pending the following clarifications prior to rereview.

a. In Form A, item IV c, references to work in animals is indicated in this section, but no description of the work with animals is included. If PI will be infecting animals with HSV, then this work needs to be described in this protocol. In addition, box 4 of item II should be checked and the ACC number under which the work will occur needs to be provided. If work in whole animals will not occur, then please remove this statement from the protocol.
b. Please ensure the Biosafety cabinet has been certified within the last year. UIC requires that certifiers be NSF49 certified. Two approved certifiers are Clean Air ([redacted]) and Salus ([redacted]). Please provide a copy of the certification certificate to IBC office. Please contact EHSO (996-7427) to arrange inspection to verify BSC model and certification.
c. Plumbed eyewash station needs to be provided within 10 seconds travel time or 100 feet of where work is occurring.
d. Please indicate whether or not any potentially infectious material (e.g. any human cell lines, viral vectors, etc.) will be shipped from your lab off campus. If yes, the personnel in the laboratory responsible for the packaging and shipping of potential infectious biologicals must complete IATA shipping and receiving training for air shipments or DOT training for ground shipments. Please contact the EHSO (996-7429) to obtain an IATA training disc (via air) or access EHSO web site for on line DOT (ground) training. Please provide a copy of the training certification to the IBC office.

I-05-040- Developmental Estrogenization of the Rat Prostate

The Committee discussed the following issues: 1) that the purpose of the research was to study the role of Wnt genes, a family of morphoregulatory genes, in the developing rat prostate and changes in gene expression patterns in response to neonatal estrogen exposure, 2) that Wnt genes or portion of genes would be cloned using plasmids into E. coli for expression and formation of molecular probes, 3) that Wnt genes would be transfected into various mammalian cell lines, 4) that primary cells from developing prostates would be cultured and cells and media would be examined for Wnt levels, 5) that siRNA would be used to inhibit Wnt expression in vitro, and 6) that there were no clarifications required. Following discussion, a motion to approve this protocol passed unanimously.

I-05-041- Characteristics of Multidrug Resistance and Biomarkers in Human Tumors

The Committee discussed the following issues: 1) that the purpose of the research was to study the mechanisms involved in multidrug resistant phenomenon, 2) that several classes of genes which are potentially involved in drug resistance, which could serve as potential markers for early cancer diagnosis and/or may have predictive value for therapeutic outcome would be studied, 3) that genes would be expressed in vitro in a variety of cell lines using various plasmid vectors, 4) that expression levels and protein levels would be monitored in patient samples, 5) that genes of interest would be overexpressed or silenced (siRNA technology) to study downstream effects of these genes and proteins on cell phenotype, and 6) that the PI needed to clarify the method of disinfection. Following discussion, a motion to approve this protocol passed unanimously.

a. In Form A, item VIe, 70% alcohol is not considered to be an effective sterilant when used alone in an operating biosafety cabinet. Other methods of decontamination followed by alcohol would be more appropriate.

5. **Adverse Event Reports-**

None to report

6. **New Business-**

   a. **Plant Field Study Protocol**

Dr. Bowman directed that Committee's attention to the protocol requesting permission for a field release of transgene plants. The Committee discussed the following issues: 1) that the plant was Arabidopsis thaliana, a common non-noxious weed used in plant genetic studies, 2) that the research involved the study of R genes, which are involved in the immune response of plants to pathogens, 3) that plants using the cre-lox system had been created with or without Rmp 1 gene, 4) that the field release will determine the cost/benefit of having Rmp 1 gene to seed production, 5) that the PI had notified APHIS and was awaiting approval for release, and 6) that the PI had proposed appropriate control measures to prevent spread and control volunteers. Following discussion a motion to approve this protocol passed unanimously with the following condition.

a. Condition of approval: Project cannot be initiated until APHIS has granted approval. Please provide UIC IBC with copy of APHIS notification and approval when obtained.

   b. [redacted] **Ventilation**

Dr. Bowman and Ms. Hau informed the Committee that there had been a ventilation problem in the [redacted]. This ventilation problem was related to the whole building ventilation and not specific to the BSL3 laboratory and was related to the automated system. Ms. Hau indicated that they had investigated the problem and were told that the BSL3 laboratory had been switched from the automated system to manual to maintain negative pressure. She indicated that to the best of their knowledge negative pressure had not been lost in this laboratory. She also indicated that the problem was now fixed.

c. CDC Change in BSL for H2N2 Virus

Ms. Hau informed the Committee that CDC was recommending that the biosafety level for laboratory work involving some human influenza A (H2N2) viruses be upgraded from BSL2 to BSL3.

The meeting was adjourned at 4:35 PM

Institutional Biosafety Committee
Minutes of
June 9, 2005
3:00 P.M. - Room 307 C AOB

PRESENT: Dr. Randal Jaffe, Dr. Aixa Alfonso, Mr. Richard Anderson, Dr. Mary Bowman, Dr. Edward Cohen, Ms. Anne Cousin, Dr. Jeffrey Fortman, Dr. Paul Goldspink, Ms. Marilyn Hau, Dr. William Hendrickson, Dr. Roberta Mason-Gamer, Dr. Alex Neyfakh, Dr. Jeffrey Oswald, and Dr. Maria Rudisch

ABSENT: Dr. Thomas Hope

STAFF: Ms. Soudabeh Soura (non-voting)

GUEST: [redacted]

1. **Announcements-**

Dr. Bowman introduced a new community member, Dr. Jeff Oswald, to the Committee and asked the Committee to introduce themselves. She also indicated that she was distributing a handout that would be discussed under new business as item b.

2. **Minutes-**

The minutes of May 12, 2005 IBC meetings were approved pending a minor editorial clarification.

3. **Old Business-**

   a. **Maintenance Template**

Ms. Anne Cousin and Dr. Paul Goldspink arrived

Ms. Hau directed the Committee's attention to the handout she distributed for maintenance issues related to BSL3 laboratories. She indicated the routine maintenance should be requested through Facility Management's web site, FMweb, and that the handout described the procedure. Urgent maintenance should be requested thorough the Facility Management Service Desk and immediate or medical emergency requests should be directed to the UIC fire or police departments, respectively. The Committee discussed that the handout included a calling or contact tree that informed the EHSO for all levels of maintenance, except routine. Ms. Hau indicated that there is a comment section on the request form and the requester should indicate in this section, to notify the EHSO. In addition, the handout included contact numbers for specific maintenance issues. The

Committee discussed the following issues: 1) how investigators would be notified if requests were generated by building engineers or building managers, 2) how outside maintenance requests and notification of EHSO should be handled, and 3) what training maintenance personnel were required to have prior to initiating work. Ms. Hau indicated that she would incorporate these suggestions into the template and present it to the Committee next month.

b. Deferred Protocols

Dr. Jeffrey Oswald arrived.

I-05-022- Expression of cDNA Clones in E. Coli and Eukaryotic Cells

The Committee discussed the following issues: 1) that the purpose this research was to study genes that regulate brain function in adult mice, and in particular, small RNA pathway genes (dicer, drosha, elf2c, fmrp, microRNA precursors, BC1, etc.) and genes involved in synaptic plasticity (CAMKII, PSD-95, glutamate receptor, etc.) would be studied, 2) that this protocol had been previously deferred and the PI had addressed the majority of the concerns, but needed to indicate the specific PPE used, the use of bleach prior to ethanol for decontamination, that waste was autoclaved prior to disposal, and provide copies of bloodborne pathogen training certificates to the IBC office. Following discussion a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item VI e, please address the following concerns:
    i. 10% bleach followed by 70% ethanol should be used to decontaminate the biosafety cabinet.
    ii. Please indicate the specific personnel protective equipment that is worn when working with human cell lines in the biosafety cabinet (e.g., gloves and lab coats).
    iii. Please indicate that solid biohazardous material is autoclaved prior to final disposal and/or disposed of in biohazard sharps containers.
b. In Form A, item VI f, BSL 2 is the appropriate biosafety level for work with human cell lines. Please change to NO.
c. Copies of BBPT certificates must be submitted to the IBC office for all personnel listed on Appendix 1.

I-05-032- Genes in Painful Conditions and Their Influence by Treatment

The Committee discussed the following issues: 1) that the purpose of the study was to study genes involved in pain control, drug addiction, Alzheimer's disease and other disease states including opioid receptors, dopamine receptors, 5HT receptors, uptake transporters, GABA receptors, NDMA receptors, and kinase genes, 2) that the genes would be cloned into a variety of plasmid vectors and transfected in vitro in a number of

established cell lines to examine their effects in these cells, and 3) that the PI had addressed the majority of the concerns previously raised by the Committee and needed to indicate how the biosafety cabinet was decontaminated, elaborate on how personnel were trained for working with rDNA, and provide copies of bloodborne pathogen training certificates to the IBC. Following discussion a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item VI e, please indicate how biosafety cabinet is decontaminated following experiments. Recommended method is to wipe down with 10% bleach followed by 70% ethanol.
b. In Appendix 1, please expand on how personnel are trained to work with rDNA and to work safely with biohazards in the laboratory (e.g., UIC biosafety manual? Molecular biology texts? Etc.). In addition, copies of BBPT certificates must be provided to the IBC office prior to final approval being granted.

I-05-039- Entry of Alpha Herpes Viruses into Mammalian Cells

The Committee discussed the following concerns: 1) that the purpose of the research was to gain a better understanding of the mechanisms involved in receptor-mediated Herpes Simplex viral entry and cell-to-cell viral spread and that the role cellular receptors (HVEN, nectin, and 3-O-sulfated heparan sulfate) and viral envelope glycoproteins (gB, gC, gD, gH and gL) play in viral entry would be examined, and 2) that although the PI had addressed the previous concerns of the Committee, the eyewash stations in the PI's laboratory were not plumbed eyewashes and one would need to be installed. Following discussion a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. The eyewash stations present in your laboratory are not plumbed eyewash stations and they do not meet code. A plumbed (e.g., connected to running water) eyewash station must be installed. Please contact EHSO (Marilyn Hau or Richard Anderson) at 996-7411 if you have questions regarding what is needed to meet code. When instillation is complete, please notify the IBC office. Final approval cannot be granted until that time.

4. June Protocol Summary Reports-

a. Protocols and Modifications for Expedited Approvals-

No protocols or modifications were submitted this month that were eligible for expedited approvals were summarized for the Committee.

b. Protocols and Modifications for Full Committee Review-

I-05-042- Heterotrimeric G Protein Signaling in Yeast

The Committee discussed the following issues: 1) that the purpose of this research was to understand how cells sense and respond to environmental stimuli via the G-protein coupled receptor family and associated intracellular G-protein signaling network and that yeast would be used as a model organism and environmental stimuli would include mating pheromone, 2) that the goals of the study included determining how yeast responds to the direction of pheromone, how mating-specific G-alpha protein regulates microtubule dynamics effecting nuclear placement, how pheromone controls localization of signal-transducing kinase, and elucidation of the role of a novel gene thought to function as a scaffolding protein for signaling enzymes, 3) that the project used laboratory strains of E. coli, that all plasmids were E. coli-yeast shuttle vectors, and that genes of interest included mating-specific G-proteins and kinases, pheromone receptors, and structural proteins, and 4) why it was being requested of this PI to list specifically the biosafety manual as part of training and the nature of how the PI had expressed training of personnel in Appendix 1 and whether the Assurance statement signed by the PI should cover this aspect. The consensus of the Committee was that the biosafety manual should be listed as part of training on this protocol. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Appendix 1, as part of the training required for new personnel, PI should also indicate these personnel will be required to read and understand the relevant portions of the UIC biosafety manual which can be found at (www.uic.edu/depts/envh).
b. Please note that if any work will be performed in fume hood, it must be repaired to ensure proper function. Please contact physical plant routing at ServDesk@physpl.uic.edu to request service.

I-05-043- Structural Basis for Serpin Function and Regulation and Molecular Basis of Blood Coagulation Regulation

The Committee discussed the following issues: 1) that the purpose of this research was to elucidate the structure/function relation of members of the serpin superfamily, a family of genes that regulate proteolytic enzyme cascades in key physiological process such as blot clotting, host defense, and apoptosis and gain a better understanding how mutations in these genes are associated with human diseases, and 2) that a number of genes in this family would be expressed as wildtype or mutant proteins in E. coli, Sf9 cells, or BHK cells using a variety of plasmid vectors. The Committee also had an extensive discussion on the role of the IBC in relation to chemical safety issues. Ms. Hau indicated that the mission of the IBC was to empower the EHSO. The Committee agreed that when problems related to chemical safety are identified in a laboratory that these issues are important and should be addressed; however, members of the Committee indicated that

the responsibility lies with the EHSO to develop a program for ensuring that these deficiencies are addressed and these issues are not within the scope of the IBC. Moreover, the Committee indicated that the IBC only reviewed protocols from a small portion of the laboratories in which chemicals were used and the program needed to encompass all laboratories. In addition, [redacted] indicated that this matter had been discussed with the Vice Chancellor for Research, and that the Vice Chancellor was in agreement that matters related to chemical safety are outside the purview of the IBC. Ms. Hau indicated that her vote on a protocol would only be cast as the interim biosafety officer and not as the director of EHSO. A motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. PI and laboratory personnel involved in this research are required to read and understand the relevant portions of the UIC Biosafety manual, which can be found at (www.uic.edu/depts/envh. Please provide a statement signed by the personnel on the protocol and the PI indicating that this has been done.
b. PI needs to update laboratory identification and data cards with current information. Please provide a statement indicating that this has been done.

I-05-045- Regulation of Aerobic Gene Expression

The Committee discussed the following issues: 1) that the purpose of the research was to determine how aerobic enzymes genes regulate transcriptional changes that occur in response to exercise, 2) that the promoter regions of two genes, COX VIII and COX VIa, would be mapped to determine the specific DNA sequences responsible for response to exercise induced changes using luciferase reporter constructs for in vitro and in vivo transfection assays in mouse skeletal muscle cell line or directly into rat muscle, respectively, and 3) that this research would occur in the same laboratory as protocol 05-038 which was recently approved. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IV c, please address the following concerns:
    i. Please indicate the method of DNA construct delivery (e.g., percutaneously? Via skin incision and injection directly in muscle?).
    ii. Please indicate the muscles that will be injected.

I-05-046- Functional Analysis of Viral Proteins

The Committee discussed the following concerns: 1) that the purpose of this protocol is to elucidate the domain functions of VP35 protein of the Ebola virus and the NS1 protein of the influenza virus, two proteins thought to be involved in viral replication, 2) that proteins with deletions or site-directed mutations would be expressed in recombinant

HSV and that no live Ebola or influenza virus would be used, 3) that a variety of cell lines would be used for viral infection assays, 4) that the origin of the genes and the vector needed to be elaborated on, and 5) that the certification on the biosafety cabinet needed to be updated and personnel needed to update bloodborne pathogen training. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item III, please mark box #1 for forming rDNA using less then 2/3 of genome of eukaryotic virus.
b. In Form A, item IV c, please address the following concerns:
    i. Please indicate specifically from where the plasmids carrying NS1 or VP35 DNA will be obtained (e.g., were they shipped from elsewhere? Did you synthesize the gene and insert into plasmid?).
    ii. Please describe the vector and the surrogate system being used in greater detail.
c. Please ensure the Biosafety cabinet has been certified within the last year. UIC requires that certifiers be NSF49 certified. Two approved certifiers are Clean Air ([redacted]) and Salus ([redacted]). Please provide a copy of the certification certificate to IBC office.
d. All personnel listed on Appendix 1 must complete Bloodborne pathogen training. Please see IBC web site for a list of seminar training dates (http://www.research.uic.edu/protocolreview/ibc/education/index.shtml). This is a yearly requirement of OSHA and current training will expired on June 8, 2005. Please provide copies of BBPT verification to the IBC office.
e. PI needs to update laboratory identification and data cards with current information. Please provide a cover letter signed by the PI indicating that this has been done.
f. Food or drink intended for human consumption should not be stored in the lab or lab refrigerator. Please provide a cover letter signed by the PI indicating that this laboratory is in compliance with this issue.
g. Bottles and flasks must be labeled with content and all samples must be identified. Please provide a cover letter signed by the PI indicating that this has been done.
h. Compressed gas cylinders must be secured. Please provide a cover letter signed by the PI indicating that this has been done.

I-05-048- Structure-Function Analysis of Recombinant Serpin Variants

Following discussion that the purpose of this research was to elucidate the structure/function relationship of members of the serpin superfamily, a family of genes that regulate proteolytic enzyme cascades in key physiological process such as blot clotting, host defense, and apoptosis and in particular, research would focus on elucidating the role of alpha1-antitrypsin, thyroxine binding globulin, C1-inhibitor and other members of the serpin family, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarification.

a. Food or drink intended for human consumption should not be stored in the lab or lab refrigerator. Please provide a cover letter signed by the PI indicating that this laboratory is in compliance with this issue.

