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May 4, 2006

Edward H. Hammond
Director
The sunshine project
P. O. Box 41987
Austin, TX 78704

Dear Mr. Hammond:

This letter is in response to the Open Records portion of your letter received by Marcia Finucane. You requested that we provide you with the following records by Friday, April 28, 2006:

“Pursuant to the National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules (NIH Guidelines), Section IV-B-2-a-(7),¹⁷³ the Sunshine Project hereby requests the Minutes of all meetings of the University of Kentucky Institutional Biosafety Committee (IBC) since 1 May 2003.”

RESPONSE: Provided herewith are copies of the requested minutes. We redacted from these minutes, the identities of the Principal Investigators, the identifiers of locations where research is being conducted, and any references to information restricted under the U.S. Patriot Act, pursuant to KRS 61.878(1)(k), (l) and (m).

KRS 61.878(1)(k), (l) and (m) exempts from disclosure:

- (k) All public records or information the disclosure of which is prohibited by federal law or regulations; and
- (l) Public records or information the disclosure of which is prohibited or restricted or otherwise made confidential by enactment of the General Assembly; and
- (m) 1. Public records the disclosure of which would have a reasonable likelihood of threatening the public safety by exposing vulnerability in preventing, protecting against, mitigating, or responding to a terrorist act and limited to:
 - a. Criticality lists resulting from consequent assessments;

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- b. Vulnerability assessments;
- c. Antiterrorism protective measures and plans;
- d. Counterterrorism measures and plans;
- e. Security and response needs assessments;
- f. Infrastructure records that expose vulnerability referred to in this subparagraph through the disclosure of the location, configuration, or security of critical systems, including public utility critical systems. These critical systems shall include but not be limited to information technology, communication, electrical, fire suppression, ventilation, water, wastewater, sewage, and gas systems;
- g. The following records when their disclosure will expose a vulnerability referred to in this subparagraph: detailed drawings, schematics, maps, or specifications of structural elements, floor plans, and operating, utility, or security systems of any building or facility owned, occupied, leased, or maintained by a public agency; and
- h. Records when their disclosure will expose vulnerability referred to in this subparagraph and that describe the exact physical location of hazardous chemical, radiological, or biological materials.

In accordance with the laws of this state, we have redacted the minimum amount of information necessary to avoid disclosure of information on vulnerabilities of critical systems and the exact locations of hazardous materials. Because this information can be readily determined based on the identity of the researchers, we have redacted researcher's names.

"When you respond, I would appreciate your answer to the following question (please circle one):

The University of Kentucky IBC HAS/HAS NOT implemented written policies for the identification, review, and oversight of research involving any of the seven categories of experiments of concern identified by the National Academies of Science in its report *Biotechnology Research in an Age of Terrorism* (the "Fink Committee" report)."

RESPONSE: Regarding your question relating to "written policies," in an Attorney General publication entitled "Outline: The Law of Open Records and Open Meetings," Section VI. Exceptions to Right of Inspection, Part C., the Attorney General states, "A public agency is not obligated to honor a request for information, as opposed to a request for specifically described records." The reference opinions to this section are: 97-ORD 182, 96-ORD-150, 96-ORD-146, 96-ORD-53, 95-ORD-150, and 95-ORD-131.

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The total charge for the copies provided at this time is \$13.10 which includes 10¢ per page for 91 pages and \$4.00 for postage. Please remit your payment to the University of Kentucky, Office of Legal Counsel, 301 Main Building, Lexington, Kentucky 40506-0032.

Sincerely yours,

A handwritten signature in black ink that reads "Frank Butler / BaA". The signature is written in a cursive, slightly slanted style.

Frank Butler
Official Records Custodian

km

c: Marcia Finucane

**Minutes – Institutional Biosafety Committee
May 7, 2003**

Members Present:

Judith Lesnaw
Kelly Breeding
Thomas Chambers
Robert Jacob
Harry Enoch
Marcia Finucane
Anthony Sinai
Kenneth Dickey
Richard Wheaton

Members Absent

Chuck Staben
Jack Hiatt
Glenn Telling
Arthur Hunt

COMMITTEE BUSINESS

Dr. Judith Lesnaw called meeting to order at 12:10.

Approval of Minutes

April 9, 2003 minutes approved with modification request from ~~Dr. Thomas Chambers~~. Dr. Chambers requested that section of minutes on modification that refers to Dr. Chambers be changed to reflect that it is for Dr. Anthony Sinai moved and Mr. Richard Wheaton seconded that the minutes be approved as modified. The motion carried unanimously.

Dr. Harry Enoch meet with the IBC to explain the importance of the committee and to commend the committee on the fine job they are doing. Dr. Enoch reported that the role of the IBC will be changing. The major roles will be risk assessment, determining containment levels and conditions, and reviewing the risk of research knowledge (whether research should be performed because of security concerns and once performed should it be published).

To speed up the review process Dr. Enoch suggested some different scenarios that might be taken. One was for the establishment of a primary and secondary reviewer process. The two reviewers and the Biological Safety Officer would review the protocols and correspond with the researcher, after that protocol would be submitted to the full committee.

The second review process would have the researcher invited to the IBC meeting to answer committee member questions.

The third protocol review would be by email, which is what the Radiation Safety Office does. After the Biosafety Officer works on the protocol with the principal investigator, it would be sent to the committee members for approval via email or campus mail.

Most of the committee members preferred the primary reviewer system and Ms. Finucane will start that process with the next protocols that come in. She has already sent one protocol out this way.

Dr. Enoch informed the committee that he has requested additional members be added to the committee.

A chart of the NIH Guidelines and the review processes required was handed out to the IBC members.

The committee was asked to review the By-Laws of IBC and be prepared to discuss changes at the next meeting. A discussion of the definition of a "quorum" began when it was brought up that with a larger committee membership, it might be harder to have a quorum present.

Ms. Finucane informed the committee of the continuing process with dealing with field trials. She and Dr. Hunt have worked out a process and will keep the committee abreast of what is going on. A copy of the procedure was handed out to the members present.

Information of the comparison of disinfectants and their efficacy was given to the committee for review and reference.

Meeting adjourned at 1:35 p.m.

**Minutes – Institutional Biosafety Committee
June 11, 2003**

Members Present:

Judith Lesnaw
Kelly Breeding
Thomas Chambers
Robert Jacob
Harry Enoch
Marcia Finucane
Anthony Sinai
Richard Wheaton
Chuck Staben
Jack Hiatt
Glenn Telling
Arthur Hunt

Members Absent

Peter Nagy
Kenneth Dickey

COMMITTEE BUSINESS

Dr. Judith Lesnaw called meeting to order at 12:07pm.

Old Business

Approval of Minutes : May 7, 2003 minutes approved with no modifications. Dr. Tom Chambers moved and Dr. Anthony Sinai seconded that the minutes be approved as written. The motion carried unanimously.

FIELD TRIAL PROCEDURES : Modification of protocol #

B020620206

The following procedures for field trials was developed in a meeting with
on Tues. 4/15/03 at 10am in KTRDC

1. APHIS authorities are concerned with the safe field testing of transgenic plants, ask the same type of questions the IBC is concerned about, and are very familiar with the genes and applications in plants. An APHIS permit reflects an authority similar to the NIH and recognized by the NIH as the federal agency with regulatory purview of field releases (see NIH response to M. Finucane's questions; OBA RESPONSE: The NIH Guidelines detail containment requirements for work involving recombinant DNA, including transgenic plants. The NIH Guidelines don't, in effect, allow for field releases unless another federal agency has regulatory purview. As you pointed out, APHIS has purview with respect to field releases of transgenic plants. EPA also has purview when transgenic plants are designed to create their own pesticidal substances. Because the Guidelines do not include specifications for field releases, they do not detail any specific IBC role or review responsibilities with respect to the act of release) Therefore, APHIS permits are required to be submitted with the IBC registration forms. The application for APIS permits can be submitted to the IBC but final approval will not be granted until the final permit is received.