I-05-051- Light and Hormonal Regulation of Plant Development

The Committee discussed the following issues: 1) that the purpose of this research was to elucidate the mechanisms by which blue light and the plant hormone ABA effect the signal transduction mechanisms regulating when germination and leaf development occur, 2) that *Arabidopsis thaliana* (wildtype, mutant or transgenic forms) would be irradiated with blue light or treated with abscisic acid and other common plant hormones and monitored for phenotypic development, 3) that mutants would be purchased, ordered through seed banks, created via mutagenic agents, T-DNA insertion or were natural mutants, and 4) that the laboratory needed to be inspected. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. Please contact EHSO (996-7411) to arrange an inspection of the laboratory facilities.

I-05-052- Pathogenic Mechanisms of Enteropathogenic and Enterohemorrhagic E. Coli (EPEC and EHEC)-

The Committee discussed the following issues: 1) that the purpose of this research was to elucidate the mechanisms by which pathogenic E. coli (enteropathogenic-EPEC or enterohemorrhagic- EHEC) caused diarrhea and specifically, the role of effector molecules (Esp family, Tir, Orf3, and Map) would be studied, 2) that targeted mutations of these genes would be produced and transfected into E. coli and mammalian cells, 3) that EPEC and EHEC strains deficient in one of the above effector molecules would be used to infect mice to determine the role of these genes in vivo, 4) that the PI had indicated that none of the organisms with targeted mutations have displayed greater pathogenicity than the parent strains, 5) that when rodent animals are housed in [redacted] biohazard rooms that PI can refer to [redacted] SOP for decontamination and clean-up, and 6) that bloodborne pathogen training certification was required for personnel listed on appendix 1. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item II, mark box 4 and list ACC number 03-012.
b. In Form A, item IV c, please address the following concerns:
    i. Please indicate the dose and volume of E. coli used for infection.
    ii. Please indicate the duration of the study with mice.

iii. Please indicate the source of the wildtype EPEC and EHEC.

c. In Form A, item VI e, please address the following concerns:
   i. Lab coat, tyvek wrap gown or apron must be worn over street clothes. Please indicate what type of PPE is used.
   ii. Please expand on how access to the laboratory by non-laboratory personnel is handled including maintenance personnel.
d. In Appendix 1, all personnel working under ACC protocol 03-012 who work with infectious agents or recombinant strains must be listed here, their level of expertise and training needs to be listed and they must complete bloodborne pathogen training as indicated below. In addition, please indicate that these personnel will complete the [redacted] biosafety training for work in animal biohazard rooms. If any personnel listed on 03-012 have left the laboratory or are not working with infectious agents, please clarify this for the Committee.
e. All personnel listed on Appendix 1 must complete Bloodborne pathogen training. Please see IBC web site for a list of seminar training dates (http://www.research.uic.edu/protocolreview/ibc/education/index.shtml). This is a yearly requirement of OSHA. Please provide copies of BBPT verification to the IBC office. Please note that training for [redacted] is not current (expired on 2/11/04).

I-05-053- Regulation of HBV Transcription-

The Committee discussed the following issues: 1) that the purpose of this research was to understand the mechanisms that control the coordination and differential regulation of Hepatitis B virus transcription, 2) that mutant HBV genomes designed to prevent synthesis of the viral genome would be constructed in plasmid vectors to determine the role of the specific gene or portions of genes in viral transcription, 3) that transfection studies of HBV into human or murine cells in vitro with wild-type or mutant virus would be conducted to determine the role of specific transcription factors binding sites on HBV transcription and replication and that farther determinations of the role of specific transcription factors in HBV transcription and replication would be studied in mice which are knockouts for specific transcription factors and are transgenic for the HBV genome, 4) that the investigator was in the process of transferring from another institution to UIC and would be transferring the mice carrying HBV, 5) that these mice would be bred, genotyped, bleed, and then euthanatized in a single user [redacted] room since all personnel working in the room will require vaccination, and 6) that the PI needed to elaborate on sharp precautions and access of the laboratory, provide bloodborne pathogen training certification, and review the exposure control plan at UIC. Following discussion, a motion to defer this protocol was passed with 1 abstention. Deferral was with the understanding that it is pending the following clarifications.

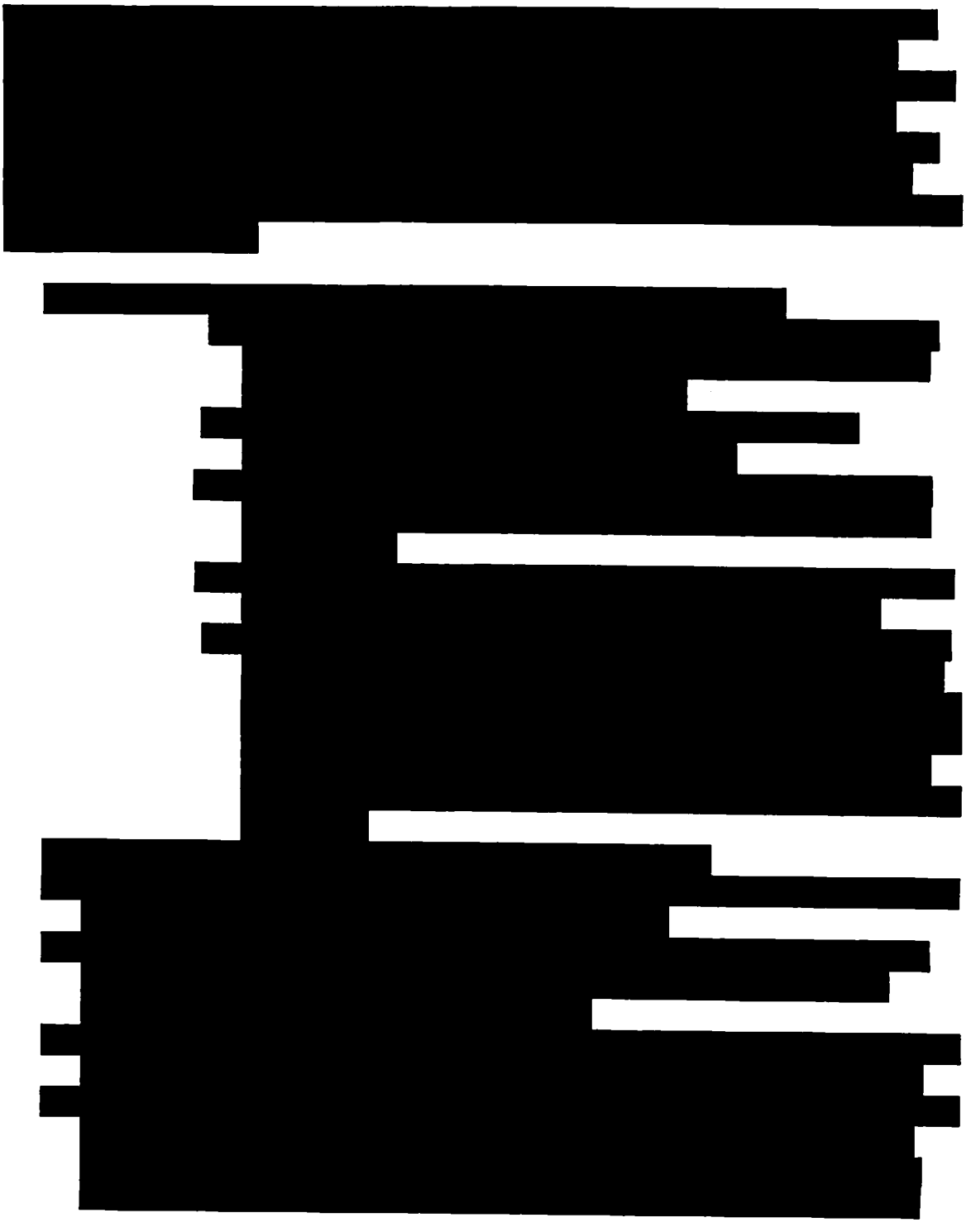
a. In Form A, item II b, please indicate ACC number 05-122. ACC number should also be placed in section VI e.
b. In Form A, item IV c, please describe the nature of the transcription expression vectors that will be used in transfection studies.

c. In Form A, item V a, indicate room [redacted] and [redacted] for use.
d. In Form A, item V b, indicate room [redacted] for storage of rDNA molecules and virus.
e. In Form A, item VI c, please address the following concerns:
    i. Please expand item #1 to include all animal care staff that have the potential to come into contact with mice, contaminated bedding, or other potentially contaminated materials. These personnel will also need to be immunized.
    ii. Please indicate that animal biohazard room will be a single user (PI) room in [redacted].
    iii. Please indicate the specific sharp precautions being used in the laboratory as well as with work with mice such as plastic pipets, needleless systems where feasible, etc. that limit exposure to sharps.
    iv. Please indicate that gloves will be nitrile gloves 8 mm in thickness.
    v. Lab coats should not be worn outside of containment lab. It is recommended that solid front or wrap-around disposable gowns, scrub suits, or coveralls be used in lieu of lab coats.
    i. Please indicate how access to the laboratory by non-laboratory personnel is handled including maintenance personnel.
f. PI needs to contact UHS (996-7040) to determine documentation needed to confirm immunization with Hepatitis B vaccine and that personnel have appropriate titers for all personnel listed in Appendix 1.
g. PI needs to provide documentation of bloodborne pathogen training within the last year. All personnel will need to review bloodborne pathogen exposure control plan with EHSO director. Please contact Marilyn Hau at 996-7429.
h. PI will need to update contact information regarding phone, fax, emergency phone and email when it is determined.

Dr. Jeffrey Fortman and Ms. Soudabeh Soura left.

I-05-050- A Phase I Dose-Ranging Study of the Safety, Tolerability, and Immunogenicity of a 3-Dose Regimen of the MRKAd5 HIV-1 Trigene and the MRKAd6 HIV-1 Trigene Vaccines Alone and in Combination in Healthy Adults

[redacted]



5. Adverse Event Reports-

No report this month.

6. New Business-

a. Suggested Changes to IBC Form A and Form B-

Dr. Bowman suggested that these items be tabled until next month. The Committee was in agreement.

b. Receiving Document-

Dr. Bowman reminded the Committee that last month the Committee discussed whether those personnel who are only receiving potential infectious materials and not shipping these materials were required to complete DOT or IATA training. She indicated that Ms. Hau had reviewed the regulations and found that the above-mentioned training was not required for the consignee. Dr. Bowman indicated that although specific training was not required, personnel receiving potentially infectious material should still be vigilant as to potential problems and contamination of a package. She directed that Committee's attention to a draft of a document for receiving potentially infectious materials. She stated that the IBC office would provide this document with each approved protocol to ensure that investigators were informed of the proper procedures for receiving packages. The consensus of the Committee was to accept the document with minor editorial changes.

The meeting was adjourned at 5:10 PM

Institutional Biosafety Committee
Minutes of
July 14, 2005
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Mary Bowman (served as chair designee), Dr. Aixa Alfonso, Ms. Anne Cousin, Dr. Jeffrey Fortman, Dr. Paul Goldspink, Ms. Marilyn Hau, Dr. William Hendrickson, Dr. Thomas Hope, Dr. Roberta Mason-Gamer

ABSENT: Dr. Richard Anderson, Dr. Edward Cohen, Dr. Randal Jaffe, Dr. Jeffrey Oswald, Dr. Alex Neyfakh and Dr. Maria Rudisch

STAFF: Ms. Soudabeh Soura (non-voting)

1. **Announcements-**

There were no announcements.

2. **Minutes-**

The minutes of June 9, 2005 IBC meetings were approved without revisions.

3. **Old Business-**

   a. **Maintenance Template-**

Dr. Bowman reminded the Committee that last month changes to the maintenance template had been requested to include use of an outside service provider. She directed the Committee to the revised template provided by Ms. Hau. A motion to approve the template for maintenance was approved unanimously. Dr. Bowman indicated that she would distribute the template to the BSL3 laboratories.

   b. **Deferred Protocols-**

I-05-036- Regulation of the Reelin Gene

The Committee discussed that this protocol had been previously deferred regarding the need to clarify constructs used, defining the appropriate biosafety level and practices, and need for bloodborne pathogen training. The Committee discussed that the PI had addressed most of these concerns, but needed to clarify use of gloves and how waste was decontaminated. In addition, personnel still needed to complete bloodborne pathogen training. A motion to approve this protocol passed unanimously approval was with the understanding that it is pending the following clarifications.

a. In Form A, item VIe, please address the following concerns:

i. Use of gloves should be used when handling rDNA and human cells.
ii. Please indicate how waste is decontaminated. Is liquid biohazardous waste bleached prior to disposal? Is solid waste autoclaved?

b. Personnel listed on appendix 1 need to complete bloodborne pathogen training and copies of the training certificates need to be submitted to the IBC. See the attached sheet for the next scheduled seminar.

I-05-053- Regulation of HBV Transcription

The Committee discussed that this protocol had been previously deferred pending clarification as to the nature of the expression vectors used, identification of laboratory and animal room used, elaboration on methods of inactivation, sharp procedures, and protective equipment, and OSHA requirements for bloodborne pathogen training and vaccination. The Committee discussed that the investigator had address all of the requested clarification from the previous deferral. Ms. Hau indicated that investigator should contact her to review UIC exposure control plan once they have relocated to UIC. A motion to approve this protocol passed unanimously. Approval was with the understanding that it is with the following condition.

Condition of Approval: Prior to initiation of work at UIC, please contact Ms. Marilyn Hau to review the UIC Bloodborne Pathogen Exposure Control Plan.

4. July Protocol Summary Reports-

A. Protocols and Modifications Eligible for Expedited Review

03-020- Antibody-Directed Gene Delivery to the Pulmonary Circulation- (*Modification 03-020-01*)-

PI requested the addition of new plasmid constructs containing small antibody fragments against ACE. Plasmids will be cloned in laboratory strains of E. coli. In addition, PI indicated that this portion of the protocol would be funded by a [redacted].

B. Protocols and Modifications for Full Committee Review

I-05-049- Effects of Mechanical Forces on Endothelial, Smooth Muscle and Bone Cells

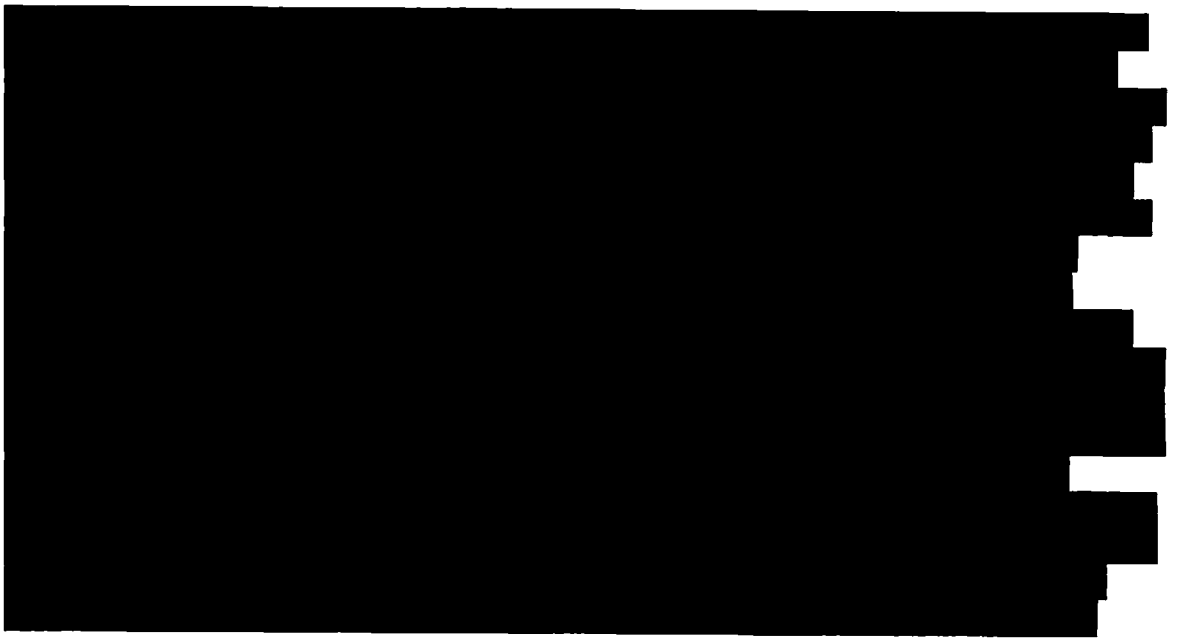
The Committee discussed the following issues: 1) that the purpose of this research is to quantify the effects of mechanical forces such as shear stress, ultrasound, and vibration on gene expression in endothelial cells, smooth muscle and bone cells, 2) that the goal

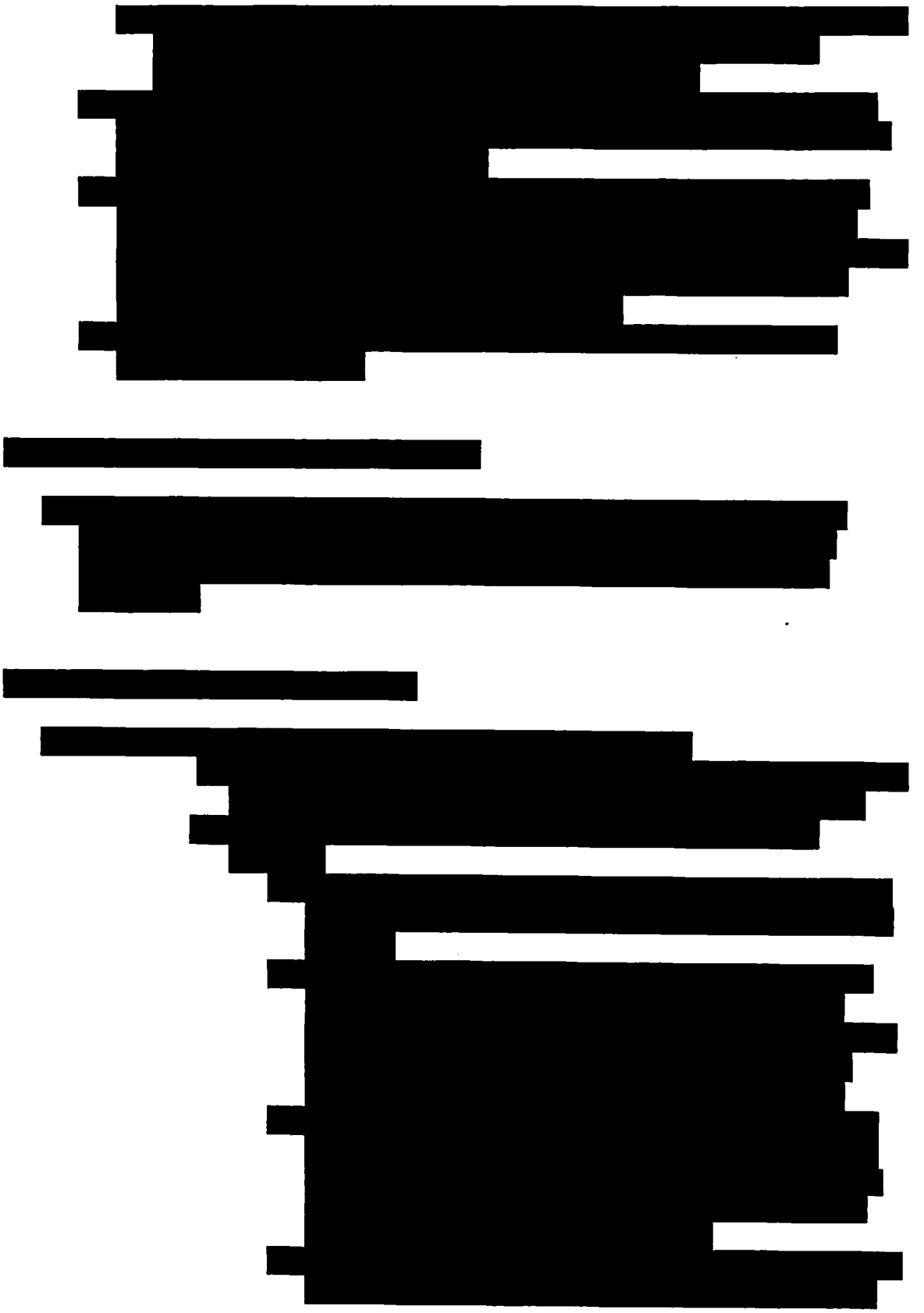
was to gain a better understanding of mechanobiology in order to develop better treatment plans for diseases such as artherosclerosis, intimal hyperplasia and osteoporosis, 3) that the genes of interest are eNOS, BMP-4, Calveolin, and PGHS-2, 4) that genes are expressed in plasmid constructs in laboratory strains of E. Coli and cDNA probes are isolated for Northern Blots, 4) that RNA for Northerns is isolated from human or mouse tissues, and 5) that there were no concerns of the reviewers and all personnel had completed bloodborne pathogen training. A motion to approve this protocol passed unanimously.

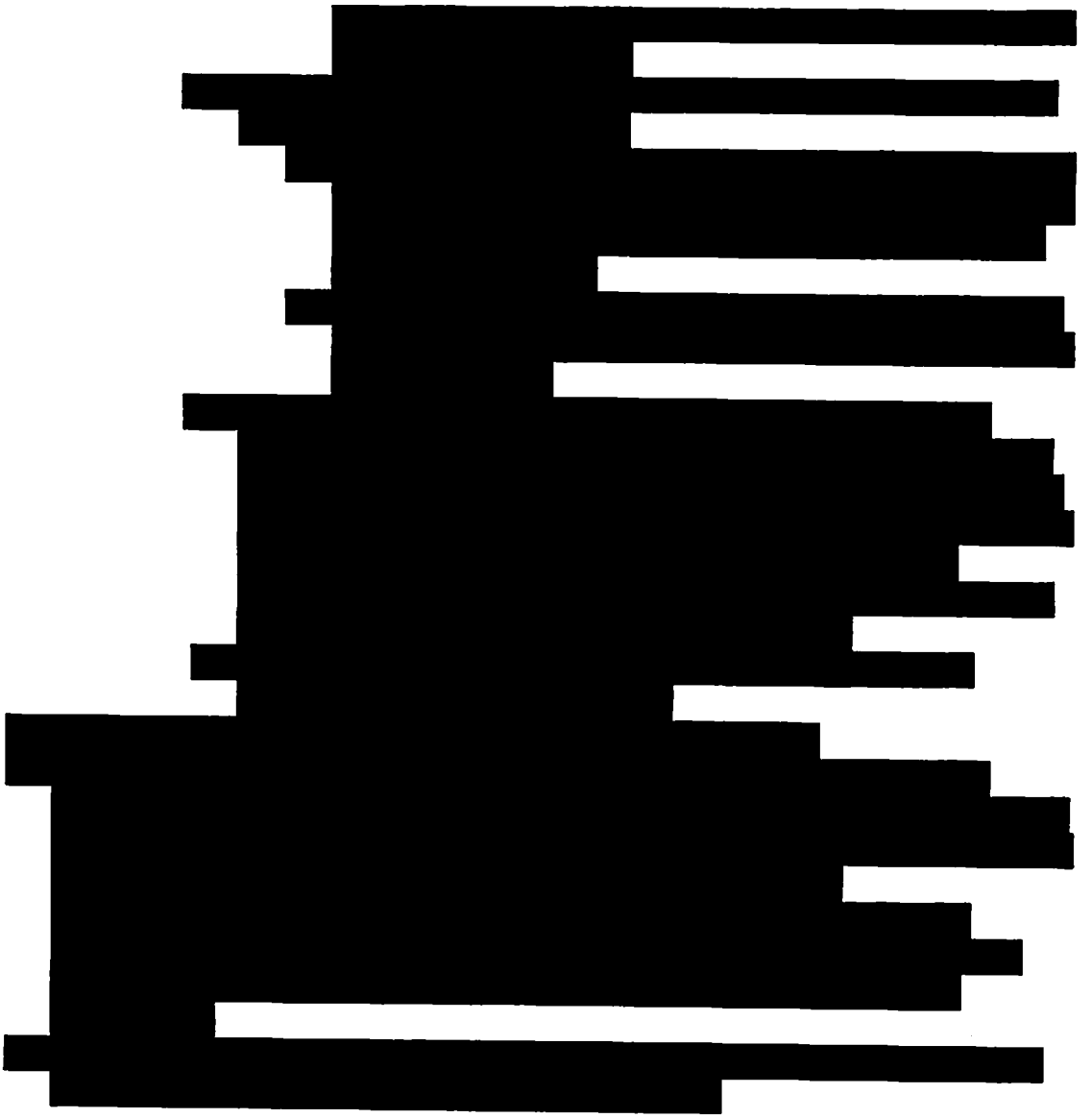
I-05-054- Regulation of G Protein Signaling by Cytoskeletal Components

The Committee discussed the following issues: 1) that the purpose of this research is to gain a better understanding of how G protein-coupled receptors and G protein-mediated cell signaling regulate changes in the cytoskeleton resulting in changes in cell shape and how these changes relate to conditions, such as depression and other mood disorders, 2) that the genes of interest included beta2-adrenergic receptor, muscarinic acetylcholine receptor, mGluRI, and G protein alpha and betagamma subunits, 3) that all genes are in plasmid constructs and will be expressed in a variety of mammalian cells or laboratory strain of E. coli, 4) that GFP constructs and adenoviral constructs will also be used and the adenoviral vector is replication defective due to the deletion of E1 and E3, 5) that there were no concerns of the reviewers and all personnel had completed bloodborne pathogen training. A motion to approve this protocol passed unanimously.

I-05-055- M-Vax: A Feasibility and Bio-Equivalence Study Using a DNP-Modified Autologous Melanoma Tumor Cell Vaccine as Therapy in Patients with Stage III or IV Melanoma







5. Adverse Event Reports-

No report this month.

6. New Business-

a. Suggested Changes to IBC Form A and Form B-

Dr. Bowman summarized the suggested changes in IBC Forms A and B including the following changes: 1) removing references to Appendix 2 from both forms as this was used as an internal tracking document, 2) removal of requirement for IATA training for

receiving and addition of question related to shipping and receiving and appropriate information on required training, 3) addition of LD50 for infectious agents to Form B, and 4) addition of editorial changes to form layout. The committee discussed the need to include transfer procedures and inactivation procedures in the protocol and the need to update phone numbers for select agent issues. Dr. Bowman indicated that she would incorporate the requested additions/changes and would provide the revised forms to the Committee for review in August.

The meeting was adjourned at 3:16 PM

Institutional Biosafety Committee
Minutes of
August 11, 2005
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Randal Jaffe, Dr. Aixa Alfonso, Dr. Mary Bowman, Dr. Edward Cohen, Dr. Paul Goldspink, Dr. Roberta Mason-Gamer, Dr. Alex Neyfakh, Dr. Jeffrey Oswald, and Dr. Maria Rudisch

ABSENT: Mr. Richard Anderson, Ms. Anne Cousin, Dr. Jeffrey Fortman, Ms. Marilyn Hau, and Dr. William Hendrickson

STAFF: Ms. Soudabeh Soura (non-voting)

1. **Announcements-**

Dr. Bowman informed the Committee that Dr. Hope had resigned from the Committee due to his relocation to another institution. She informed the Committee that she was in the process of recruiting a new virologist to the Committee.

2. **Minutes-**

Following discussion that the condition of approval for protocol 05-053 regarding review of UIC bloodborne pathogen exposure control plan with biosafety officer prior to initiation should be added, a motion to approve the minutes of the July 14, 2005 IBC meeting was approved by all those eligible to vote in accordance with UIC policies and procedures (1 abstention).

3. **Old Business-**

   a. **IBC Form A and Form B-**

Dr. Bowman reminded the Committee that last month she had presented proposed changes on Forms A and B to the Committee and that addition of inactivation methods and transportation methods had been requested. She stated that these items were now incorporated into the forms. She indicated that contact information for Co-Investigators or other personnel had also been added to the front page of the protocol forms to assist in contacting laboratory personnel and for collaborating investigators. The Committee requested that this purpose be clarified on the forms. In addition, it was suggested that the last assurance statement relating only to review category 1 be moved until after this category and that the language regarding rDNA on Form B, item I, be changed from *without rDNA* to *not involving rDNA*. The Committee was in agreement that following these changes the new versions of the forms should be posted on the IBC web site.

b. Deferred Protocols-

I-05-026- Proposed Role of Neuronal Serotorin N-Acetyltransferase: Aging and Epigenetic Regulation of Brain 5-Lipoxygenase

Following discussion that the PI had addressed all of the major concerns raised previously by the Committee and that clarification as to the hands-on role of the PI on this protocol was needed, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarification.

a. In Appendix 1, if PI will be working directly on this project, then PI should be listed on this appendix.

I-05-027-5-HT N-Acetyltransferase and Cocaine-Induced Behaviors: Circadian Mechanisms in Cocaine Addiction-

Following discussion that the PI had addressed most of the concerns raised previously by the Committee, but needed to clarify which biosafety level would be used for the project as all work proposed was BSL1 and also needed to remove all references to use of rDNA in whole animals, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item III, box #4 should be checked and in situ hybridization should be checked. In addition, box #8 is checked, but A IVc does not describe any mouse cell lines. Please clarify.
b. In Form A, item V c, BSL2 is marked, but as submitted work is BSL1. If PI will be using BSL2 conditions, then section A VI e needs to be answered completely. Please contact IBC office if help is needed in completing this section.
c. In Form A, item VI d, please check "Yes" for expression of a foreign gene and "No" for expression in animals and remove ACC number from protocol in this section and in item II.
d. Please complete Form A, VI f.

4. August Protocol Summary Reports-

A. Protocols and Modifications Eligible for Expedited Review

There were no protocols or modifications eligible for expedited review this month.

B. Protocols and Modifications for Full Committee Review

I-05-057- Mechanism of Acid-Base Balance by the Kidney-

The Committee discussed the following issues: 1) that the purpose of this protocol was to study the molecular mechanisms of bicarbonate reabsorption in the kidney, 2) that the truncated portions of the bicarbonate cotransporter 1 gene would be cloned into E. coli or HEK 293 cells to access activity and to determine the molecular determinants, and 3) that the laboratory at the VA needed to be inspected by EHSO. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarification.

a. Please contact the UIC biosafety officer, Ms. Marilyn Hau, at 312-996-7429, to arrange an inspection of the laboratory in which rDNA work will be conducted. Please in form the IBC office when inspection has occurred.

I-05-059- NMR Studies of Proteins-

The Committee discussed the following issues: 1) that the purpose of this protocol was to study the structure of viral proteins (HIV, SARS Coronavirus, Ebola envelope proteins, and coxsackievirus receptor protein) and determine how they function in viral entry, 2) that the source of DNA samples from the BSL3 and BSL4 pathogens and how these samples were processed for inactivation needs to be clarified. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item IVc, please indicate how it was determined that only a totally and irreversibly defective fraction of the agent's genome is present in a samples provided to PI for SARS and Ebola virus proteins. Were genes in plasmids synthesized de novo? Were they isolated from inactive virus and if so, how was virus inactivated and how was this verified?
b. In Form A, item VIe, please indicate that work will take place in biosafety cabinet.

I-05-061- Identification of Cellular Proteins that Interact with P-Selectin Glycoprotein Ligand-1 (PSGL-1)-

The Committee discussed the following issues: 1) that the purpose of this protocol was to understand the role that surface molecules on leukocytes play in the migration of leukocytes along the surface of endothelial cells and their interaction with cytoskeletal proteins and signaling molecules, 2) that methods used to minimize aerosol production needed to be indicated, and 3) the biosafety cabinet needed to be recertified. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item III, box #6 should also be checked.

b. In Form A, item VIe, please indicate the methods used to minimize aerosol production and please indicate the type of centrifuge used.
c. Biosafety cabinet (e.g., laminar flow hood) that was moved when PI moved to [redacted] must be recertified prior to use. All biosafety cabinets must be recertified annually and after any move. The UIC IBC and EHSO specify that biosafety cabinets should be certified by personnel with NSF 49 Certification. The approved certifiers are Clean Air ([redacted] and Salus ([redacted]. Please provide documentation of recertification of this cabinet to IBC office.
d. In Appendix 1, please indicate that UIC Biosafety Manual will be incorporated into training of personnel in the laboratory.

I-05-062- Signaling Mechanisms of Platelet Activation-

The Committee discussed the following issues: 1) that the purpose of this protocol was to understand the factors involved in platelet activation, 2) that the PI needed to elaborate on the cell transfection studies and indicate which constructs and genes would be used for generation of transgenic/knockout mice, and 3) that the UIC Biosafety manual should be incorporated into the training. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item III, please check box #6 should be checked.
b. In Form A, item IVc, please address the following concerns:
    i. Please indicate the proposed function of the genes listed.
    ii. Please elaborate on the cell transfection studies proposed in eukaryotic and prokaryotic cells.
    iii. Please indicate which constructs or gene will be used for the generation of transgenic and/or knockout strains in mice.
c. In Appendix 1, please indicate that UIC Biosafety Manual will be incorporated into training of personnel in the laboratory.