2. The seeds from _____, developed with the IBC approval # B020822218, and with the appropriate APHIS permits, are acceptable. A copy of _____ field trial modification and containment practices will be placed in _____ protocol folder this one time.
3. In the future, field trials with seeds from UK researchers should be sent to the IBC from the PI who does the rDNA work, as a modification to his IBC-approved protocol. The appropriate APHIS permits are to be attached to the IBC submission.
4. _____ will write a short summary about each of the seeds to be used in the field trials, explaining the genetic changes that have been made (for example, an insect-resistance gene, from what source), what protein or compound is expressed, and addressing the human health and environmental impact issues of the plant and this gene. This is the procedure to be used for seeds from other institutions, or from UK researchers who produced the seed years ago (for example, _____, seeds made 1985-1990) before anyone realized the IBC was to review and approve this work. Again, appropriate APHIS permits must be supplied.
5. According to the NIH Guidelines, Section III-E, _____ germination and growth of seedlings for field trials require IBC notice simultaneous with initiation; "approval prior to initiation of the experiment is not required"; However, the IBC review will be helpful in keeping track of transgenic plant work on the campus.

Dr. Hunt moved for IBC acceptance of this procedure and Dr. Sinal seconded. The vote in favor was unanimous.

New Business:

12:30pm _____ Plant Pathology Department –
SUMMARY OF PRESENTATION ON BLUE MOLD

1. Blue mold is an important disease of tobacco in Kentucky and the region. Annual farm losses in the decade have ranged from a few thousand to nearly \$200 million.
2. This means it warrants our research efforts, but we must appreciate that our research can also serve as inoculum for farm and campus epidemics unless contained. Our greatest containment tools in the past have centered on working during the fall and winter months.
3. Tobacco blue mold is actually - Downy Mildew of Tobacco, The causal agent is *Peronospora tabacina*, a Stramenophyte, which are fungus-like organisms in the Kingdom Chromista that include diatoms, kelp, water molds, and the downy mildews.
4. Downy mildews organisms are obligate biotrophs - obligate parasites - so they grow and reproduce in nature only on a live host.
5. This *Peronospora*'s host range is essentially confined to the genus *Nicotiana* -tobaccos, to the best of our knowledge, but experimentally it can be taken to a few other solanaceous hosts.
6. This organism produces both asexual spores (sporangiospores) and sexual spores (Oospores), but the sexual spores are rarely found.

7. Primary inoculum is usually from the asexual spores coming from activity in tobacco, where it can easily produce a million spores/sq centimeter of infected leaf.

8. Sporangiospores are about 15x 25 u , are very fragile and short live, unless in the frozen state, being very sensitive to UV light. Most spores are killed within a few minutes to an hour by exposure to direct sunlight during the summer months.

Airborne: These sporangiospores are essential like balloons, so they easily float in the air and can be spread long distance on air currents, when protected from UV light.

Once they land on their host, infection can occur within 2 to 4 hours, which requires darkness and free water. The symptom-free incubation period is 4-14 days, but sporulation can occur on day 3, but usually is on day 4-5.

Sporulation requires high relative humidity 95%>, in darkness. - usually more than 6 hours, but it can occur with as little as 2 hours.

Spores are liberated naturally with drop in humidity, or through physical agitation. They can be carried on clothing and body hair.

There are 5- recognized Patho-systems in the world: North America/Central America, South America, Mediterranean/Europe, and Austria.

New Protocol Review:

- Resistance of Nicotiana Species to Tobacco Blue Mold and Black Shank (protocol # B03-257)

- Responses of Nicotiana Species to Agrobacterium Tumefaciens Infection (protocol # B03-258)

- Effect of R genes on Tobacco Responses to the Major Tobacco Diseases Blue Mold and Black Shank (protocol # 259)

- Identification of Nicotiana Species Resistant to Blue Mold Via Root Inoculation (protocol # 260)

A discussion of , protocols followed the presentation and the committee deferred a decision on the protocols until . has reviewed them and made recommendations for containment facilities and procedures. **The protocol is sent back to the PI for revision.**

- Identification and Characterization of Mutants Exhibiting Attributes Resulting in Robust Seed Germination and Seedling Establishment.(protocol # B03-263)..- Written reviews from were handed out. After a short discussion of this work, Dr. Jacobs moved and Dr. Telling seconded that the committee grant **full approval**, contingent upon the field work being conducted by per his approved protocol. The vote for approval was unanimous.

NEW PROTOCOL REVIEW (Continued)

- Adeno-Associated Virus Gene Therapy and Stem Cell Transplantation in a Novel Mouse Model of Age-Related Macular Degeneration OR Novel Mouse Models of AMD (protocol # B03-264)

After discussion, Dr. Wheaton moved and Dr. Tom Chambers seconded, that the IBC committee grant **provisional approval**, contingent upon the following issues being addressed:

1. The location of laboratory
2. The testing done by to assure that the AAV is not replication competent
3. The details of that testing
4. Specify that all persons working with the AAV have had blood borne pathogen training and put copies of the certificates in the safety manual (amend page 2 of the rDNA form in training section, delete that "no special training" statement and put in who is trained in BSL2 practice, experience with tissue culture, infectious agents at BSL2)
5. Is there a chance of AAV leaking from the eye immediately following the injection?
6. What steps will be taken should someone be accidentally injected with the AAV? Before work is initiated, notify Worker's Care as to the agent being worked with and the names of people working with it.
7. Rewrite the safety/spill plan to state that 0.5% NaOCl is used first on a spill, then covered with paper towels, wiped up and put into biohazard trash. (Please revise the second paragraph of amendment #3)
8. Address the issue of the transportation of mice from the animal facility to the laboratory
9. How is the AAV received and handled? The person(s) responsible for receiving this should have documentation of IATA training (offered through the Hazardous Materials office).

- JC Virus Expression in the Oropharynx and Human Immunodeficiency Virus (HIV) (protocol # B03-262) After discussion, Dr. Jacobs moved and Dr. Telling seconded, that this be granted **full approval**. The vote was unanimous for approval.

Issues discussed:

1. Drosophila containment requirements

BSO was directed to determine how other institutions deal with the containment of transgenic flies.

2. VA PROTOCOLS

Acceptable for PIs moving to Allied Health Building?

The committee decided that UK IBC registration forms will have to be submitted for work performed on the UK campus.

3. ADENOVIRUS WORK

Small room with 2 BSC versus large room with 6 BSC

Open lab plan

The IBC committee discussed the pros and cons of different facilities for adenovirus research and the consensus favored this work to be done in a dedicated room with dedicated equipment.

4. RDNA TOXIN: EXPERT/REVIEWER?

Dr. Sinai and Dr. Staben agreed to review a new protocol dealing with a recombinant toxin administered to human subjects and to make comments and recommendations before the next IBC meeting.

5. NEW IBC REGISTRATION FORM

Copies of the new form were handed out and members were solicited for comments. This will be discussed at the next meeting in July.

The meeting was adjourned at 2:45pm.

**Minutes
Institutional Biosafety Committee
July 16, 2003**

Members Present

Arthur Hunt
Glenn Telling
Thomas Chambers
Robert Jacob
Marcia Finucane
Richard Wheaton
Chuck Staben
Jack Hiatt

Members Absent

Peter Nagy
Kenneth Dickey
Judith Lesnaw
Kelly Breeding
Anthony Sinal

COMMITTEE BUSINESS

Tom Chambers called meeting to order at 12:07pm.

Old Business

Approval of Minutes June 11, 2003 minutes approved with no modifications. Richard Wheaton moved and Chuck Staben seconded that the minutes be approved as written. The motion carried unanimously.

PROTOCOL REVIEW

Calpain Inhibition Strategies for Spinal Cord Injury B03-271

Comments: Discussion

Action: Glenn Telling moved and Chuck Staben seconded that the committee grant full approval to this protocol. The motion carried unanimously.

- Resistance of Nicotiana Species to Tobacco Blue Mold and Black Shank -B03-257

Comments:

The following changes are required:

1. 0.5% NaOCl in the spill during transportation protocol
2. Use of disposable coveralls or lab coats, hair and shoe coverings, and gloves, as well
3. N95 respirators during aerosol inoculation (to prevent irritation or sensitization of the respiratory tract)
4. Testing of the growth chamber to ensure no dissemination of infectious materials into the environment BEFORE aerosol inoculations are started and periodic checks on this system
5. Containment equipment to include biological safety cabinet and growth chamber (biosafety chamber, clean room)
6. Certification of BSC to 7/2004

- Effect of R genes on Tobacco Responses to the Major Tobacco Diseases Blue Mold and Black Shank - B03-259

Comments:

The following changes are required:

1. 0.5% NaOCl in the spill during transportation protocol
2. Containment equipment to include biological safety cabinet and growth chamber (biosafety chamber, clean room)
3. Certification of BSC to 7/2004

- Identification of Nicotiana Species Resistant to Blue Mold Via Root Inoculation - B03-260

Comments:

The following changes are required:

1. 0.5% NaOCl in the spill during transportation protocol
2. Containment equipment to include biological safety cabinet and growth chamber (biosafety chamber, clean room)
3. Certification of BSC to 7/2004

Action: Chuck Staben moved and Richard Wheaton seconded, that the committee grant **provisional approval** pending receipt of these changes. The motion carried unanimously.

PROTOCOLS ISSUED REGISTRATION NUMBERS

These protocols do not require review by IBC and are registered with the BSO. Marcia Finucane briefly summarized these projects and the safety implications in them.

Is administering recombinant toxin from a pharmaceutical company, to patients. The safety/spill procedures have been modified to use a chemical agent that will inactivate these toxins specifically.

B03-265 - A Multicenter Phase II Study of TP-36 in Those Patients with Glioblastoma Multiforme Who Have Recurred or Progressed After Previous Resection and radiation Therapy and Are Scheduled for Gross Total Resection

B03-270 - A Phase III Multicenter Study of Intratumoral/Interstitial Therapy with TransMID™ Compared to Best Standard of Care in Patients with Progressive and/or Recurrent, Non-Resectable Glioblastoma Multiforme

The following protocol falls within the NIH Guidelines, Section III E2a, BL1-P, disarmed *Agrobacterium*.

B03-258 - Responses of Nicotiana Species to *Agrobacterium tumefaciens* Infection

PROTOCOLS GRANTED APPROVAL

B03-264 - Adeno-associated virus gene therapy and stem cell transplantation in a novel mouse model of age-related macular degeneration – Provisionally approved at the June 11, 2003 IBC meeting. The revisions were made per IBC request and checked by the IBC chair and BSO.

New Business

NEW IBC REGISTRATION FORM

Comments from the members were discussed and suggestions taken down by the BSO. These will be incorporated into the new form and made available electronically as a Word document from the EH&S website.

The meeting was adjourned at 1:15pm.

**Minutes
Institutional Biosafety Committee
August 13, 2003**

Members Present

Arthur Hunt
Glenn Telling
Thomas Chambers
Robert Jacob
Marcia Finucane
Jack Hiatt
Kenneth Dickey
Judith Lesnaw
Anthony Sinai

Members Absent

Peter Nagy
Kelly Breeding
Richard Wheaton
Chuck Staben

COMMITTEE BUSINESS

The meeting was called to order at 12:10pm. Judith Lesnaw introduced the new Co-Chair, Louis Hersh.

Old Business

Approval of Minutes July 16, 2003 minutes approved with no modifications. Anthony Sinai moved and Jack Hiatt seconded that the minutes be approved as written. The motion carried unanimously.

PROTOCOL REVIEW

**- Group V sPLA2 and Atherosclerosis Macrophage-derived GX secretory phospholipase
AA2 and atherosclerosis**

Comments: After a long discussion the following clarifications are required:

1. Submit copies of training documents for the UK laboratory safety and blood borne pathogens courses for laboratory staff
2. Specify no eating or drinking in laboratory, not just work areas; the write up areas of the new laboratory space is considered part of the laboratory and cannot have food or drink in them; especially since staff must walk through the write up areas to get to the common equipment rooms and the autoclave rooms
3. Change "10% (bleach) of volume" to final concentration of 0.5% NaOCl
4. Retroviral use needs explanation of safe handling instructions
5. SOP on centrifuge use, especially how to handle centrifuge malfunctions or accidents.
6. Adenovirus and retroviruses need to be defined as defective not deficient
7. Fill out animal use page
8. Explanation of how the adenovirus-infected cells are tested/guaranteed to be free of infectious agents so that further manipulations can be conducted at BSL1 and a more complete discussion of what those manipulations will be
9. Discussion of how the retroviral bio-waste will be handled if different from the BSL2 procedures

Action: Judith Lesnaw proposed a sub-committee perform a site visit (Marcia Finucane, Robert Jacob and Glenn Telling) of proposed laboratory space. **Protocol returned.**

**- Role of Glutathione Reductase and Glutaredoxin in Oxidative Stress-Induced
Macrophage Dysfunction and Cell Death**

Comments:

1. Clarify need for autoclave use : specify that autoclaving WILL be done, not that it is not necessary; and what the specific conditions are (temperature, time, psi, validation procedure)
2. Change room to on page 11 #3. Note that the cold room is
3. Site visit by sub-committee of the IBC to proposed laboratory facilities

Action: Robert Jacob moved and Arthur Hunt seconded that a site visit be performed and that **provisional approval** be granted upon receipt of changes. The vote was unanimous.

– Adenoviral delivery of the Hpr6.6 protein

Comments:

1. Letter from . authorizing work in adenovirus core facility must be attached and she must be listed as co-PI if she is doing any of the adenovirus construction
2. List workers and training, including any workers in lab who will work on project
3. Change 1:10 dilution to 0.5% NaOCl
4. Describe lab specific safety and spill procedures

Action: Protocol returned to investigator for revisions.

· Re-activation of Murine cytomegalovirus in Bone marrow transplantation and its impact on pneumonitis

Comments:

1. Revise CHS to Clinical Health Sciences
2. Change "no" to "yes" for potential for aerosols (injections pose potential for aerosols)
3. Change DLAR room from CB26 to CB27
4. Explain autoclaving procedures
5. Define infectious dose for mice
6. Submit rDNA form
7. Attach the SOP for disinfection of the instrument after processing unfixed cells, from the flow cytometry facility
8. Address how the pfu are determined for the inoculation of the mice and by whom

Action: Tom Chambers motioned and Glenn Telling seconded **provisional approval** upon comments being amended. Unanimously agreed.

The committee was reminded that the next review meeting will be September 10, 2003 in Coombs 308 and that the training and dinner will be September 17, 2003 at 5pm at the Faculty Club.

The meeting ended at 1:30pm.

**Minutes
Institutional Biosafety Committee
September 10, 2003**

Members Present

Arthur Hunt
Glenn Telling
Thomas Chambers
Eric Smart
Lou Hersh
Brian Rymond
Marcia Finucane
Jack Hiatt
Kenneth Dickey
Anthony Sinal
Chuck Staben
Richard Wheaton
Kelly Breeding
Peter Nagy

Members Absent

Nader Hanna
Robert Jacob

COMMITTEE BUSINESS

The meeting was called to order at 12:10pm. Thomas Chambers began introduction of all members present. New members include Lou Hersh co-chair, Brian Rymond, Eric Smart, Nader Hanna.