I-05-063-Pathogenic Mechanisms of *Yersinia Entercolitica* and *Yersinia Pseudotuberculosis*-

The Committee discussed the following issues: 1) that the purpose of this protocol was to study mechanisms by which the pathogens *Y. entercolitica* and *Y. pseudotuberculosis*, cause disease by studying the YscN, YopE, and YopK genes, 2) that the manipulation of these genes was not expected to increase the pathogenicity of these pathogens, 3) that the PI needed to expand on the PPE used, renew bloodborne pathogen training and incorporate UIC Biosafety manual into training. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item VIe, please address the following concerns:
    i. Please list the method of chemical disinfection.
    ii. Please indicate what additional PPE is used such as disposable gowns, eye protection, etc.
b. In Appendix 1, please indicate that UIC Biosafety Manual will be incorporated into training of personnel in the laboratory.
c. PI must renew bloodborne pathogen training. Training must be renewed annually per OSHA requirements. Please see IBC website for a list of training seminar dates and locations. Please forward copy of updated training certificate to IBC office.

I-05-064- The Role of Serum Amyloid A in Inflammation-

The Committee discussed the following issues: 1) that the purpose of this protocol was to understand the function of acute-phase protein, serum amyloid A (SAA), in leukocyte activation, inflammation and bacterial infection and to understand the chemoattractant receptors that regulate SAA function, and 2) that the PI needed to incorporate the UIC Biosafety manual into training. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarification.

a. In Appendix 1, please indicate that UIC Biosafety Manual will be incorporated into training of personnel in the laboratory.

5. Adverse Event Reports-

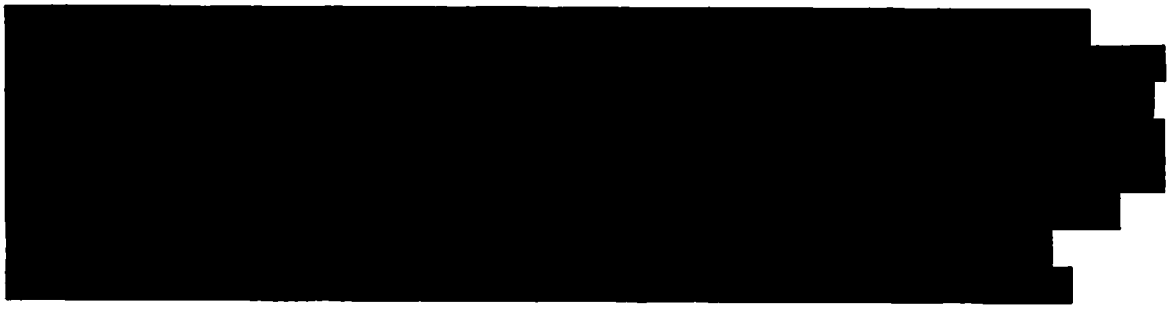
[redacted]

[redacted]

6. New Business-

a. Modification of Protocol 04-062 (*04-062-02*)-

[redacted]



The meeting was adjourned at 3:10 PM

Institutional Biosafety Committee
Minutes of
September 8, 2005
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Randal Jaffe, Dr. Aixa Alfonso, Mr. Richard Anderson, Dr. Mary Bowman, Dr. Edward Cohen, Dr. Jeffrey Fortman, Dr. Paul Goldspink, Dr. William Hendrickson, Dr. Roberta Mason-Gamer, and Dr. Jeffrey Oswald

ABSENT: Ms. Anne Cousin, Ms. Marilyn Hau, Dr. Alex Neyfakh, and Dr. Maria Rudisch

1. **Announcements-**

Dr. Bowman informed the Committee that the new Senior Biosafety Specialist had started his position and would be appointed to the Committee beginning in October 2005. In addition, she indicated that modification of protocol 03-054 was added as item a under new business and a corresponding handout was being distributed.

2. **Minutes-**

The minutes of August 2005 IBC meetings were approved pending a minor editorial clarification.

3. **Old Business-**

None to report.

4. **September Protocol Summary Reports-**

   A. **Protocols and Modifications Eligible for Expedited Review and Approval**

I-05-073- Molecular Phylogenetic Studies of the Wheat Tribe

The purpose of this research is to determine the evolutionary history of a group of grasses (wheat tribe) which include economically important crop plants such as wheat, barley and rye. DNA will be isolated from approximately 90 species of the tribe Triticeae and a variety of nuclear or chloroplast genes will be amplified via PCR, cloned using plasmids and propagated in laboratory strains of E. coli.

B. Protocols and Modifications for Full Committee Review-

I-05-047- Role of Scaffolding Proteins in Regulation of Signal Transduction Pathways-

The Committee discussed the following issues: 1) that the purpose of this research was to determine the mechanisms by which scaffolding proteins regulate biochemical pathways in mammalian cells, 2) that a wide variety of genes encoding for scaffolding proteins, phosphatases, ubiquitin ligases, kinases, and GTPases would be studied, 3) that genes or genes with mutations, deletions, or truncations would be propagated in E. coli or a variety of mammalian cell lines using plasmid vectors, 4) that RNA interference vectors would be used to block expression of proteins of interest, 5) that clarification was needed as to whether use in animals referred to transgenics rodents or use in whole animals, and 6) the origin of the SuperRetro plasmid and whether it was from a retrovirus needed to be clarified. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item II box 4, and item VI d, the protocol indicates that rDNA will be expressed in whole animals, but item IVc does not indicate the nature of this work. If work involves generation of transgenic/knockout animals, please indicate in Form A, IVc, which constructs will be used if known. Item II box 4 does not apply for generation of transgenic/knockout animals and ACC number should be removed. If work involves administration of rDNA directly to whole animals, then please include a description of that work in Form A, item IVc including the constructs that will be administered.
b. In Form A, item IV c, please clarify the origin of pSuperRetro. Is this based on a retrovirus? If so, which one and how is it attenuated? A vector map would be helpful.
c. In Form A, item VIe, biosafety cabinets should be wiped down with 10% bleach first or other appropriate disinfectant and then 70% ethanol.

I-05-065- Molecular Biology of Cryptococcus-

The Committee discussed the following issues: 1) that the purpose of this research was to identify genes in Cryptococcus neoformans that are important to infection of this fungus using a mouse model and the goal was to create mutations in genes thought to be important in virulence and determine if the mutations result in a decrease in the virulence in mice, 2) that the genes of interest included CNLAC 1, URA5, HgR, and GFP and cloning would be done using plasmid vectors, and 3) that the PI needed to describe the in vivo work with mice and the biosafety procedures in place for handling infected mice. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item IVc, there is no indication of in vivo work. Please describe procedures for inoculation of animals.
b. In Form A, item VIe, please describe biosafety precautions used to inoculate, handle, house and dispose of the animals (mice).

I-05-066- Prolactin and Estrogen Regulation of Reproductive Tissues in the Rat and Mouse-

The Committee discussed the following issues: 1) that the purpose of this research was to understand the role of prolactin and estrogen in reproductive tissues especially the corpus luteum, ovary and deciduas, 2) that the signaling pathways activated by the short form of the prolactin receptor and by the estrogen receptor would be studied, 3) that the gene of major interest was PRAP/17β hydroxysteroid dehydrogenase type 7, 4) that commercially available lentiviral vectors would be used with limited passages and luteal and decidual cells would be transfected with these vectors, and 5) that the PI needed to verify the room in which work would be conducted and needed to recertify the biosafety cabinet prior to initiation. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item V a and V b, please clarify laboratory room numbers for lab and storage.
b. Biosafety cabinet must be certified prior to the initiation of work. Please contact the IBC office (996-1972) or check the EHSO web site for a list of approved certifiers. Please send a copy of verification of certification to IBC office.

I-05-067- HIV Entry Mechanisms-

The Committee discussed the following issues: 1) that the purpose of this research was to understand the entry mechanisms of HIV into cells with the long term goal of developing novel anti-viral drugs, 2) that the genes of interest are gp41 and gp120, 3) that no live virus would be used and genes or mutated genes would be cloned in plasmid vectors and introduced into cell lines using an attenuated HIV vector with frameshifts for env and vpr genes, and 4) that the PI needed to elaborate on the HIV vector used and that a special subcommittee of Drs. Bowman, Jaffe and Neyfakh should review the revisions. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. Note to PI: Revisions to this protocol will be reviewed by a subcommittee of the IBC. If the HIV vector is able to convert to wildtype, then revisions will require review by the committee and additional information may be requested.
b. In Form A, item IV c, please elaborate on the HIV vector being used. Is this vector replication defective? Please elaborate on the functions eliminated by

frameshifts in env and vpr genes. Please clarify where HIV vector was obtained from and whether PI monitors for conversion to wildtype virus. A map of the vector would be helpful.

I-05-068- Protein Kinase C and Cardiac Maladaptation-

The Committee discussed the following issues: 1) that the purpose of this research was to determine the role of various isoforms of PKC in cardiac muscle growth and contraction and the various isoforms would be overexpressed or knocked out in mouse models, and 2) that the PI needed to clarify the nature of the work related to animals and recertify biosafety cabinet. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item II, box 4, use of rDNA in whole animals is checked, but item IVc does not indicate the nature of this work. Please indicate in Form A, IVc, which constructs will be used if known. Item II box 4 does not apply for generation of transgenic/knockout animals and ACC number should be removed. If work involves administration of rDNA directly to whole animals, then please include a description of that work in Form A, item IVc including the constructs that will be administered.
b. Biosafety cabinet must be recertified prior to the initiation of work. Please contact the IBC office (996-1972) or check the EHSO web site for a list of approved certifiers. Please send a copy of verification of recertification to IBC office.

I-05-069- NMDA Receptor Modulation by Kinases-

The Committee discussed the following issues: 1) that the purpose of the research was to identify which potential phosphorylation sites on the NMDA family of glutamate receptors are important for its function in learning, development and degeneration of brain cells, 2) that various NMDA subunits or site-directed mutants would be transcribed in vitro using plasmid vectors and cRNA would be injected into Xenopus oocytes for expression and HEK and other cells lines would be used for transient transfection studies using plasmid vectors, and 3) that the protocol was BSL2 and required bloodborne pathogen training. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item V c, this item should be marked BSL2 for the use of HEK cells, which are of human origin. All human cell lines must be used at BSL2.
b. In Form A, item VI, please complete all sections for BSL2 project.
c. All personnel listed on Appendix 1 working with human cell line must complete bloodborne pathogen training on an annual basis per OSHA

requirements. Please see IBC web site for a list of seminar training dates. Please provide a copy of verification of IBC training to the IBC office.

I-05-070- Etiologies and Hormonal Criteria for 3-Beta-Hydroxysteroid Dehydrogenase Deficiency-

The Committee discussed the following issues: 1) that the purpose of this research was to investigate the role of mutant forms of Type II 3β-hydroxysteriod dehydrogenase (HSD2B2) to determine if the instability of various mutant forms arises from compromised folding of the protein, whether various mutant forms can have a cooperative effect on causing disease, and to identify mutations in new intron sites that result in severe disease, 2) that wildtype and mutant forms of the enzyme would be transfected into mammalian or yeast mutant cells using plasmid or baculovirus vectors, 3) that primary monocytes would be transfected with enzyme promoter constructs using pTARGET and pCMV vectors, and 4) that the PI needed to complete the form appropriately for BSL2, certify the biosafety cabinet, complete bloodborne pathogen training, and appropriate indicate specific training. Following discussion, a motion to defer this protocol passed unanimously. Deferral was with the understanding that it was pending the following clarifications prior to rereview.

a. In Form A, item V a and b, the room number should be [redacted], not [redacted].
b. Biosafety cabinet must be certified prior to the initiation of work. Please contact the IBC office ([redacted]) or check the EHSO web site for a list of approved certifiers. Please send a copy of verification of certification to IBC office.
c. In Form A, item VI, this section must be completed for approval at BSL2. Sections a, b, d, e and f are all applicable and must be completed. Please contact the IBC office (996-1972) for questions regarding this section.
d. PI must have completed bloodborne pathogen training within the last year. Please provide verification of training from NET Learning. OSHA requires that bloodborne pathogen training be renewed on an annual basis. Additional personnel when hired will also need to complete bloodborne pathogen training.
e. In Appendix 1, please list the **specific** training or expertise of the PI in handling and working with rDNA.

I-05-071- Role of BRCA1 in Homologous Recombination-

The Committee discussed the following issues: 1) that the purpose of this research was to determine the mechanism by which BRCA1 contributes to DNA repair, 2) several genes involved in homologous recombination would be overexpressed or knocked out in cultured human cell lines, insect cell lines, or laboratory strains of E. coli, 3) that plasmids or replication defective adenoviral or retroviral vectors would be used for

transient and stable transfection of cell lines, and 4) that the copies of bloodborne pathogen training needed to be provided and the biosafety cabinet needed to be recertified. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form A, item VI b, please provide the sources from which the sequences were initially cloned.
b. In Form A, item VI d, please specify the proteins that will be produced in vitro.
c. In Form A, item VI e, biosafety cabinets should be wiped first with 10% bleach or equivalent disinfectant and followed by 70% ethanol to disinfect. In addition, please clarify whether the PI plans to periodically assay for recombinant replication-competent adenovirus, and what procedures would be followed in the event of a reversion.
c. Please provide copies of bloodborne pathogen certification to the IBC office.
d. Biosafety cabinet must be recertified prior to the initiation of work. Please contact the IBC office (996-1972) or check the EHSO web site for a list of approved certifiers. Please send a copy of verification of recertification to IBC office.

I-05-072- Identification of Targets for Structure-Based Design of Novel B. Anthracis Therapeutic Agents-

The Committee discussed the following issues: 1) that the purpose of this research was to determine which proteins are essential for the growth and survival of Bacillus anthracis (anthrax) to aid in the development of new therapeutic agents, 2) that an avirulent strain of anthrax (Delta ANR) lacking the toxin producing plasmid (pXO1) and the capsid producing plasmid (pXO2) would be used, 3) that the genes of interest would be identified via knockout of potential targets or by use of genetic inhibitors and monitoring for effects on growth and survival of *B. anthracis* Delta ANR, 4) that once genes of interest were identified, they would be cloned in using plasmid expression vectors and expressed in laboratory strains of E. coli, and 4) that the Committee had no concerns regarding this protocol. Following discussion, a motion to approve this protocol passed unanimously.

I-05-074- Molecular Study of the Evolution of Virulence of Plant Pathogen in the Enterobacteriaceae-

The Committee discussed the following issues: 1) that the purpose of the research was to determine the evolutionary history of several virulence genes from plant pathogens to test the theory that genes related to virulence have a greater tendency to be horizontally transferred among species, 2) that DNA would be isolated from a variety of plant bacterial pathogens including several *Erwinia, Brenneria,* and *Pectobacterium* species and select virulence and housekeeping genes would be amplified via PCR, cloned using plasmids and propagated in laboratory strains of E. coli, 3) that no plants would be

infected with pathogens, 4) that the investigator is obtaining appropriate USDA permits for transport, and 5) that this type of research could be conducted at BSL1. Following discussion, a motion to approve this protocol was passed by all those eligible to vote in accordance with UIC policies and procedures (1 abstention).

I-05-075- T-cell response in Rhesus Macaque SHIV-Malaria Coinfection-

The Committee discussed the following issues: 1) that the purpose of this research was to determine the effects of co-infection by SHIV and malaria on CD4, CD8, and Vγ2Vδ2T cells in a [redacted] model and the immunotherapeutic effects of administration of HMBPP phospholigand, 2) that [redacted] would be inoculated intravenously with vehicle, SHIV, malaria, or both pathogens + therapeutics, 3) that [redacted] would be housed in BSL2 conditions in a room separated from the remainder of the colony, 3) that only [redacted] veterinarians or [redacted] staff will work directly with monkeys, 4) that samples collected from [redacted] would be handled by PI's staff under BSL2 conditions and processed for a variety of immunological and biochemical tests, 5) that the PI needed to clarify the source of malaria, 6) that the BSL2 manual needed to revised for medical surveillance plan, to remove references to BCG and for addition of animal procedures, and 7) that the revisions should be reviewed by a special subcommittee of Drs. Bowman and Fortman. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it was pending the following clarifications.

a. In Form B, item III, please clarify the source of malaria. If PI plans to propagate malaria at UIC, then provide details on propagation.
b. The BSL2 biosafety manual needs to be revised for this specific project. Revisions should include the following:
    i. Updated to include a medical surveillance plan that is specific for this project with malaria and SIV. PI should contact Dr. David Marder for review of MSP.
    ii. References to BCG need to be removed.
    iii. Procedures for transporting samples to the laboratory from BRL should be indicated.
    iv. Manual should refer to IBC protocol regarding the handling of infectious agents in animals.
    v. Please attach procedures for ELISPOT, ELISA and DNA/RNA purification.
c. Appendix 1 needs to be submitted specifically for this protocol. PI needs to indicate that as members of his laboratory are trained by the [redacted] veterinary and animal staff that their role of this protocol will be amended via modification of this protocol to include working directly with animals.

5. Adverse Event Report-

Dr. Bowman directed the Committee's attention to the adverse event reports. There were no reports related to the use of gene therapy products reported this month.

6. New Business-

a. Modification of Protocol I-03-054-

Dr. Bowman directed the Committee's attention to the PI's request to add the use of adenoviral vectors using the same genes as approved on his original protocol. She indicated that these vectors would be used on a tissue culture room in the PI's laboratory in [redacted] that the room was BSL2, that the original protocol was approved at BSL2, and the vectors is replication defective. The PI was also requesting the addition and deletion of personnel. A motion to approve this modification was unanimously passed.

b. [redacted]-

[redacted]

The meeting was adjourned at 3:03 PM

Institutional Biosafety Committee
Minutes of
October 20, 2005
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Randal Jaffe, Mr. Richard Anderson, Dr. Mary Bowman, Ms. Anne Cousin, Dr. Jeffrey Fortman, Dr. William Hendrickson, Dr. Roberta Mason-Gamer, Dr. Alan McLachlan, Dr. Alex Neyfakh, and Dr. Paul Umbeck

ABSENT: Dr. Aixa Alfonso, Dr. Edward Cohen, Dr. Paul Goldspink, Dr. David Marder, and Dr. Jeffrey Oswald

STAFF: Ms. Sou Soura

VA Representative: Dr. Pradip Dudeja

1. **Announcements-**

Dr. Bowman introduced Dr. Paul Umbeck, the new Senior Biosafety Specialist, Dr. Pradip Dudeja, the new VA Representative, and Dr. Alan McLachlan, to the Committee and asked that Committee members introduce themselves to Drs. Umbeck, Dudeja, and McLachlan.

2. **Minutes-**

The minutes of September 2005 IBC meetings were approved.

3. **Old Business-**

   a. **05-070- Etilogies and Hormonal Criteria for 3-Beta-Hydroxysteroid Dehydrogenase Deficiency-**

The Committee discussed the following concerns: 1) that the PI had not addressed many of the prior concerns, 2) that the biosafety cabinet must be recertified prior to resubmission, and 3) that the PI needs to specify the specific safety practices in place in her laboratory. Following discussion, a motion to defer this protocol passed unanimously. Deferral was with the understanding that it is pending the following clarifications prior to rereview.

a. The biosafety cabinet must be recertified and verification of that certification must be provided prior to rereview.
b. In Form A, item VId, this question is not answer appropriately. 3-Beta hydroxysteroid dehydrogenase in not a foreign gene, therefore, the answer to each of these questions is NO.

c. In Form A, item VIe, please list specifically how each of the biosafety procedures is handled in the laboratory. The answer provided is too vague and does not indicate how these processes are handled in the PI's laboratory.

4. October Protocol Summary Reports-

A. Protocols and Modifications Eligible for Expedited Review and Approval

None this month

B. Protocols and Modifications for Full Committee Review-

I-05-078- Entry Mechanisms of Filoviruses

The Committee discussed the following issues: 1) that the purpose of this research was to study the entry mechanisms of filoviruses including Ebola and Marburg viruses, 2) that the viral glycoproteins, Ebola GP and Marburg GP, would be examined for entry mechanisms, 3) that the Ebola gene was synthesized in the laboratory and the Marburg gene was originally isolated >20 years ago and had been used at lower containment for years, 4) that an attenuated replication deficient HIV vector with blunted VPR and ENV genes and lacking gag and pol would be used to create a pseudovirus for single cycle infection, 5) that the biosafety cabinet had been recertified, and 6) that the PI had completed appendix 1 for personnel training and experience. Following discussion, a motion to approve this protocol passed unanimously.

I-05-079- Structure and Function Analysis of the CCN Angiogenic Regulators

The Committee discussed the following issues: 1) that the purpose of this research was to study the function of the CCN family of angiogenic inducers at the cellular level and in the context of the whole animal (knock-in and knock-out models), 2) that the genes of interest include Cyr61, CTGF, and NOV, 3) that genes will be cloned in E. coli or inserted to mammalian or insect expression vectors for transfection studies in mammalian or insect cell lines, 4) that most personnel had completed bloodborne pathogen training and approval should be conditional for those that had completed this training. Following discussion, a motion to approve this protocol passed unanimously.

I-05-080- Assess Expression and Function of Endothelial Cell Specific Proteins Utilizing Mammalian Expression Vectors and Recombinant Adenovirus

The Committee discussed the following issues: 1) that the purpose of this research was to study the mechanism of thrombin-induced vascular injury and, in particular, how

thrombin increases endothelial permeability and polymorphonuclear leukocyte adhesion to the vascular wall, 2) that the genes of interest include transient receptor potential (TRP) channel genes C1, C4, and C6; PKC isoforms α, δ, ξ, and ζ; calcineurin subunit A, calcineurin inhibitor cain, nuclear factor kB inhibitor proteins (IκBα, and IκbB), and IκB kinases. 3) that plasmid expression vectors, attenuated replication deficient adenoviral vector, and E. coli expression vectors will be used for transfection studies in human or mouse endothelial cells in culture, and 4) that the PI needs to clarify who will work wtiht the adenoviral vectors, and check the appropriate categories of work. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item II, box 2 does not apply to this protocol. Please uncheck. In addition, if helper virus is being used, please indicate the helper virus used or uncheck this box.
b. In From A, item III, box 7 and 9 do not apply to this protocol. Please uncheck.
c. In Appendix 1, please indicate specifically who will be with adenoviral vectors so that the Committee can determine who require BBP training. Training must be completed on an annual basis. Please provide copies of training certificates for verification of training. Training must be completed on an annual basis per OSHA requirements. Should personnel require training, training is available via seminars offered by EHSO. Please see IBC web site for a list of training dates (http://tigger.uic.edu/depts/ovcr/research/protocolreview/ibc/education/index.shtml#calendar).

I-05-081- Papillomavirus Oncogenes and Cancer

The Committee discussed the following issues: 1) that the purpose of this research was to study the expression of E7, an oncogene in human papillomavirus (HPV) involved in cancer induction and maintenance, and identify the proteins involved in E7 proteolysis in an effect to enhance this process and block growth of HPV-expressing cancer cells, 2) that E6, E7 and multiple E7-interacting cellular protein genes will be studied, 3) that standard cloning and subcloning using plasmid vectors in E. coli will be done, 4) that in vitro transfection studies in numerous cell lines will be done, 5) that replication defective adenoviruses will be used to express cellular genes or HPV genes in mammalian cell lines, 6) that the PI needs to justify why an adenoviral vector is required for expression of an oncogene, 7) that the PI needs to prepare and submit a project specific biosafety manual for use of adenoviruses with oncogenes, and 8) that the laboratory needs to be inspected. Following discussion, a motion to defer this protocol passed unanimously. Deferral was with the understanding that it is pending the following clarifications prior to rereview.

a. In Form A, item IV c, please address the following concerns:
    i. Due to the ability of adenoviral vectors to readily infect human cells and their ability to express genes in vivo, the committee requests that the PI strongly justify the use of an adenoviral vector

for expression of an oncogene. Manufacturer's safety guidelines strongly recommend against the use of these vectors with oncogenes.

ii. If the PI will continue to request use of this vector for this purpose, then please indicate the specific vector used and specifically how it is attenuated.

iii. Please indicate the packaging cell line used.

b. In Form A, item Vc, if adenoviral vector will be used with oncogenes, then BSL must be BSL2* (BSL2 facility uses BSL3 practices) and a project specific biosafety manual must be prepared and submitted with the protocol for review and approval. Attached is a sample outline of the issues that need to be covered in the manual. Please see the UIC Biosafety Manual for guidance in completing this manual.

d. All personnel working with human cell lines must complete bloodborne pathogen training on an annual basis. Training is available via seminars offered by EHSO. The seminar training schedule is posted on the IBC web site (http://tigger.uic.edu/depts/ovcr/research/protocolreview/ibc/education/index.shtml#calendar). Please provide copies of training certificates as verification of training.

c. Please contact Dr. Paul Umbeck (umbeck@uic.edu or 413-8732), UIC Senior Biosafety Specialist, to arrange for an inspection of the laboratory.

I-05-082- Structural Biology of Enzymes

The Committee discussed the following issues: 1) that the purpose of this research was to overexpress various genes encoding for nucleoside kinases, nucleosidase monophosphate kinases, choline kinase, deaminases, and proteins involved in forming supra-molelcular assemblies in an E. coli expression system using plasmids, 2) that the PI needed to specify the specific genes, sources of those genes, and the selectable markers used, and 3) that review category I didn't apply to this research. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item I, box 1, this should not be checked for this protocol. Only when the use of this drug resistant gene compromises its use as a therapeutic should this be checked. This doesn't apply to this situation. Please uncheck and do not sign the first assurance.

b. In Form A, item III, please check box 6 for this protocol.

c. In Form A, item IV c, please indicate the following:

i. Please indicate the specific genes that are currently been cloned and expressed. Only classes of genes are listed.

ii. Please elaborate on what is being done. No procedures are listed here. Please indicate the quantity of recombinant proteins to be propagated.

iii. Please indicate the sources of the cloned genes. Please indicate the surfaces and spent cultures are decontaminated.
iv. Please indicate the selectable marker and the specific plasmids used.
v. Please indicate the strain of E. coli used.

d. In Form A, item Va, please add room 1107 to the protocol.
e. In Form A, item VI d, expression of proteins in vitro should be marked "yes".
f. In Appendix 1, please indicate specifically how personnel are trained.

I-05-083- Role of Tumor Suppressor Foxo3a in Regulation of the NF-κB Pathway Activated by Enteric Pathogens in Intestinal Epithelial Cells

The Committee discussed the following issues: 1) that the purpose of this research was to determine if signals involved in tumorigenesis regulate inflammation in cells infected with bacterial-colitis, 2) that the gene of interest was Foxo3a, a transcription factor and that it will be inserted in retroviral vectors based on MMTV and amphotrophically packaged in Phoenix cells for infection of human and mouse intestinal epithelial cell lines and that infected cells will be employed to study the effects of overexpressed Foxo3a gene on the NF-κB pathway and cytokine expression, and 3) that PI needs to clarify experiments with mice and safety practices. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, under PI information, please indicate the Department Name/Section Name under "Department Affiliation" and not role within department.
b. In Form A, item IVc, the previous section, Form A IVb, references infection of mice with C. rodentium (a mouse pathogen), but in this section there is no mention of using this with the retroviral vector. Please indicate how this relates to this protocol and what will be done with these mice or cells from these cells. If this does not apply to this protocol, please remove.
c. In Form A, item VIe, please address the following concerns:
    i. Lab coats or disposable wrap-around gowns should also be worn.
    ii. Bleach should be used and not alcohol for decontamination. Alcohol should be used after bleach for decontamination of the biosafety cabinet.
    iii. Please indicate that work with vectors and cells will take place in biosafety cabinet.

I-05-084- Human Intestinal Anion Exchangers: Function & Regulation

The Committee discussed the following issues: 1) that the purpose of this research was to determine the regulation of intestinal anion exchangers in normal physiology and in disease states such as inflammatory bowel disorder, 2) that the genes of interest include DRA, PAT-1 and MCT-1, 3) that commercially available mammalian expression vectors

or vectors containing reporter constructs would be used for propagation in laboratory strains of E. coli or in human cell lines, 4) that this project would be conducted in the same laboratory as 05-085 and 05-086, but this project does not directly involve work with EPEC, and 5) that the PI needed to expand on sharp procedures and specific training of personnel. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. Please provide protocol on current IBC forms. These can be downloaded from the IBC web site (http://tigger.uic.edu/depts/ovcr/research/protocolreview/ibc/forms/index.shtml). Form A should be completed for this work.
b. In biosafety procedure section, please elaborate on how sharps and needles are handled.
c. It should be clarified that EPEC is not used directly for this protocol.
d. In Appendix 1, please elaborate on the specific training of personnel listed with rDNA and pathogens.
e. All personnel working with human cell lines must complete bloodborne pathogen training on an annual basis. Training is available via seminars offered by EHSO. The seminar training schedule is posted on the IBC web site. Please provide copies of training certificates to the IBC office. If bloodborne training was provided by JBVA, please provide verification of training.

I-05-085- Modulation of Sodium-Hydrogen Exchanger Activity by EPEC Infection

The Committee discussed the following issues: 1) that the purpose of this research was to determine the regulation of intestinal anion and sodium hydrogen exchangers as well as bile acid transporters in normal physiology and in response to pathophysiological stimuli such as infection with enteropathogenic E. Coli (EPEC), 2) that the genes of interest are transporter genes and they will be cloned into commercially available mammalian expression vectors, vectors containing reporter constructs, bacterial expression vectors or yeast expression vectors for propagation in E. Coli, or transfection into cultured human or yeast cell lines, 3) that cultured cell lines will also be infected with EPEC and the activity, cellular distribution and state of phosphorylation of the transporters will be examined, 4) that a mouse model of EPEC infection will also be utilized to assess the effect of EPEC on water and electrolyte absorption in mice, and 5) that the PI needs to expand on how sharps and needles are handled, the work conducted with EPEC and the additional safety precautions in place when this pathogen is used, and how infected mice are handled and where they are housed. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. Please provide protocol on current IBC forms. These can be downloaded from the IBC web site

(http://tigger.uic.edu/depts/ovcr/research/protocolreview/ibc/forms/index.shtml). Form A should be completed for rDNA work and Form B for work with EPEC.

b. In biosafety procedure section, please elaborate on how sharps and needles are handled.
c. In both procedure section and biosafety section, please elaborate on the work conducted with EPEC and the additional safety precautions in place when this pathogen is used. Also, please indicate specifically how infected mice are handled and where they are housed.
d. In Appendix 1, please elaborate on the specific training of personnel listed with rDNA and pathogens.
e. All personnel working with human cell lines must complete bloodborne pathogen training on an annual basis. Training is available via seminars offered by EHSO. The seminar training schedule is posted on the IBC web site. Please provide copies of training certificates to the IBC office. If bloodborne training was provided by JBVA, please provide verification of training.

I-05-086- Regulation of Intestinal Bile Acid Transport

The Committee discussed the following issues: 1) that the purpose of this research was to determine the regulation of intestinal bile acid transporters in normal physiology and the modulation of their function and expression in diseases such as diabetes mellitus, 2) that the genes of interest will be the promoter/enhancer regions of the intestinal bile acid transporters and that genes will be cloned into commercially available mammalian expression vectors, vectors containing reporter constructs, bacterial expression vectors or yeast expression vectors for propagation in E. Coli or transfection into cultured human or yeast cell lines, 3) that this project would be conducted in the same laboratory as 05-084 and 05-085, but this project does not directly involve work with EPEC, and 4) that the PI needed to expand on sharp procedures and specific training of personnel.. The project also involves experiments in which DM will be chemically induced in rats and the alterations to function and expression of intestinal bile acid transporters will be assessed. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. Please provide protocol on current IBC forms. These can be downloaded from the IBC web site (http://tigger.uic.edu/depts/ovcr/research/protocolreview/ibc/forms/index.shtml). Form A should be completed for this work.
b. In biosafety procedure section, please elaborate on how sharps and needles are handled.
c. It should be clarified that EPEC is not used directly for this protocol.
d. In Appendix 1, please elaborate on the specific training of personnel listed with rDNA and pathogens.
e. All personnel working with human cell lines must complete bloodborne pathogen training on an annual basis. Training is available via seminars offered by EHSO. The seminar training schedule is posted on the IBC web site. Please provide

copies of training certificates to the IBC office. If bloodborne training was provided by JBVA, please provide verification of training.

I-05-087- Study of Cytoskeletal Linkages at Caveolae-Rich Domains of the Plasma Membrane

The Committee discussed the following issues: 1) that the purpose of this research was to determine the function of the plasma membrane (caveolae)-associated chicken glycoprotein gp 105 and chicken caveolin genes which are thought to be involved in cell signaling, 2) that the genes will be cloned in plasmid vectors in E. coli or expressed in mammalian cell lines, 3) that the project needs to be conducted at BSL2 and the appropriate safety precautions and training needs to be specified. Following discussion, a motion to defer this protocol passed unanimously. Deferral was with the understanding that it is pending the following clarifications.

a. Please contact Paul Umbeck, UIC Senior Biosafety Specialist (umbeck@uic.edu or 413-8732), to arrange an inspection of the laboratory and biosafety cabinet.
b. Please provide a copy of BSC certification.
c. In Form A, item Vc, COS cells are BSL2. Please change biosafety level.
d. In Form A, item VI, a-e, all sections must be completed for BSL2 work. Be sure to answer all questions.
e. All personnel working with human cell lines or nonhuman primate cell lines must complete bloodborne pathogen training on an annual basis. Training is available via seminars offered by EHSO. The seminar training schedule is posted on the IBC web site. Please provide copies of training certificates to the IBC office.