Old Business

Approval of Minutes August 13, 2003 minutes approved with no modifications. Lou Hersh moved and Richard Wheaton seconded that the minutes be approved as written. The motion carried unanimously.

PROTOCOL REVIEW

- Characterization the role of Abelson kinases in growth factor signaling B03-287

Comments:

1. Clarify mouse and human cells in BSC are fixed with formaldehyde? Amounts of volatile chemical in BSC?
2. Lab audit needs to be performed.

Action: Chuck Staben moved for and Lou Hersh seconded **provisional approval** upon completion and clarification of comments. The vote was unanimous.

- Natural killer cells in health, aging, cancer and infection B03-274

Comments: After discussion the following clarifications are needed:

1. Epstein Barr in blood samples or culturing?
2. How disposing of waste, autoclave?
3. How are blood samples obtained? If drawing human blood samples himself needs IRB approval.
4. Please expand your experimental protocol to give more details

Action: Thomas Chambers proposed the protocol **returned** to clarify issues.

- Class B scavenger receptors and foam cell formation: HDL receptor

SR-BI: influence of apoAII B03-289

Comments:

1. Lab audit performed when you are moved into laboratory facilities
2. Certification of biological safety cabinets.

Action: Eric Smart moved and Glenn Telling seconded **provisional approval** upon completion of comments. The vote was unanimous.

- SAA and sPLA2: Role in atherogenesis B03-288

Comments:

1. Lab audit performed when you are moved into laboratory facilities
2. Certification of biological safety cabinets.

Action: Eric Smart moved and Glenn Telling seconded **provisional approval** upon completion of comments. The vote was unanimous.

Pathogenic mechanisms of chronic wasting disease and scrapie prions B03-286

Comments:

1. BBP training not necessary for everyone, but a good idea for all lab personnel.
2. Pg. 10 **infected** brain homogenates.
3. Cells will be fixed in DLAR CB27
4. Needles are luer-lock
5. Mouse carcasses are incinerated
6. Final solution 2% NaOCl

excused from room for vote.

Action: Anthony Sinai moved and Arthur Hunt seconded **approval of protocol**. The vote was unanimous

- Development of ligand inducible gene switches for simultaneous and independent regulation of expression of two genes in transgenic tobacco plants B03-284

Comments:

1. Form not filled out correctly, Section 2 number 1 should be "yes" for work to express a foreign gene.
2. Need greenhouse information on first page.
3. Page 8 *Mus musculus* listed as "rat" needs to be "mouse".

Action: Arthur Hunt moved and Peter Nagy seconded the protocol granted **provisional approval** upon clarifications in comments. The vote was unanimous.

PREVIOUSLY REVIEWED PROTOCOLS

- Group V sr4PLA2 and Atherosclerosis Macrophage-derived GX secretory phospholipase AA2 and atherosclerosis B03-272

Comments:

3. Lab audit performed when you are moved into laboratory facilities
4. Certification of biological safety cabinets.

Action: Lou Hersh moved and Richard Wheaton seconded **provisional approval** upon completion of comments. The vote was unanimous.

- **B03-283** - Adenoviral delivery of the Hpr6.6 protein

B03-281 - The role of Dap1p and Hpr6.6 in damage repair and cancer

Comments:

5. Change 0.5% NaCl to 0.5% NaOCl.

2. Certification of biological safety cabinets

Action: Anthony Sinai moved and Lou Hersh seconded **provisional approval granted** upon revisions and BSC certification.

New Business:

The committee was reminded about the training and dinner will be September 17, 2003 at 5pm at the Faculty Club.

An update on the testing of the growth chamber used by for blue mold experiments was handed out to the members.

The meeting ended at 1:30pm.

MINUTES
Institutional Biosafety Committee
Wednesday, October 8, 2003

Members Present

Arthur Hunt
Peter Nagy
Thomas Chambers
Eric Smart
Lou Hersh
Brian Rymond
Marcia Finucane
Jack Hiatt
Kenneth Dickey
Chuck Staben
Peter Nagy
Robert Jacob

Members Absent

Nader Hanna
Glenn Telling
Kelly Breeding
Richard Wheaton
Anthony Sinai

COMMITTEE BUSINESS

The meeting was called to order at 12:10am. The order of protocol review was changed to accommodate members who had to leave early.

OLD COMMITTEE BUSINESS

Minutes of the September 10, 2003 IBC meeting were unanimously approved with no modifications.

PROTOCOLS MEETING FULL APPROVAL REQUIREMENTS:

B03-283 Adenoviral delivery of the Hpr6.6 protein

B03-285 - Development of ligand inducible gene switches for simultaneous and independent regulation of expression of two genes in transgenic tobacco plants

B03-273 - Re-activation of Murine cytomegalovirus in Bone marrow transplantation and its impact on pneumonitis

PROTOCOLS WAITING ON MOVE INTO NEW FACILITIES AND/OR BSC CERTIFICATION FOR FULL APPROVAL:

B03-272 - Group V sPLA2 and atherosclerosis"; "Macrophage-derived GX secretory phospholipase A2 and atherosclerosis

B03-289 - Class B scavenger receptors and foam cell formation; HDL receptor SR-BI: influence of apoAII

B03-288 - SAA and sPLA2: Role in atherogenesis

B03-287 - Characterization the role of Abelson kinases in growth factor signaling

B03-277 - Role of Glutathione Reductase and Glutaredoxin in Oxidative Stress-Induced Macrophage Dysfunction and Cell Death

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

- B03-281** - The role of Dap1p and Hpr6.6 in damage repair and cancer
- B03-293** - Molecular Mechanisms of dietary fatty acids on breast cancer growth and development
- B03-275** - Cell-Permeable Small-Molecule Proteolysis Inducers

PREVIOUSLY REVIEWED PROTOCOLS, RESUBMITTED:

B03-274 - Natural killer cells in health, aging, cancer and infection

Provisionally approved pending revisions addressing the following:

1. Specifically state how the free EBV will be used once produced by the marmoset cells
2. Complete the tissue/cell culture section in the infectious agent form
3. Complete the biological safety cabinet certification information

A motion was made by Eric Smart, seconded by Art Hunt, that the revision be e-mailed to the IBC members and that they e-mail their accept/deny vote to the BSO. If the majority of the members accept the revision, full approval will be given. A unanimous vote accepted this motion.

NEW BUSINESS

PROTOCOL REVIEW

B03-291 - Effects of dietary fatty acids on HUVEC, Effects of Tat protein on tight junction proteins, Effects of Tat protein on PPAR activity, Effects of Nicotine on cultured spinal cord neurons

Provisionally approved pending the receipt of the following information and revisions:

1. Please supply a copy of the UK and/or hospital IRB approvals or exemptions which cover the current source of the umbilical cords
2. All laboratory workers need to take the Hazardous Material training, then send copies of the certificate to the BSO
3. Change the first page of the form, #1, no infectious agents are being worked with; human cell lines are considered potentially infectious and do not require the infectious agent form
4. Who is performing the screening for human pathogens, who is paying for this testing, which pathogens in particular?
5. Add homogenization and surgery to procedures that will be performed in the BSC (page 8, 1A)
6. Do not list the "agents" in the laboratory on the biohazard signs on the doors to the laboratories
7. Send the BSO the final procedure for transporting animals from the animal facility to your laboratory and a copy of the IACUC approval
8. Successful completion of laboratory biosafety audit and certification of the biological safety cabinet

Chuck Staben moved and Eric Smart seconded that full approval be granted after the BSO receives this information. It was unanimously passed.