I-05-088- Evaluation of Candidate Smallpox Vaccines in Dose Formulations and Biological Samples

The Committee discussed the following issues: 1) that the project involves the administration of the currently licensed vaccine, Dryvax, or an attenuated modified vaccinia vaccine, Ankara (MVA), to normal and immunocompromised strains of mice that will be monitored as part of a GLP study for various time points up to 3 months post-inoculation, 2) that procedures to be performed include blood collection, necropsy with collection of ovarian samples, laboratory processing of samples including measurement of viral titers, 3) that the mice will be housed in microisolator cages in a room separated from other animals during the time in which they are considered infectious and capable of shedding virus (e.g., while pustule and scab are present) and that all handling of infectious mice will be in a biosafety cabinet, 4) that laboratory work will take place in a laboratory designated for work with vaccinia, 5) that only those vaccinated with vaccinia will have authorized access, 6) that following completion of renovations, the laboratory will require reinspection, 7) that the biosafety manual should include specifics on housing of animals and procedures performed, and 8) that the PI needed to clarify the what would

be shipped and verify the appropriate training has been conducted. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. Laboratory will need to be reinspected following completion of renovations and prior to initiation of work.
b. In biosafety manual, please address the following concerns:
    i. Under section III, please indicate what PPE will be worn at [redacted]. If the same, please indicate this specifically in this section.
    ii. Under section IV, please address the following:
        1. Procedures for handling of animals during inoculation, sampling and necropsy need to be outlined in this section.
        2. Please indicate that during the time in which animals are considered infectious (capable of shedding virus), they will be housed separately from other animals, that only vaccinated personnel will work with infectious animals, and they will only be handled in biosafety cabinet.
        3. Please clarify what PI will be shipping. In addition, IATA and DOT regulations should be followed. Please change reference.
        4. Under item f, BSL3 should be changed to BSL2.
    iii. Under section VI, please specify what work will occur on bench versus biosafety cabinet.
    iv. Under section VII, please indicate method of contaminated sharps disposal.
    v. Under section XI, please indicate that training will be presented by senior biosafety specialist or biosafety officer.
c. In Appendix 1, protocol indicates that individual's training records are attached. These were not provided. Please attach training records that indicate that personnel are appropriately trained to work with pathogen or indicate how they will be trained.

I-05-089- Role of p67phox in Alpha-1-AR-Stimulated Cardiac Hyperthrophy

The Committee discussed the following issues: 1) that the purpose of this research was to determine the role of NADPH oxidase as a myocardial source of reactive oxygen species in mediating alpha-1-AR-stimulated cardiac hypertrophy both in vivo and in vitro, 2) that the gene of interest s p67 phox, a cytosolic subunit of NADPH oxidase, 3) that dominant negative p67 phox transgene will be overexpressed in cell lines using adenoviral vectors or plasmid reporter construct, 4) that DN-p67 phox will be used for generation of transgenic mice with myocardial cell specific overexpression and these mice will be crossed with an established transgenic mouse overexpressing CAM-A1B-AR gene in myocardial cells, and 5) that the PI needed to elaborate on the adenoviral vector used and schedule an inspection of the laboratory with EHSO. Following

discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IVc, please indicate specifically which adenoviral vector will be used and how the vector has been attenuated.
b. Please contact Dr. Paul Umbeck, UIC Senior Biosafety Specialist (umbeck@uic.edu or [redacted]), to arrange an inspection of the laboratory and biosafety cabinet.

5. Adverse Event Report-

[redacted]

6. New Business-

a. Modification of Protocol I-03-053-

Dr. Jaffe directed the Committee's attention to the PI's request to add the use of replication defective adenoviral vector expressing the LH/hCG receptor. The Committee discussed that the protocol was already conducted at BSL2 and that the personnel responsible for handling the vector had been trained by experienced personnel and had completed bloodborne pathogen training. Following discussion a motion to approve this modification passed unanimously.

The meeting was adjourned at 3:12 PM

Institutional Biosafety Committee
Minutes of
November 10, 2005
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Randal Jaffe, Mr. Richard Anderson, Dr. Mary Bowman, Ms. Anne Cousin, Dr. Paul Goldspink, Dr. Roberta Mason-Gamer, Dr. Alan McLachlan, Dr. Jeffrey Oswald and Dr. Paul Umbeck

ABSENT: Dr. Aixa Alfonso, Dr. Edward Cohen, Dr. Jeffrey Fortman, Dr. William Hendrickson, Dr. David Marder, and Dr. Alex Neyfakh

STAFF: Ms. Sou Soura

1. **Announcements-**

Dr. Bowman informed the Committee that there were three additions to the agenda under new business. Modification to protocol 03-069 was added as item a, update to protocol 05-010 was added as item b, and IBC accreditation was added as item c. Handouts were distributed for items a and b.

2. **Minutes-**

The minutes of the October 2005 IBC meeting were unanimously approved by all those eligible to vote in accordance with UIC policies and procedures (1 abstention).

3. **Old Business-**

a. **05-081- Papillomavirus Oncogenes and Cancer-**

The Committee discussed that the reason for deferral of this protocol at the last meeting was the use of an adenoviral vector to express E7, a known oncogene and that the PI was no longer requesting to use this vector and gene together and therefore the protocol could be conducted at BSL2. Dr. Umbeck indicated that the appropriate personnel had completed bloodborne pathogen training and that the laboratory had been inspected and the facilities were appropriate for BSL2 work. The Committee also discussed that a condition of approval should be placed on the protocol that specifically indicates that it is not approved for used of adenoviral vectors and oncogenes unless the PI submits and has approved a modification to the protocol. Following this discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is with the following condition.

a. Condition of Approval: This protocol is not approved for the use of oncogenes in adenoviral vectors.

4. **November Protocol Summary Reports-**

A. Protocols and Modifications Eligible for Expedited Review and Approval

None this month

B. Protocols and Modifications for Full Committee Review-

I-05-060- Study of BV, Vaginal Lactovacilli and Phages

The Committee discussed the following issues: 1) that the purpose of this research was to document that bacterial vaginosis (BV) is an infectious disease and can be sexually transmitted, to classify vaginal lactobacilli and their viruses (phages), and to study their interactions, 2) that this work would include isolation of lactobacilli from vaginal samples, induction of phages from the lactobacilli, purification of DNA, and performing DNA/DNA hybridization and/or PCR reactions to classify the phages, 3) that 16S rRNA genes would be amplified by PCR and their sequences determined to identify bacterial species, 4) that the rDNA work in this project would involve subcloning the phage genome to facilitate the DNA sequencing and that the PI should indicate this under category III, and clarify the plasmids and organisms used for subcloning, and 5) that the PI should contact EHSO regarding use of a biosafety cabinet. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item III, please check other and indicate cloning of bacteriaphage genes into E. coli (see comment below).
b. In Form A, item IVc, please clarify the nature of the subcloning you are conducting. What genes are being subcloned, what vectors and/or plasmids are being used, and what organism (e.g., E. coli K-12?) are these being cloned in?
c. In Form A, item VI e, please address the following concerns:
    i. Personnel should wear lab coats or disposable gowns during isolation procedures.
    ii. Please contact Dr. Paul Umbeck, UIC senior biosafety specialist, at 413-8732, to discuss concerns related to work station use. The Committee recommends conducting isolation work in Biosafety Cabinet (BSC).
    iii. Please indicate if a BSC is available to the PI for conducting this work and the location of this cabinet. In addition, please indicate how infectious samples are transported between laboratories.

I-05-090- Effects of Apolipoprotein E Isoforms on A Beta-Induced Neurotoxicity and Neuroinflammation

The Committee discussed the following issues: 1) that the purpose of this research was to investigate the isoform-specific interactions between apoE, a primary risk factor for Alzheimer's disease (AD), and amyloid Beta (Aβ, whose accumulation is a primary causative factor of AD), 2) that the genes of interest included ApoE isoforms (2, 3, and 4) and various truncated ApoE constructs subcloned in pCMV4 vector, 3) that Neuro2a cells would be transfected with plasmids containing ApoE constructs and treated with fibrillar and oligmeric Aβ to assess neurotoxicity and levels of apoE expression, 4) that established HEK293 cell lines stably transfected with ApoE 3 and E4 would also be used, and 5) that the PI needed to sign all assurances and some of the personnel needed to complete bloodborne pathogen training.. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. PI's signature is required on assurances and appendix 1.
b. All personnel listed on Appendix 1 who work with human cell lines must complete annual bloodborne pathogen training. IBC records reflect that [redacted] has not completed this training. Please see IBC web site for list of training seminars offered by EHSO.

I-05-091- Characterization of DMP1 and DMP2, Dentin Phosphoproteins

The Committee discussed the following issues: 1) that the purpose of this research was to identify and understand the function of genes involved in the biomineralization process of bone and dentin, 2) that the genes of interest included dentin matrix protein 1 (DMP1), DMP2, and Dentin sialophosphoprotein, 3) that plasmid vectors would be used for cloning and expression in E. coli or mammalian (rodent) cells, 4) that pSIREN-RetroQ, a retroviral vector, based on MMLV with a hybrid promoter from CMV and MSV, would be used to express siRNA to knockout genes of interest, 5) that the PI needed to clarify whether existing transgenic mice would be used or new transgenic animals would be made, and 6) that the PI needed to clarify the biosafety level for the project. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item III, please address the following concern:
    i. Please list the ACC number covering the production of transgenic rodents.
    ii. Box 6 should be checked, but not box 7. Please reconcile.
b. In Form A, item IVc, please address the following concerns:
    i. In section III production of transgenic rodents is marked. Please indicate the constructs that will be used and whether these mice currently exist or will be made.

ii. If mice are not produced yet, please indicate whether or not they will be produced by the UIC [redacted] in the protocol. If not, then indicate where transgenics will be produced.

c. In Form A, item Vc, please uncheck BSL1 and check BSL2. pSIREN-RetroQ vector that is using a packaging cell line that packages the vector for amphotrophic infection (e.g., capable of infecting human cells). Work with an amphotrophically packaged retroviral vector needs to be conducted at BSL2.

I-05-092- Identifying Genes in C. Elegans that Regulate Synaptic Transmission

The Committee discussed the following issues: 1) that the purpose of this research was to test the function of proteins involved in synaptic transmission, 2) that the genes of interest included tom-, unc-18, unc-13, unc-10, unc-31, unc-64, acr-16, syd-9, unc-7, unc-8, lev-9, lev-10. and were all genes are involved in synaptic transmission, 3) that wildtype or mutant forms produced via site-directed mutagenesis would be cloned into one of the vectors from the Andy Fire Kit (one of the 288 vectors for work with *C. Elegans*) for transfection of *C. Elegans* cells or nematodes or into commercially available vectors for transformation of E. coli, and 4) that the PI needed to clarify whether transgenic nematodes were being developed and the personnel involved in the project. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item III, box number 6 should also be checked.
b. In Form A, item IVa, this purpose of the work needs to be written in lay language. Please rewrite this section in lay language.
c. In Form A, item IVc, please clarify if PI is using plasmids from Andy Fire Kit to created transgenic nematodes and/or to transfect cells from nematodes in vitro.
d. Appendix 1 for personnel needs to be completed. Please be specific regarding training of personnel.

I-05-093- Cytokine Modulation of Estrogen Receptor Activity in Human Breast Cancer Cells

The Committee discussed the following issues: 1) that the purpose of this research was to examine how inflammation affects estrogen action in breast cancer and specifically, whether different cytokines could enhance or repress estrogen action and the molecular mechanisms for the different effects of these cytokines, 2) that human breast cell lines (e.g. MCF-7 and ZR75-1 cells) would be transfected with plasmids to overexpress genes of interest or for promoter-reporter studies, 3) that the plasmids would be pCMV5 (or similar) for overexpression studies and pGL3 luciferase reporters for promoter studies and would be prepared in transformed competent E.coli bacterial strains such as DH5-alpha, 4) that an attenuated replication defective lentivirus would be used for delivery of

short hairpin (shRNA) for RNA interference to knockout the expression of genes involved in estrogen transcriptional activity and cytokine signal transduction, and 4) that the PI needed to identify the specific genes to be studied. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IVc, please identify the specific genes that will be of interest, not just the categories. Additional genes can be added via modification when they are identified.
b. In Form A, item VIe, the dilution of bleach should be 1:10, not 1:100. Please correct.

I-04-059-[redacted]. G-0029: A Phase III Randomized, Open-Label Study of CG 1940 and CG8711 Versus Docetaxel and Prednisone in Patients with Metastatic Hormone-Refractory Prostate Cancer Who Are Chemotherapy-Naïve- ***(Modification 04-059-01)***

[redacted]

5. Adverse Event Report-

[redacted]

6. **New Business-**

a. **Modification of Protocol I-03-069-**

b. **Update on Protocol I-05-010-**

Dr. Bowman directed the Committee's attention to the letter from the PI of protocol I-05-010 indicating that the strain of malaria being used is a laboratory adapted strain that is highly attenuated and modified and noninfectious to humans. She stated that she had requested the letter for clarification based on an addition to the PI's animal care protocol and to ensure that the strain was noninfectious. The Committee accepted this letter for information.

c. **IBC Accreditation-**

Dr. Bowman asked Dr. Umbeck to provide the Committee with an overview of the recent discussion at the annual American Biological Safety Association (ABSA) meeting on accreditation of IBCs. Dr. Umbeck indicated that there had been a talk at ABSA about developing an accreditation program for IBCs. The purpose would be to provide consistency of standards for committee membership and expertise and more uniformity in risk assessment among committees and that initially only Committees would be considered and not facilities. He indicated that the audience was split as to whether they were in favor of the proposal, but that OBA had indicated verbally that they would not be opposed to this process. Dr. Umbeck also indicated that modeling the program after an AAALAC type program had been discussed, as well as, how ABSA would participate it the process, cost and timeline. Drs. Bowman and Umbeck indicated that they would keep the Committee apprized of any developments in this area.

The meeting was adjourned at 2:50 PM

Institutional Biosafety Committee
Minutes of
December 8, 2005
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Randal Jaffe, Dr. Aixa Alfonso, Dr. Mary Bowman, Ms. Anne Cousin, Dr. Jeffrey Fortman, Dr. Paul Goldspink, Dr. Roberta Mason-Gamer, Dr. Dr. Alex Neyfakh, Jeffrey Oswald and Dr. Paul Umbeck

ABSENT: Mr. Richard Anderson, Dr. Edward Cohen, Dr. William Hendrickson, Dr. David Marder, and Dr. Alan McLachlan

STAFF: Ms. Sou Soura

1. **Announcements-**

Dr. Bowman informed the IBC that a revised December monthly report was being distributed to the Committee with the clarifications outlined.

2. **Minutes-**

The minutes of the November 2005 IBC meeting were unanimously approved.

3. **Old Business-**

   a. **05-070- Etilogies and Hormonal Criteria for 3-Beta-Hydroxysteroid Dehydrogenase Deficiency -**

The Committee discussed that the reason for deferral of this protocol at a previous meeting was that the PI had not outlined the specific safety practices used in the laboratory. The PI has since addressed this issue, had the biosafety cabinet recertified and completed appropriate training. A motion to approve this protocol passed unanimously. Following approval the Committee discussed that the PI had proposed use of a flame in the biosafety cabinet. Dr. Umbeck stated that the EHSO had sent a notice to all investigators with gas lines attached to the BSC regarding the requirement to justify the use of the flame and the need to use only controlled flames, appropriate tubing, shut off valves, and no flammable materials in the presence of the flame. He indicated that although manufacturers did not recommend flames, under certain controlled circumstances and with justification the EHSO would allow the use. He indicated that he would contact this investigator regarding this issue. Dr. Bowman informed the Committee that the gas source would be capped off for all investigators who do not justify the use.

4. **December Protocol Summary Reports-**

   A. **Protocols and Modifications Eligible for Expedited Review and Approval**

I-04-013 (*Modification 04-013-03*)- Addition of personnel.

   B. **Summary of Protocols and Modifications for Full Committee Approval**

I-05-076- Studies of Keratoconus Corneas

The Committee discussed the following issues: 1) that the purpose of this research was to gain a better understanding of the cause of Keratoconus, a disease characterized by thinning and scarring of the central portion of the cornea, as well as potential treatment and prevention of the disease, 2) that the gene of interest was Sp1, which had been shown to be expressed at abnormally high level in the cornea of patients with Keratoconus disease, 3) that the gene would be over expressed in vitro in cultured corneal stromal cells to test whether this affects gene regulation and proliferate and apoptotic activities of the corneal cells, 4) that in vivo effects of Sp1 would be examined by targeting a Sp1cDNA to corneal Keratocytes under the control of Keratocyte-specific Keratocan promoter using standard transgenic mouse technology, 5) that a minor clarification as to the institutional affiliation of the Co-PI needed to be addressed. Following this discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IV b, please clarify institutional affiliation of collaborator. At one point, the [redacted] is listed, but elsewhere the protocol indicates the [redacted].

I-05-077- Studies of the Trabecular Meshwork

The Committee discussed the following issues: 1) that the purpose of this research was to study myocilin and optineurin, two genes identified as glaucoma genes, 2) that myocilin, opineurin, or truncated forms would be over expressed in tissue cultured TM cells using expression vectors (plasmids) to examine the affects on the activities and structure of TM cells, and 3) that a minor clarification regarding checking an appropriate section of the application was required. Following this discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

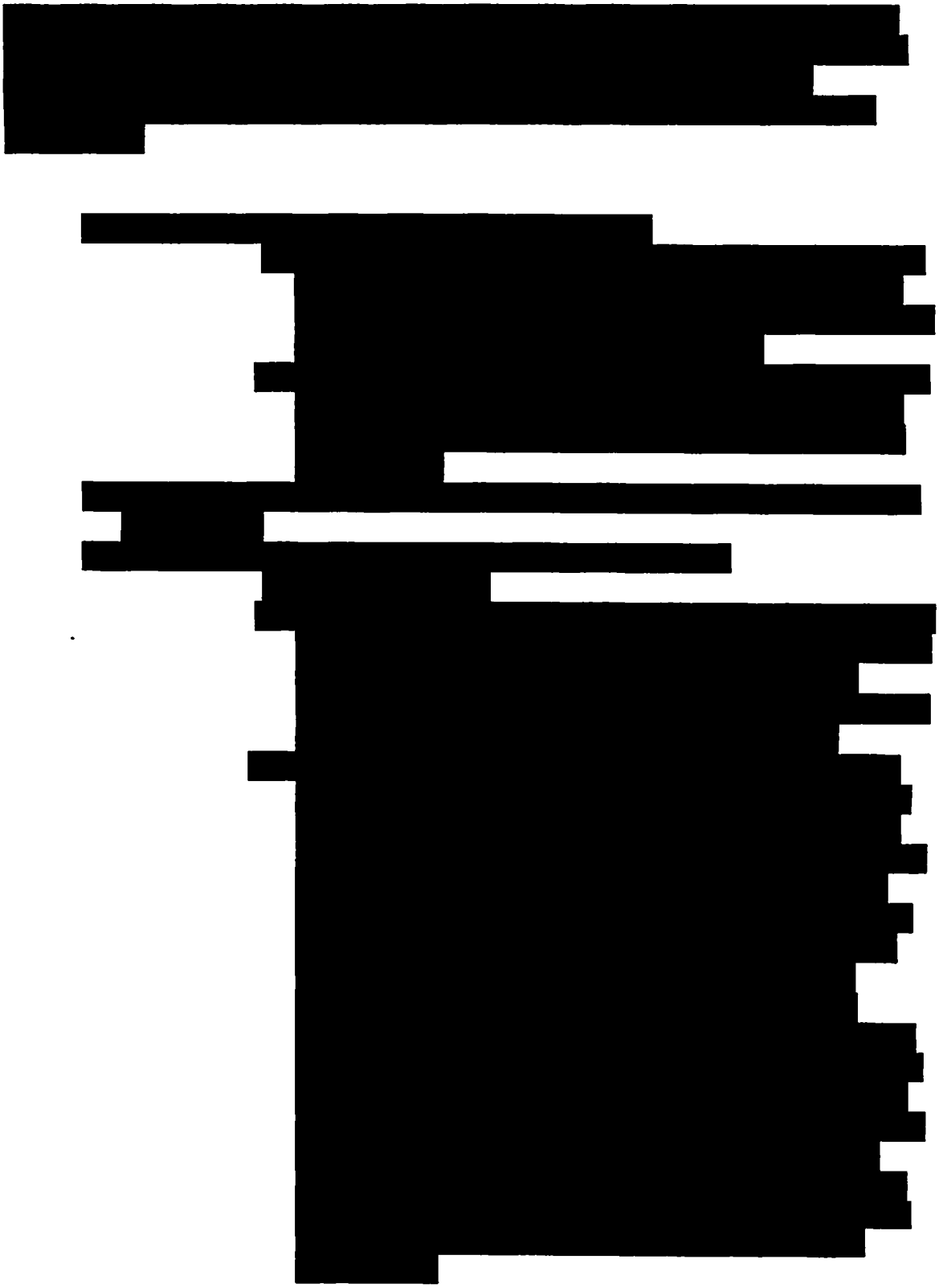
a. In Form A, item VI d., "yes" box should be checked. Also "yes" should be checked under subcategory "In Vitro".

I-05-094- Cell Differentiation During Decidualization

The Committee discussed the following issues: 1) that the purpose of these research was to confirm the critical role of MAPKs during decidualization, 2) that cells would be infected with different adenovirus constructs affecting EPK and p38 MAPK pathways to study their affects on the synthesis of IGFBP-1 and prolactin after decidualization stimuli treatment, 3) that a constitutively active cdk4 lentiviral construct would be used to confirm that regulation of cdk4 is critical for decidualization, 4) that the PI needed to specify the specific cell types used for transfection and the specific location where transfection work would occur, and 5) that PI should transport vectors via approved carrier and complete IATA training. Following this discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IVc, please indicate the specific cell types that will be transfected with viral vectors.
b. In Form A, item V a, please list the specific room in which the work with lentiviral vectors will be conducted. This should be the room in which the biosafety cabinet is located. Also, please provide the date of certification of the cabinet. The cabinet must be certified within the last year.
c. Lentiviral vectors should not be shipped via personnel car. PI will need to use an approved carrier (e.g., Fed Ex). PI will also need to check "Yes" for Form A, item V d and complete IATA training if PI will be the person responsible for packing and shipping of vectors. If not, please indicate in protocol which personnel are going to be responsible for packaging and shipping of vectors. These personnel must complete IATA training. Please contact Dr. Paul Umbeck (312-413-8732 or umbeck@uic.edu) to obtain a CD for IATA training.

I-05-095- [redacted]



The Committee discussed the following issues: 1) that the purpose of this research was to understand the complex gene regulation of Salmonella typhimurium and to determine the affect of various genetic manipulations on the infection process by infecting mice with different Salmonella strains (some genetically modified), 2) that strains would be genetically modified by deletion of virulence genes, 3) that macrophages, liver and spleen would be collected from infected animals for analysis, will be isolated, 4) that although the laboratory work with these strains of salmonella is covered by protocol 04-018, the PI needs to cover the laboratory work in this protocol also, 5) that the PI needs to elaborate on the details of the experiments with mice, and 6) that the biosafety cabinet needs to be recertified. Following this discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. General Comment: The PI needs to fold work covered under protocol I-04-018 into this protocol. As the laboratory work with these strains is a prerequisite to the animal work, it must be detailed in this protocol. Therefore, please submit Form A covering the laboratory aspects of the work including details on the propagation of the wildtype and mutant forms of salmonella.
b. In Form B, item I e and f, please clarify the building in which the work will be conducted. What building is [redacted]?
c. In Form B, item I e, please add [redacted] BSL2 room as a location of the work.
d. In Form B, item II b, please address the following concerns:
    i. Please list the ACC protocol under which work will be conducted.
    ii. Provide an overview in this section as to how genes are inactivated or what removal of specific genes is intended to do or refer reader to Form A if this will be covered in this section.
    iii. Please include procedures for preparation of Salmonella stocks for injection.
    iv. Please describe the details about what is being done to the animals including dose of salmonella, route of administration, and duration of study post-inoculation.
e. Biosafety cabinet must be recertified. Biosafety cabinets must be certified on an annual basis. EHSO maintains a list of approved certifiers. Please contact Dr. Paul Umbeck (413-8732 or umbeck@uic.edu) for additional information. Once certified, please provide a copy of the recertification with the revisions to this protocol.

5. Adverse Event Report-

None to report this month

6. New Business-

a. Modification of protocol I-04-047 (*04-047-02*)-

Dr. Bowman directed the Committee's attention to the PI's request to use attenuated replication incompetent adenoviral and retroviral vectors for the production of siRNAs. She indicated that the protocol was already approved for the use of adenoviral vectors, that work was conducted at BSL2 and that the PI had appropriate described the safety measures taken. A motion to approve this modification passed unanimously.

b. Modification of protocol I-04-052 (*04-052-01*)-

Dr. Bowman directed the Committee's attention to the PI's request to expand the study of viral entry to SARS and influenza viruses. She indicated that the PI was requesting the addition of SARS (S protein) and Influenza (H5 and N1 genes) viral entry genes. Genes were in plasmids and would be shipped to the PI from collaborators. The PI planned to insert genes into the attenuated replication defective vector currently being used for other studies to pseudotype the virus and to study the mechanism of entry. The Committee discussed that there were similar concerns regarding the potential for recombination with the H5 and N1 genes as those discussed for protocol 05-095 that these genes could change the virulence of human influenza viral strains, that if recombination were possible additional safety precautions would be necessary and that the risk of exposure was potentially greater with this protocol than the other due to the potential of extended use of the pseudovirus and repeated exposure. Following discussion, a motion to defer this protocol unanimously passed. Deferral was with the understanding that it is pending the following clarifications prior to rereview.

a. Please list the specific strains from which the H5 and NA genes were obtained.
b. There were concerns raised as to whether the possibility of a recombination event with wildtype human influenza virus could occur should personnel with human influenza virus be accidentally exposed to the pseudotype viruses or to pcDNA-3 plasmids containing the genes from avian flu. Please elaborate on the possibility of a recombination event between wildtype virus and the attenuated HIV vector or pcDNA-3 plasmids containing H5 and NA genes. Please be specific as to the reasons why this may or may not be possible. In addition, if such a possibility exists, then additional precautions must be included in the protocol and these precautions should include the stipulation that anyone who displays **any** flu-like signs or symptoms will not come into contact with these genes during the time in which they are thought to have the flu. In addition, the protocol must specifically state that any known accidental expose to the vaccine will be immediately reported to EHSO, UHS, and the IBC office. Additional safety precautions should be discussed with Dr. Paul Umbeck (413-8732 or umbeck@uic.edu) prior to resubmission.

c. 2006 IBC Calendar-

Dr. Bowman directed the Committee's attention to the 2006 Calendar of IBC business.

The meeting was adjourned at 2:55 PM

Institutional Biosafety Committee
Minutes of
January 12, 2006
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Randal Jaffe, Dr. Aixa Alfonso, Mr. Richard Anderson, Dr. Mary Bowman, Ms. Anne Cousin, Dr. Jeffrey Fortman, Dr. Paul Goldspink, Dr. William Hendrickson, Dr. Roberta Mason-Gamer, and Dr. Paul Umbeck

ABSENT: Dr. Edward Cohen, Dr. David Marder, Dr. Alan McLachlan, Dr. Alex Neyfakh, and Dr. Jeffrey Oswald

STAFF: Ms. Sou Soura

1. **Announcements-**

Dr. Bowman informed the Committee that a supplement to protocol 05-104 was being distributed for discussion with that protocol.

2. **Minutes-**

The minutes of the December 2005 IBC meeting were unanimously approved with minor editorial changes.

3. **Old Business-**

   a. **I-04-051- Atopic Dermatitis and Vaccina Network: Animal Studies Consortium-**

The Committee discussed the following issues: 1) that the purpose of the project was to understand the immune responses and parameters following exposure to currently licensed smallpox vaccine (Dryvax, an attenuated, live Vaccinia virus) using a transgenic mouse model that develops atopic dermatitis, 2) that mice (healthy and those with atopic dermatis) would be inoculated with the vaccine and monitored for development of a wide-spread lesion called "eczema vaccinatum" (EV), 3) that blood would be collected from some mice during the study and tissues (skin, lymph nodes and blood) would be collected following euthanasia, 4) that this protocol had been on hold pending a MTA and appropriate space being identified, both of which were now addressed, 5) that the laboratory needed to be inspected by the EHSO, 6) that the PI needed to clarify the personnel involved in the project, and 7) that the PI needed to clarify the procedures for spills outside the biosafety cabinet so that they are consistent with the UIC biosafety manual. Following discussion, a motion to approve this protocol was passed unanimously. Approval was with the understanding that it is pending the clarifications.

a. Dr. Paul Umbeck, Senior Biosafety Specialist, will need to inspect the laboratory. Dr. Umbeck will contact the PI.
b. In Form B, item I e and f, please clarify all locations where Dryvax and infected samples will be stored and used.
c. In Form B, item III, please address the following concerns:
    i. Under #1, please subdivide into 1a and 1b. In 1a, remove [redacted] veterinarians and animal care personnel.
    ii. Under #1b, indicate the following: All [redacted] veterinarians and animal care staff who have direct contact with vaccinia or vaccinia infected mice will be vaccinated with Dryvax prior to contact. Contact will not begin until three weeks post-positive immunization. [redacted] veterinarians and animal care staff who enter animal rooms for observation only when experiments are not in progress, do not require vaccination.
    iii. Under #7, please indicate that personnel will be instructed to report any signs or symptoms of conjunctivitis or eye irritation.
d. In Appendix 1, only [redacted] is listed in this appendix, however, training records for [redacted] (IATA) and [redacted] (Respirator Fit Test) were included with this protocol submission. If either of these personnel will be involved with the project, then they must be listed on Appendix 1, their experience and/or training elaborated on, and they must be vaccinated. Please clarify in a letter of response their status with the project.
e. In Biosafety Manual, please address the following concerns:
    i. For large spills outside the biosafety cabinet, the following procedures should be followed to be consistent with the recommendations of the UIC Biosafety Manual:
        1. Notify all personnel in the laboratory, evacuate laboratory and close door.
        2. Remove contaminated clothing turning inside out and place in biohazard bag.
        3. Wash all exposed skin.
        4. Put warning sign on door; notify PI, and EHSO on call safety officer (6-SAFE).
        5. Allow aerosols to settle for 30 minutes prior to re-entry and gather appropriate supplies for cleaning (bleach, sharps container, autoclave bag, tongs, etc.).
        6. Don appropriate PPE and enter laboratory.
        7. Surround entire spill area with 10% bleach-soaked paper towels; allow at least 15 minutes of contact time.
        8. Wipe down all non-autoclavable items with appropriate disinfectant.
        9. Dispose of contaminated sharps in sharps container and dispose of contaminated non-sharp waste, including materials used for spill cleanup, in autoclave bags.

10. Remove PPE and place in autoclave bag.
11. Autoclave waste and wash hands.

ii. Under E, please specify the room in which the flow cytometer will be located. This room must be one of the rooms listed in B I e.

f. Condition of Initiation: Verification of positive vaccination for laboratory personnel involved in the project prior to initiation of the study.

b. I-04-052- Entry Mechanisms of Enveloped Viruses (*Modification 04-052-01*)-

Dr. Bowman reminded the Committee that this modification had been deferred last month pending assurances regarding potential recombination events. The Committee discussed the PI's response, the fact that under these circumstances recombination could not occur, and that there were no additional concerns. Following discussion, a motion to approve this modification passed unanimously.

4. January Protocol Summary Reports-

A. Summary of Protocols and Modifications Eligible for Administrative Approval

I-05-098- Myosin Isoform Function

The purpose of this research is to determine the functional properties of various isoforms of smooth muscle myosin heavy chain using a transgenic approach and also as how the presence or absence of these myosins can affect function particularly under pathological conditions. Genes of interest are various isoforms of smooth muscle myosin heavy chain. Genes will be cloned in laboratory strains of E. coli using bacterial expression plasmids and transgenic mice will be produced.

I-05-100- Patterning of Sensory Organs of the Drosophila Adult Peripheral Nervous System

The purpose of this research is to understand the genetic and molecular mechanisms involved in development of sensory organs of the peripheral nervous system of the fruit fly, *Drosophila melanogaster*. Three genes essential for proper sensory organ patterning have been identified (hairy and achaete- bHLH transcription factors, and delta- a transmembrane ligand). Proper spatially defined expression of these genes is essential for formation of sensory organs in their normal positions. The role of growth factor pathways for decapentaplegic, wingless, hedgehog and EGF in regulating these genes will be studied. Plasmids with reporter constructs and transgenic fruit flies will be used. Approval was with the understanding that it was pending the following clarification.

a. In Appendix 1, PI should consider using 10% bleach as a disinfectant rather than ethanol for decontamination. Please reconcile. In addition, PI needs to sign Appendix 1.