B03-292- Natural Product Inhibitors and their Biological Targets in Angiogenesis

Full approval was granted. The motion was made by Lou Hersh, seconded by Robert Jacob, and carried unanimously.

B03-290 - Axonal growth and guidance for nervous system repair.

Provisional approval granted, pending receipt of the following revisions:

1. On page 3, section dealing with animal bites, the recommended disinfectant is either iodine or chlorhexidine ' not sodium hypochlorite;
It is recommended that if a bitten person's tetanus vaccination is over three years old, they seek the advice of Worker's Care
2. State in the protocol that all adenovirus production and purification is carried out in the PI's lab, not a shared facility and that the centrifuge used is in that dedicated room
3. State the species of the source of the DNA in the rDNA form
4. Describe the lab coats used, especially when performing manipulations, like the injections, outside of the biological safety cabinet. Please note what the BSO has recommended as a prototype (water resistant, knit cuffed, solid front, closure in the back, disposable, worn only in the surgical room).
5. Contact David Acker in Occupational Health & Safety for the fit testing of the disposable respirators workers will wear when performing the injections and consult <http://ehs.uky.edu/ohs/respgate.html> for a respirator program

Eric Smart moved, Robert Jacob seconded, the motion carried unanimously.

COMMITTEE BUSINESS

ITEM FOR DISCUSSION: Registration of diagnostic work for plant pathogens : Extension laboratory

After a discussion of various options, it was decided that the BSO will work with the director of the laboratory, Dr. Vincelli, to develop a safety SOP for the laboratory in general. The IBC will review, make suggestions, and finally approve a general plan for the diagnostic work.

Criteria for which research projects require IBC review and approval will also be developed and sent to the IBC for approval.

The meeting was adjourned at 1:15pm.

MINUTES
Institutional Biosafety Committee
Wednesday, November 12, 2003

Members Present

Arthur Hunt
Peter Nagy
Thomas Chambers
Eric Smart
Anthony Sinal
Brian Rymond
Marcia Finucane
Jack Hiatt
Kenneth Dickey
Chuck Staben
Peter Nagy
Robert Jacob
Kelly Breeding
Nader Hanna

Members Absent

Lou Hersh
Glenn Telling
Richard Wheaton

COMMITTEE BUSINESS

The meeting was called to order at 12:10am by Tom Chambers..

Committee members given hand out on cell disruption procedures which are alternatives to sonication, the NIH letter finding the University of Kentucky Institutional Biosafety Committee compliant for another year (September 22, 2004), and samples of the biohazard labels given to researchers who require appropriate signage.

OLD COMMITTEE BUSINESS

Minutes of the October 8, 2003 IBC meeting were unanimously approved with only one modification in the list of members present (Robert Jacob added).

PROTOCOLS MEETING FULL APPROVAL REQUIREMENTS:

- B03-292** - Natural Product Inhibitors and their Biological Targets In Angiogenesis
- B03-286** - Pathogenic mechanisms of chronic wasting disease and scrapie prions
- B03-274** - Natural killer cells in health, aging, cancer, and infection
- B03-290** - Axonal growth and guidance for nervous system repair

PROTOCOLS WAITING ON MOVE INTO NEW FACILITIES AND/OR BSC CERTIFICATION FOR FULL APPROVAL:

- B03-272** - Group V sPLA2 and atherosclerosis"; "Macrophage-derived GX secretory phospholipase A2 and atherosclerosis
- B03-289** - Class B scavenger receptors and foam cell formation; HDL receptor SR-BI: influence of apoAII
- B03-288** - SAA and sPLA2: Role in atherogenesis
- B03-287** - Characterization the role of Abelson kinases in growth factor signaling

B03-277 Role of Glutathione Reductase and Glutaredoxin in Oxidative Stress-Induced Macrophage Dysfunction and Cell Death

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B03-293 Molecular Mechanisms of dietary fatty acids on breast cancer growth and development

B03-296 - Drosophila chromosome structure and function

MODIFICATIONS

B011219191 - GV-001.003 An Open Label, Phase I, Dose-Escalation Study of TNFerade Biologic with Radiation Therapy as an Adjunct to Surgery or for Palliation in Soft Tissue Sarcoma of the Extremities, Amendment 2, April 20, 2002 GenVec, Inc.

- Personnel changes

NEW BUSINESS

PROTOCOL REVIEW

B03-295 . - Mechanisms of Ocular Vascular Regression

Fully approved, pending :

1. remove reference to serum banking, p.16, #28; UK does not keep serum banks
2. add sentence addressing the issue of the testing for reactivation of the replication incompetent adenovirus, who does it and where
3. naked plasmids do not require an infectious agent form, remove this page from the application

Robert Jacob moved, Eric Smart seconded the motion, it carried unanimously.

Meeting was adjourned at 12:26pm by Tom Chambers after Eric Smart moved and Art Hunt seconded the motion.

MINUTES
Institutional Biosafety Committee
Wednesday, January 14, 2004

Members Present:

Arthur Hunt
Peter Nagy
Thomas Chambers
Eric Smart
Brian Rymond
Marcia Finucane
Kenneth Dickey
Chuck Staben
Peter Nagy
Kelly Breeding
Glenn Telling
Richard Wheaton

Members Absent

Lou Hersh
Anthony Sinai
Jack Hiatt
Robert Jacob
Nader Hanna

COMMITTEE BUSINESS

The meeting was called to order at 12:10am by Tom Chambers.. It was adjourned at 2:30pm.

OLD COMMITTEE BUSINESS

Minutes of the November 12, 2003 IBC meeting were unanimously approved .

NEW BUSINESS

PROTOCOL REVIEW

B03-294 – - SWOG S0011: A Phase II Trial of Surgery with Perioperative INGN 201 (Ad5CMV-p53) Gene Therapy Followed by Chemoradiotherapy for Advanced Resectable Squamous Cell Carcinoma of the Oral Cavity and Oropharynx IRB# 03-0667-F2L (INGN 201, Gene Therapy Phase II Trial)

attended the meeting 12:30 -1:05pm for questions and discussion.

The committee decided to **send the protocol back** to the researcher for further revisions and additions. The following issues need to be addressed in an "Infection Control" document:

1. **Locations:** for the second inoculation will be used; special, designated rooms should be used for this type of procedure
2. **Biohazardous waste:** details of how this will be handled in the and after the patient goes home
3. **Shedding:** a discussion of the dissemination within the patient and shedding from the patient of the recombinant virus. Please include how this will be monitored and the criteria to be used to determine when it is safe to send the patient home. (Since there is not much of this type of data published, the protocol designers are **strongly urged** to include this in the study design. If the sponsoring company has such data available, it would be most helpful to the IBC if it was made available for review.)
4. **Staff:** Please name the backup physicians and all staff from the who will deal with the patient, or with the biohazardous waste from the patient, and cleaning/decontamination of rooms used by the patient. Is strongly urged to collaborate with another University of Kentucky researcher with either laboratory or clinical experience with adenoviral vectors.

5. **Training:** Details of the staff training about gene transfer and this particular protocol must be discussed. Who is to give the training? This training should give the staff basic information about the vector (how it is replication defective and what that means, how it is manufactured, without divulging proprietary information), details of the protocol as it relates to each staff member, infection control procedures, spill procedures, exposure control plan that includes the worker's care information, etc.

The dates, times and location of this training must be submitted to the Biological Safety Officer with sufficient notice so that she can arrange to be present. An attendance sheet documenting who received the training will also be kept in the IBC file. This training must be finished before patients can be enrolled.