B. Summary of Protocols and Modifications for Full Committee Approval

I-05-097- Mechanism of Phospholipase A2 Regulation

The Committee discussed the following issues: 1) that the purpose of this research was to understand the mechanism by which inflammation is induced by a group of enzymes called phospholipase A2, 2) that phospholipase A2 genes from human would be transfected into E. coli or HEK293 cells using commercial plasmids for over expression of recombinant proteins or to study their spatiotemporal dynamics during cell activation, respectively, 3) that the procedure for decontamination of the biosafety cabinet needed to be indicated and a copy of the BSC certification needed to be provided, and 4) that the personnel involved in the project needed to be clarified and personnel required bloodborne pathogen training. Following discussion a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item VI e, please indicate how biosafety cabinet is decontaminated and how liquid waste is decontaminated prior to disposal. For the biosafety cabinet, wiping the cabinet with 10% bleach followed by 70% ethanol or similar level of disinfectant is recommended.
b. In Appendix 1, the original list of personnel submitted contained additional names that were not on the revised appendix. Please verify that all personnel currently in the laboratory that are working with rDNA under this protocol are listed.
c. All personnel listed on Appendix 1 must complete annual bloodborne pathogen training. Training is offered via seminar by EHSO. Please see IBC web site (http://tigger.uic.edu/depts/ovcr/research/protocolreview/ibc/education/index.shtml) for training schedule and location.
d. Please provide a copy of the certification of the biosafety cabinet (BSC) to be used within the last year. BSC must be recertified on an annual basis.

I-05-099- Identifying Targets in SARS-CoV Replicase

The Committee discussed the following issues: 1) that the purpose of this research was to identify and characterize novel targets for the development of therapeutics against SARS-CoV, 2) that new potential therapeutics targeting two SARS-CoV proteases, 3Clpro and Plpro, would be tested for their effectiveness in killing SARS-CoV in Vero cells in a live-

dead cell assays, 3) that this project will be conducted at BSL3 in the same BSL3 suite as the SARS project, 4) that training with EHSO is ongoing and final approval would not be granted until all training was complete, 5) that the procedures being performed would not require scrubs consistent with other projects of this nature and BSL, and the donning and doffing procedures in the BSL3 need to be revised to reflect, and 6) that personnel would need to enter the UIC MSP for SARS. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. Condition of Approval 1: All training must be completed prior to initiation. Training is comprised of BSL-3 biohazard training by the EHSO office and SARS specific agent training in the BSL-3 lab [redacted].
b. Condition of Approval 2: All personnel have entered the Medical Surveillance plan for SARS and completed initial blood sampling, influenza vaccine, and contact list information.
c. Condition of Approval 3: A copy of all documentation related to training (BSL3, bloodborne pathogen, respirator fit testing/training) must be submitted to IBC office.
d. In Form B, PI information, please provide a daytime work phone for PI.
e. In Form B, item I b, please provide the original source and strain and indicate that PI will obtain a sample from [redacted]
f. In Biosafety Manual, please address the following concerns:
    i. Note to PI: For the type of work described in this protocol, donning and doffing of scrubs will not be required. The risk analysis by the Committee does not feel that this is a necessary procedure. Reference to donning and doffing of scrubs should be removed (see below).
    ii. Under 2.2, page 6, #4, PI should inform EHSO and UHS. These offices will inform local and state authorities.
    iii. Under 3.1, page 9, #1, remove donning of scrubs. Personnel may choose to wear scrubs, but it should not be a requirement of entry.
    iv. Under 3.3, page 11, #6, remove this item.
    v. Under 3.3, page 11, #7, remove reference to scrubs. Bag will be used for inner gloves.
    vi. Under 3.3, page 11, #8, there is not a double door for corridor entry.
    vii. Under 3.11, page 19, #2, please indicate % for formalin.
    viii. Under 3.11, page 19, #3, please indicate if plates will also be wiped down with disinfectant.
    ix. Under 3.12.3, page 20, #2, please indicate that bottles will be autoclaved when 2/3 full or when procedures are finished for the day.
    x. Under 3.14- prior to exiting BSL3 laboratory, page 21, #4, remove #4. This is not necessary.

xi. Under 3.14-prior to exiting anteroom, page 21, #4, #8, and # 9, remove these items.
xii. Under 3.15.2, please refer to maintenance policy for BSL3.
xiii. Under 3.15.2, page 24, #7, this item should be removed. Laboratory or equipment needing repair should be thoroughly decontaminated prior to maintenance.

I-05-101- Creating Chronic Sinusitus in a Mouse Model

The Committee discussed the following issues: 1) that the purpose of this pilot study was to understand the cause and progression of chronic sinusitis in a mouse model in order to help provide new insight into treatment options, 2) that the procedure involved infecting mice with *S. pneumonia* intranasally via droplets, 3) that the PI needed to indicate that mice would be in microisolator cages and indicate when post-infection mice would be euthanatized, 4) that the PI needed to clarify which strain was being used and provide assurances that strain was not MDR, and 5) that appendix 1 needed to be provided and training regarding [redacted] biohazard room needed to be indicated. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form B, item I e, please indicate biohazard room at [redacted] in addition to PI's laboratory
b. In Form B, item I g, please indicate "NO" for select agents.
c. In Form B, item II b, please provide additional information as to the strain of *S. pneumonia* that will be used. Please provide assurances that the strain is not a multi-drug resistant strain and how this was determined.
d. In Form B, item II b, please indicate the length of time post-infection that mice will be used.
e. In Form B, item III, please address the following concerns:
    i. Please indicate that animals will be housed in microisolator cages.
    ii. Please indicate how infectious samples will be transported to and from PI's laboratory. Samples should be transported in unbreakable containers.
f. In Appendix 1, PI needs to include this appendix and indicate the level of training that they will undergo training prior to initiation of the study in the biohazard room.

I-05-102- Entry of Herpes Viruses Into Mammalian Cells

The Committee discussed the following issues: 1) that the purpose of this study was to identify any common molecular mechanism of virus-host interaction leading to herpes viruses entry and cell–to-cell spread, 2) that the viruses of interest included herpes simplex virus, Epstein Barr virus, Cytomegalovirus, 3) that this study would focus on

identifying and assessing receptor expression in human cells, studying interactions of viral glycoproteins with cellular proteins and generation of inhibitors to viral entry, 4) that verification of BBP and IATA training dates needed to be provided. Following discussion, a motion to approve this protocol passed unanimously. Approval was with the understanding that it is pending the following clarifications.

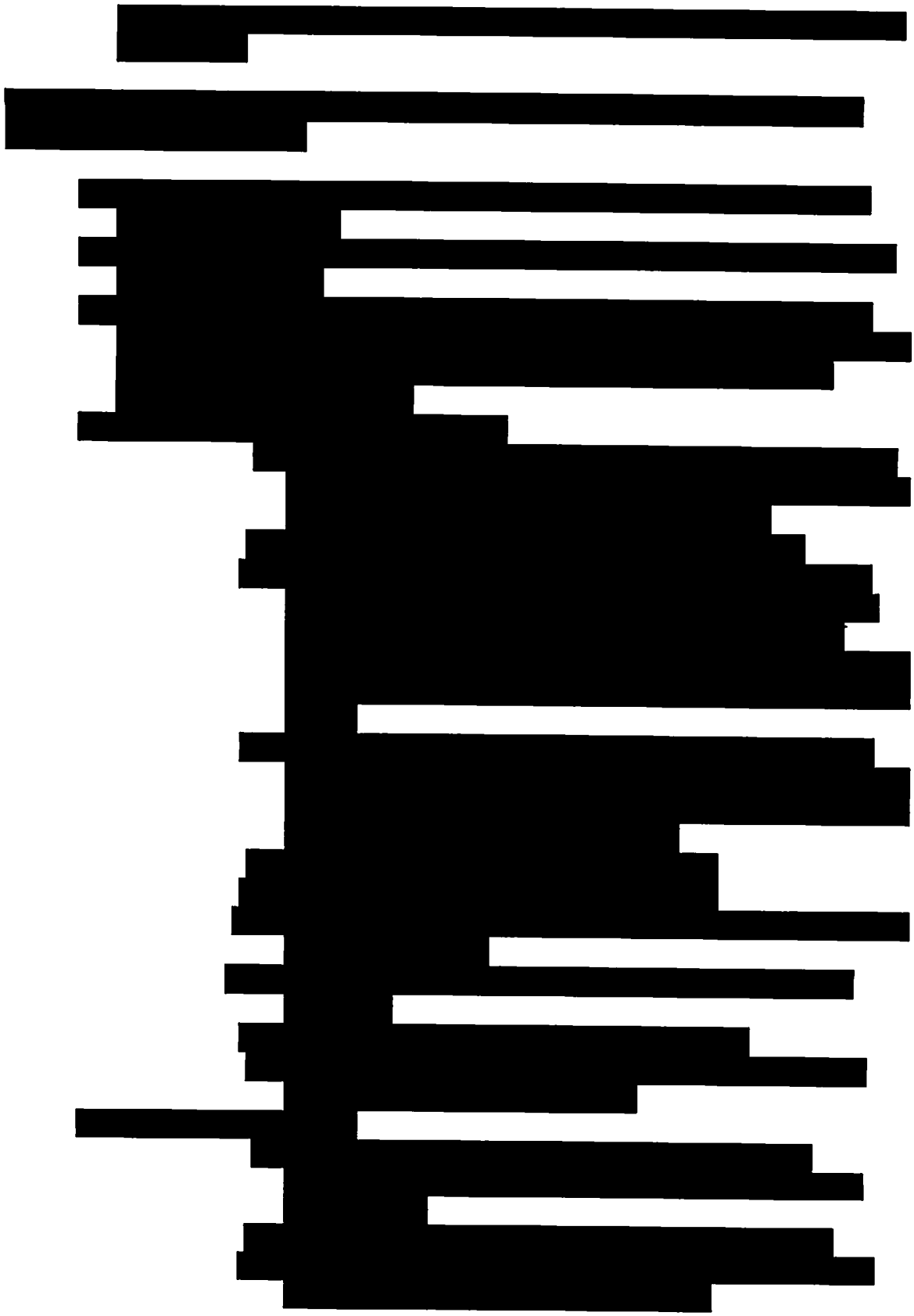
a. Please provide certificate of Hazardous Material training for [redacted] According to Appendix 1, he has completed this training.

I-05-103- Molecular Mechanisms Regulating Bile Duct Epithelia Response

The Committee discussed the following issues: 1) that the purpose of this research was to induce the expression of transcription factors into the mouse liver using the recombinant virus as a vector in order to study liver responses, 2) that vectors would be administered via tail vein injections, 3) that this study needed to be conducted at [redacted] and not [redacted] 4) that the PI needed to specify that all manipulations would be done in a biosafety cabinet and elaborate on spill procedures, and 4) that training status needed to be clarified for personnel in Appendix 1. Following discussion, a motion to approve this protocol was passed unanimously. Approval was with the understanding that it is pending the following clarifications.

a. In Form A, item IV c, indicate the duration for which mice are maintained after infection.
b. In Form A, item V a, please indicate biohazard room at [redacted] in additional to PI laboratory.
c. In Form A, item VI e, please address the following concerns:
    i. All viral manipulations and animal injections must be done in a biological safety cabinet.
    ii. [redacted] is not set up to support this project. The work should be done in the [redacted] Please correct in protocol and please contact [redacted] to discuss housing issues.
    [redacted] Please include a brief statement regarding procedures that will be followed should a spill occur in the PI's laboratory or in the [redacted]
    iv. Please indicate how vectors will be transported from PI's laboratory to [redacted] Vectors should be transported in unbreakable containers.
d. In Appendix 1, please clarify the training status of staff with regards to bloodborne pathogens, IATA/DOT, and in the mouse biohazard room.
e. Form B is not needed.

I-05-104- [redacted]



[redacted]

i. [redacted]

5. Adverse Event Report-

None to report this month

6. New Business-

a. Tour of the [redacted]

Mr. Anderson suggested that due to the renovation of the [redacted] being near completion that it would be a good time for the IBC to tour the facility. Dr. Bowman indicated that she would email the Committee members with potential dates and times in which tours would be provided.

The meeting was adjourned at 2:50 PM

Institutional Biosafety Committee
Minutes of
February 9, 2006
2:00 P.M. - Room 307 C AOB

PRESENT: Dr. Randal Jaffe, Dr. Aixa Alfonso, Dr. Mary Bowman, Dr. Edward Cohen, Ms. Anne Cousin, Dr. Jeffrey Fortman, Dr. David Marder, Dr. Roberta Mason-Gamer, Dr. Alan McLachlan, Dr. Jeffrey Oswald, and Dr. Paul Umbeck

ABSENT: Mr. Richard Anderson, Dr. Paul Goldspink, and Dr. William Hendrickson,

STAFF: Ms. Sou Soura

1. **Announcements-**

Dr. Bowman informed the Committee that she was distributing a handout that would be discussed under old business as item A and a supplement to modification 03-005 that would be discussed as part of the February report. She indicated that there was one addition to the agenda under new business. Modification of protocol 03-053 was added as item A under new business. Dr. Bowman also informed the Committee that Dr. Alexander Neyfakh had resigned from the Committee. She indicated that Dr. Neyfakh had provided a few names as potential replacements and that she would pursue these recommendations.

2. **Minutes-**

The minutes of the January 2006 IBC meeting were approved with minor editorial corrections (1 abstention). Committee member abstaining was not at January meeting.

3. **Old Business-**

   a. **Visit to** [redacted]-

Dr. Bowman directed the Committee's attention to the overview of the [redacted] She indicated that a number of IBC and ACC members had toured the facility the previous week. The Committee discussed the [redacted]

[redacted] Dr. Bowman indicated that she would keep the Committee updated.

4. **February Protocol Summary Reports-**

   A. **Summary of Protocols and Modifications Eligible for Administrative Approval**

I-03-070-06- Addition of new personnel

I-04-030-05- Addition of new personnel

I-04-046-03- Addition of new personnel

I-05-053-01- Addition of new personnel

I-06-004- Carolina Center of Cancer Nanotechnology Excellence-

The purpose of this research is to introduce the coding regions for recombinant human antibodies that will bind Her2 into bacteria (laboratory strains of E. coli) or insect cells for overexpression using pET plasmid. The antibody fragments will be purified and examined for their binding properties. The purified antibody fragments will be supplied to PI's collaborator at University of North Carolina for testing in a tissue culture model. This project will be conducted at BSL 1.

   B. **Summary of Protocols and Modifications for Full Committee Approval**

I-06-001- Streptococcus Pneumoniae Corneal Ulcers Treated with Linezolid, Daptomycin, Tigecycline, or Vancomycin in Rabbit Model-

The Committee discussed the following issues: 1) that the purpose of this research was to test topical formulations of the antibiotics, linezolid, daptomycin or tigecycline, which are effective against *Streptococcus pneumonia* as well as other gram positive organisms, to determine their effectiveness as treatment for corneal ulcers in rabbits and that topical vancomycin would be used as a control, 2) that rabbits will be inoculated intraocularly with *S. pneumonia* and treated via drops for 5 hours being 4 hours post-inoculation and then euthanatized, 3) that tissues (corneas) would be removed and examined for the presence of pathogen, and 4) that the PI had addressed the concerns raised during preview including training on animal handling, decontamination of rabbit cages, strain of

S. pneumonia being used, and handling of sharps. Following discussion, a motion to approve this protocol was unanimously passed. Following approval, the Committee indicated that the PI should provide a written procedure for re-capping syringes.

I-03-005-02- Influence of DNA Methylation on Replication and Growth of Bacteria with Multiple Chromosomes-

The Committee discussed the following issues: 1) that the PI was requesting to genetically modify *Vibrio* bacterial strains, *V. parahaemolyticus* and *V. vulnificus*, in the same manner as currently being done for *V. cholerae* using a new plasmid that contained tetracycline resistance marker, to culture these bacterial species with human cell monolayers to assay for changes in electrophysiological properties of the monolayers, and to add and delete some personnel, 2) that the PI had been contacted regarding concerns over the use of the proposed plasmid since doxicycline is currently use to treat such infections and the need to identify the stains used, and 3) that the PI had responded to the concerns and would not use a tetracycline resistant marker and would use strains obtained from ATCC or the same serotypes, but sequenced strains. Following this discussion, a motion to approve this modification passed unanimously.

I-05-050-01- A Phase I Dose-Ranging Study of the Safety, Tolerability, and Immunogenicity of a 3-Dose Regimen of the MRKAd5 HIV-1 Trigene and the MRKAd6 HIV-1 Trigene-

[redacted]

5. Adverse Event Report-

None to report this month

6. New Business-

a. Modification of Protocol 03-053 (*03-053-02*)-

Dr. Bowman directed the Committee's attention to the PI's request to administer two plasmids into the uteri of 4 [redacted] with experimentally induced endometriosis. One plasmid will express LacZ as a control and the other will express HOXA 10. The purpose is to determine the effect on endogenous HOXA10 and avb3 integrin expression, both of which are down regulated in the uterus of [redacted] with endometriosis. Plasmids

will be introduced into the uterus via tom cat catheters in a liposome suspension on day 1 following ovulation and animals will be euthanatized at day 10 post-ovulation and uteri collected for analysis. Dr. Bowman indicated that a similar modification had been approved by the ACC. The Committee discussed that there were no safety or containment concerns with this project. Following discussion, a motion to approve this modification was unanimously passed.

The meeting was adjourned at 2:30 PM