Patient training: instructions the patient will receive about wound care, infection control, care after discharge, etc. should also be discussed. Any visitation restrictions, instructions to family members should also be discussed.

6. **Patient/Drainage tube:** details of the drainage tube, how it will be handled, emptied, and other infection control measures (such as screening staff with active adenovirus-like respiratory infections, preventing the patient's contact with immunocompromised persons) should be discussed.

7. **Harm to the patient:** what are the "worse case scenarios" for the patient regarding exposure to this recombinant virus and the risk that these events might occur? (e.g. replication defective virus recombines with endogenous adenovirus to form a replication competent virus containing the p53 gene, recombination of the viral and patient p53 genes, injection of the biologic into the bloodstream, etc).

8. **Decontamination:** Dr. Marty Evans, an infectious disease specialist with knowledge and experience in infection control with gene transfer protocols, has recommended that a freshly mixed solution of 0.5% sodium hypochlorite (bleach) be used for decontamination of all hard surfaces in rooms where procedures are conducted, especially the operating room and procedure room. This is a different disinfectant from the regular hospital disinfectant/cleaner, A-456N (a quaternary ammonia). Sufficient time must be allotted to the thorough decontamination of the operating room after the initial surgery and inoculation, before the next surgery can take place in that room.

To be considered at the February 11, 2004 meeting, revisions and additions must be sent to the Biological Safety officer by January 30, 2004.

B03-301 - - Production of antibodies to equine cytokines

Provisionally approved, full approval is pending the following changes and procedures:

1. Insert the IACUC approval number on page 1
2. Check "yes" on page 8, using radioactive material in the BSC
3. Insert the appropriate form for personnel working the lab
3. Complete biosafety audit

Art Hunt moved and Peter Nagy seconded, the vote was unanimous for provisional approval.

B03-299 - - The safety, tolerability, and immunogenicity of ACAM2000 smallpox vaccine in adults without previous smallpox vaccination (H-400-009).

B03-304 - The safety, tolerability, and immunogenicity of ACAM2000 smallpox vaccine in adults with previous smallpox vaccination (H-400-012).

Provisionally approval, full approval is pending the following changes and procedures in both protocols:

1. Please provide data from the manufacturer on the testing of Wescodyne against vaccinia. The committee would like to review the actual test results. The BSO will work with you in obtaining this information.
2. Wescodyne should be made up fresh each day that vaccinations or follow up visits are planned. The proper dilution is 6oz./5 gallons, or approximately 1:100. Please add this to the spill procedure item #1.

3. In the Personnel section, please state whether blood borne pathogen training is up to date for each staff member.
4. On pages 8 & 9 in the safety plan: the "should" to be changed to "will"; also, change "study team members will be asked to wear" to "study team members will wear"
5. In the paragraph discussing adverse event reporting on page 8, add a sentence outlining the conditions which must be reported to the IBC:
fever or rash within 2 weeks of vaccination
cardiac complications at any time during the study
These reports should refer to the IBC approval # and have the patient's study identification # clearly marked so that initial and follow up reports can be matched up.
6. In the safety plan, add a paragraph addressing the handling of biohazardous waste. The IBC decided using "standard precautions" that are used for all hazardous waste is sufficient. It is to be emphasized to the environmental maintenance staff that the bins are to be taken directly to the locked storage cage on the loading dock of the to await transport to the incinerator by Stericycle. If the biohazardous disposal system changes, the Biological Safety Officer is to be notified immediately.

The motion was made by Eric Smart and seconded by Richard Wheaton. The vote for unanimously for the motion.

PROTOCOL REQUESTING MODIFICATIONS

B03-273 - Re-activation of Murine cytomegalovirus in Bone marrow transplantation and its impact on pneumonitis

Adding *Pneumocystis. carinii (jaroveci)* to infectious agents in research.

Provisionally approved, pending receipt of information about the strain to be used is a murine adapted strain.

The motion was made by Chuck Staben and seconded by Peter Nagy. The vote

COMMITTEE BUSINESS

ITEM FOR DISCUSSION:

1. IBC definition of quorum
2. Autoclave validation program
3. Signs for BSL2-P laboratories
4. Field trials with pharmaceutical plants
5. Report of the Fink Committee

PROTOCOL PENDING INVESTIGATOR RESPONSE/ACTION

B03-295 - Mechanisms of Ocular Vascular Regression

PROTOCOLS WAITING ON MOVE INTO NEW FACILITIES AND/OR BSC CERTIFICATION FOR FULL APPROVAL:

B03-272 - Group V sPLA2 and atherosclerosis"; "Macrophage-derived GX secretory phospholipase A2 and atherosclerosis

B03-289 - Class B scavenger receptors and foam cell formation; HDL receptor SR-BI: influence of apoAII

B03-288 - SAA and sPLA2: Role in atherogenesis

B03-287 - Characterization the role of Abelson kinases in growth factor signaling

B03-277 - Role of Glutathione Reductase and Glutaredoxin in Oxidative Stress-Induced Macrophage Dysfunction and Cell Death

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B03-298 – - Somatic cell transformation of insect cells and larvae

MINUTES
Institutional Biosafety Committee
Wednesday, February 11, 2004

Members Present:

Arthur Hunt
Lou Hersh
Thomas Chambers
Jack Hiatt
Robert Jacob
Nader Hanna
Marcia Finucane
Kenneth Dickey
Chuck Staben
Kelly Breeding
Glenn Telling
Richard Wheaton

Members Absent

Brian Rymond
Anthony Sinal
Eric Smart
Peter Nagy

COMMITTEE BUSINESS

The meeting was called to order at 12:09am by Tom Chambers.. It was adjourned at 2:30pm.

OLD COMMITTEE BUSINESS

Minutes of the January 14, 2004 IBC meeting were unanimously approved . Dr. Telling moved and Dr. Dickey seconded.

ITEMS FOR DISCUSSION:

1. Autoclave validation program

Suggested that each bag of biohazardous waste autoclaved have a "Comply" strip attached by the researcher or his/her designated person, to indicate that the proper conditions were met for decontamination before disposal into the dumpster/landfill. This is to be substituted for the requirement of the maintenance of a logbook in each research lab. The requirement for monthly testing of each set of parameters used to decontaminate waste in each autoclave and the results recorded in a log book for the autoclave room/facility remains. This is to be the responsibility of the owner of the autoclave.

2. Signs for BSL2-P laboratories
No objections

3. Report of the Fink Committee
Handed out, not discussed

NEW BUSINESS

PROTOCOL REVIEW

B03-294 – - SWOG S0011: A Phase II Trial of Surgery with Perioperative INGN 201 (Ad5CMV-p53) Gene Therapy Followed by Chemoradiotherapy for Advanced Resectable Squamous Cell Carcinoma of the Oral Cavity and Oropharynx IRB# 03-0667-F2L (INGN 201, Gene Therapy Phase II Trial) (reconsideration of gene transfer protocol with investigator's responses)
Provisional approval was granted, pending compliance with the following conditions:

1. meets with and works with Dr. Marty Evans (Infection Control), Ms. Sharon Berry (Infection Control) and Marcia Finucane (Biological Safety Officer) to produce a complete and

detailed exposure control plan and spill plan. Dr. Nader Hanna also offered to consult on this document. This document should include:

- a. definition of what constitutes medical regulated waste for this protocol, which is to be collected in specially marked (gene transfer protocol) containers and picked up by Hazardous Material Management for incineration, and what constitutes regular waste, to be disposed of by hospital or MCC environmental services per standard procedures
 - b. how personnel handling the viral preparation and how the patient will be protected during the administration of the gene transfer agent and during the maintenance of the drainage tube (personal protective equipment, procedures)
 - c. name and dilution of the hospital disinfectant (the requirement to use 10% bleach is dropped)
 - d. specify that occlusive dressings will be used for the surgical wound which will be inoculated with the gene transfer agent, to minimize shedding of the virus from the wound site
2. A copy of the Power Point presentation (or written outline) used in the training of hospital and Markey Cancer Center staff is to be sent to the BSO and will be placed in the IBC file for this protocol
- a. training to be given, at a minimum, twice at dates and times so that different shifts can attend
 - b. sign in sheets of those present at the training will be kept in Infection Control office and copies placed in the IBC file
 - c. names of relevant nurse managers, supervisors, etc. who will be charged with the care of patients in this protocol shall placed in the IBC file
 - d. representatives of hospital Infection Control and of the Biological Safety Office will be present at the larger training sessions to assist in answering any questions the staff may have
 - e. procedures for training personnel who do not attend the formal training sessions will be described
3. Hard copies of the exposure/spill control plan and of the training will be easily accessible at the nurse's station at each location the patient will be treated (OR, ICU, MCC-2)

Louis Hersh moved and Dr. Hanna seconded that provisional approval be granted. The vote was unanimous.

B04-308 – - Signaling Pathway regulating the fate-determination of neural stem cells in the adult hippocampal dentate gyrus

Returned to Investigator for further revisions.

1. in the rDNA attachments, please give more details about what the specific wild type genes normally do, and what the mutant genes are expected to do when expressed
2. in the scientific summary, describe why the 293 cells are infected, what will be done with the cells or if used to produce viruses, what will be done with the viruses; give a summary of what the recombinant adenovirus and retrovirus are used for
3. if animals are to be infected with these viruses, surgeries with these animals must be performed in a biological safety cabinet (not a fume hood) in order to contain the recombinant viruses; Isoflurane exposure can be addressed by the use of a scavenger; please consult with Dr. Ken Dickey in the DLAR or his staff about this
4. after this issue is worked out with DLAR, specify where these surgeries will take place, in the animal facility or your laboratory and the specifics of biological and chemical containment

5. on page 7, regarding the ultracentrifuge: state whether a swinging bucket or fixed rotor will be used and that this will be disinfected with what disinfectant after each use. Quarternary ammonium compounds are recommended because they are not corrosive to the equipment (A456-N is used in the hospital)
6. it should be stated that loading and unloading of the buckets with lids or the rotors, when used with viruses, will be done in a biological safety cabinet
7. a biosafety laboratory audit must be performed before work can be initiated

B04-306 - Efficacy of experimental vaccines for prevention of viremia following exposure of horses to equine herpesvirus-

Provisional approval was granted pending compliance with the following conditions:

1. completion of biosafety laboratory audit
2. addition of the particular strain of herpesvirus-1 used
3. addition of IACUC approval # 641A2003

Dr. Jacob moved, and Dr. Dickey seconded. The vote was unanimous.

PROTOCOLS REQUESTING MODIFICATIONS

B03-283-M - Modification of Adenoviral delivery of the Hpr6.6 protein
Room change noted.

PROTOCOLS MEETING IBC CONDITIONS AND GRANTED FULL APPROVAL:

B03-277 - Role of Glutathione Reductase and Glutaredoxin in Oxidative Stress-Induced Macrophage Dysfunction and Cell Death

B03-287 - Characterization the role of Abelson kinases in growth factor signalling

OLD BUSINESS:

PROTOCOL PENDING INVESTIGATOR RESPONSE/ACTION

B03-295 - Mechanisms of Ocular Vascular Regression
Testing requested by the IBC is progressing.

PROTOCOLS WAITING ON MOVE INTO NEW FACILITIES AND/OR BSC CERTIFICATION AND/OR BIOSAFETY LAB AUDIT FOR FULL APPROVAL:

B03-272 - Group V sPLA2 and atherosclerosis": "Macrophage-derived GX secretory phospholipase A2 and atherosclerosis

B03-289 - Class B scavenger receptors and foam cell formation; HDL receptor SR-BI: Influence of apoAII

B03-288 - SAA and sPLA2: Role in atherogenesis

B03-301 - Production of antibodies to equine cytokines
Lab audit pending.

PROTOCOL WITHDRAWN

B03-273-M - Re-activation of Murine cytomegalovirus in Bone marrow transplantation and its impact on pneumonitis

Adding *Pneumocystis. carinii* (Jarovec) to infectious agents in research.
Will keep this work at the VA facility

MINUTES
Institutional Biosafety Committee
Wednesday, March 10, 2004, 12:00 P.M.
308 Combs Cancer Research Center

Members Present

Thomas Chambers
Kenneth Dickey
Marcia Finucane
Nader Hanna
Jack Hiatt
Arthur Hunt
Robert Jacob
Peter Nagy
Brian Rymond
Anthony Sinai
Eric Smart
Chuck Staben
Richard Wheaton

Members Absent

Kelly Breeding
Louis Hersh
Glenn Telling

COMMITTEE BUSINESS

The meeting was called to order at 12:07pm by Tom Chambers.

The minutes of February 11, 2004 IBC meeting were unanimously approved. Chuck Staben moved, Richard Wheaton seconded.

RECONSIDERATION OF REVISED PROTOCOLS

B03-294 - - INGN 201. GENE THERAPY PHASE II TRIAL
SWOG S0011: A Phase II Trial of Surgery with Perioperative INGN 201 (Ad5CMV-p53) Gene
Therapy Followed by Chemoradiotherapy for Advanced Resectable Squamous Cell Carcinoma of
the Oral Cavity and Oropharynx

and were available at 12:30pm for discussion of the exposure control plan for this protocol.

Full Approval was granted. Eric Smart moved. Richard Wheaton seconded. The vote was unanimous.

The Biological Safety Officer will send an e-mail to Dr. McCormick, director of the UK Hospital Infection Control Department, asking that the hospital policy on gene therapy/transfer be revised to use standard precautions for disposal of gene therapy/transfer waste. The policy currently has this waste disposed of by Hazardous Materials Management. The preponderance of reports in the literature indicate that if the inoculation of recombinant adenoviral vector is $\leq 10^{13}$ pfu/dose, standard precautions are sufficient.

B04-308 - - Signaling Pathway regulating the fate-determination of neural stem
cells in the adult hippocampal dentate gyrus (REVISED)

Provisional Approval was granted pending compliance with the following conditions:

1. All (not most) work should be done using a biological safety cabinet, page 4.
2. Explain that dialysis waste from the purification of virus will be decontaminated with bleach, final concentration of 0.5% sodium hypochlorite, page 3.
3. Certification of biological safety cabinets
4. Laboratory biosafety audit

Eric Smart moved. Nader Hanna seconded. The vote was unanimous.

NEW BUSINESS

NEW PROTOCOL REVIEW

B04-310 – - To study the role of Manganese Superoxide Dismutase in the progression of certain types of tumor cell lines

Provisional Approval was granted pending compliance with the following conditions:

1. Blood born pathogen training was taken five years ago (see p. 5).
Please renew training through the on-line course at
<http://ehs.uky.edu/classes/bloodborne/bptrain.html>
and send copies of certificates to the Biological Safety Officer
Please fill in dates of lab safety and hazardous material training

2. Make sure cell homogenates are prepared in a biological safety hood (see p. 4).

Eric Smart moved. Chuck. Staben seconded. The vote was unanimous.

COMMITTEE BUSINESS

1. Autoclave verification program: review of next draft:

discussion was focused on minor concerns.

a. Practicality discussed. Label on outside of bag suggested.

b. Where will money come from to pay for supervision of autoclaves?

Approval was granted with the suggestion that the phrase "Use dry cycle" be removed.

Anthony Sinai moved. Art Hunt seconded. The vote was unanimous.

2. IRB/IBC Internal Adverse Event Form

-IBC-will only use this for gene transfers in human subjects enrolled in clinical trials at UK.

Full approval granted. Ken Dickey moved. Richard Wheaton seconded.

The vote was unanimous.

3. Vaccinia policy discussion (handouts given at meeting)

-We need a policy at UK. Should we simply use the CDC recommendations?

-Recommendations from IBC members requested.

Motion to adjourn was made by Brian Rymond and seconded by Robert Jacob. The vote was unanimous. The meeting was adjourned at 1:25pm.

BSO UPDATE ON PROTOCOLS:

PROTOCOL PENDING INVESTIGATOR RESPONSE/ACTION

B03-295

- Mechanisms of Ocular Vascular Regression

Results of RCA testing presented.

-Meets requirements of IBC. Full approval can now be sent to

PROTOCOLS WAITING ON MOVE INTO NEW FACILITIES AND/OR BSC CERTIFICATION FOR FULL APPROVAL:

B03-272

- Group V sPLA2 and atherosclerosis; "Macrophage-derived GX secretory phospholipase A2 and atherosclerosis

B03-289

- Class B scavenger receptors and foam cell formation; HDL receptor SR-BI; influence of apoAII

B03-288

- SAA and sPLA2; Role in atherogenesis

PROTOCOL MEETING FULL APPROVAL REQUIREMENTS:

B04-306 · Efficacy of experimental vaccines for prevention of viremia following exposure of horses to equine herpesvirus-

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B04-305-BBP · Human Adipose Studies in the Nude Mouse Model

B04-307-BBP – Proteoglycans and Artherosclerosis

B04-312-BBP r – Aspirin Related Gene Expression

MINUTES
Institutional Biosafety Committee
Wednesday, April 14, 2004

Members Present

Thomas Chambers
Kenneth Dickey
Marcia Finucane
Nader Hanna
Arthur Hunt
Peter Nagy
Brian Rymond
Anthony Sinai
Eric Smart
Chuck Staben
Richard Wheaton
Kelly Breeding

Members Absent

**Louis Hersh
Glenn Telling
Robert Jacob
Jack Hiatt**

COMMITTEE BUSINESS

The meeting was called to order at 11:59 pm by Tom Chambers.

The minutes of March 10, 2004 IBC meeting were unanimously approved. Anthony Sinai moved. Brian Rymond seconded.

NEW BUSINESS

NEW PROTOCOL REVIEW

B04-316 The safety, tolerability, and immunogenicity of three dose levels of ACAM3000 modified vaccinia Ankara (MVA) smallpox vaccine in adults without previous smallpox vaccination: A double-blind, placebo-controlled, dose-ranging, phase I study followed by a challenge with Dryvax® smallpox vaccine

Full approval granted. Chuck Staben moved. Anthony Sinai seconded. The vote was unanimous.

B03-317 Responses of *Nicotiana* hybrids to tobacco mosaic virus
Full approval granted. Arthur Hunt moved. Peter Nagy seconded. The vote was unanimous.

B04-313 Mare reproductive loss syndrome bacterial infections: Ongoing research on uterine-conceptus interactions, and mare/stallion fertility
Full approval granted. Richard Wheaton moved. Arthur Hunt seconded. The vote was unanimous.

B020620206 2 modifications to THRI field trial project
Provisional approval was granted pending compliance with the following condition:
 1. Copy of APHIS permit filed with protocol modifications.
 Chuck Staben moved. Ken Dickey seconded. The vote was unanimous.

COMMITTEE BUSINESS

1. The group discussed confidentiality issues related to protocols submitted to the IBC. It was decided that a copy of any confidentiality agreements between UK and any outside sponsor or company be submitted with the IBC application. M. Finucane will also have a "non-disclosure/confidentiality" and "conflict of interest" document drafted for IBC approval. If

adopted, every member of the IBC would sign this document when they join the committee.

2. The group determined there is a need for policies to be developed to offer or strongly suggest employees potentially exposed to vaccinia virus, recombinant vaccinia viruses, and other Orthopoxviruses receive vaccinia vaccination as follows:
 - a. Health care workers who may contact only **highly attenuated** vaccinia strains (MVA, NYVAC, ALVAC, and TROVAC) may be offered vaccination with Dryvax® (or other FDA-approved vaccine). It is **not required**. The health care worker may decline vaccination without reassignment.
 - b. Laboratory and health-care personnel who may contact **nonhighly attenuated** vaccinia strains (NYCBOH strain, WR strain, recombinants using the Copenhagen and Lister vaccinia strains) are at risk of infection and **must be offered** vaccination with Dryvax® (or other FDA-approved vaccine). If declined, the Principal Investigator may reassign the employee if he/she deems it necessary to avoid putting the employee at serious risk.
 - c. Laboratory workers who directly handle cultures or animals contaminated or infected with **nonhighly attenuated** vaccinia virus, **recombinant** vaccinia viruses derived from **nonhighly attenuated** vaccinia strains, or **other orthopoxviruses** that infect humans (monkeypox, cowpox, vaccinia, and variola) **MUST** be offered vaccination. If declined, the Principal Investigator may reassign the employee if he/she deems it necessary to avoid putting the employee at serious risk.
 - d. Revaccination every 10 years should be considered for personnel working with nonhighly attenuated vaccinia viruses
 - e. Personnel working with nonvariola Orthopoxviruses (monkeypox) should consider revaccination every 3 years.

These recommendations are based on the 2001 Advisory Committee on Immunization Practices report "Vaccinia (Smallpox) Vaccine Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2001." MMWR 50 (RR10); 1-25.

Action Item: M. Finucane will research proper funding mechanisms to cover cost of employee vaccinations. M. Finucane will also draft this policy and disseminate electronically for committee comments and approval.

3. The committee would like to see a current APHIS checklist for field release of an organism that is engineered to produce products intended for pharmaceutical use, bioremediation, or industrial nonfood/feed use. M. Finucane will provide copies to members via a weblink or hard copy distributed at the next meeting.

BSO UPDATE ON PROTOCOLS

PROTOCOLS MEETING FULL APPROVAL REQUIREMENTS:

B04-310 - To study the role of Manganese Superoxide Dismutase in the progression of certain types of tumor cell lines

B03-272 - Group V sPLA2 and atherosclerosis; Macrophage-derived GX secretory phospholipase A2 and atherosclerosis

B03-289 - Class B scavenger receptors and foam cell formation; HDL receptor SR-BI; Influence of apoAII

B03-288 - SAA and sPLA1: Role in atherogenesis

PROTOCOLS ISSUED REGISTRATION NUMBERS:

These protocols do not require review by IBC and are registered with the BSO

B04-311-BBP

– Blue Grass Care Clinic Exercise Intervention

**B04-318 –
Pacemaker**

- Neural Mechanisms of Resetting of the Aged Circadian

Motion to adjourn was made by Richard Wheaton and seconded by Chuck Staben. The vote was unanimous. The meeting was adjourned at 1:08 pm.

MINUTES
Institutional Biosafety Committee
Wednesday, May 19, 2004

Members Present

Kelly Breeding
Thomas Chambers
Louis Hersh
Jack Hiatt
Arthur Hunt
Robert Jacob
Peter Nagy
Brian Rymond
Kathy Sandford
Anthony Sinal
Chuck Staben

Members Absent

**Kenneth Dickey
Marcia Finucane
Nader Hanna
Eric Smart
Glenn Telling
Richard Wheaton**

OLD COMMITTEE BUSINESS

The meeting was called to order at 12:07 pm by Tom Chambers.

The minutes of April 14, 2004 IBC meeting were unanimously approved. Chuck Staben moved. Anthony Sinai seconded.

NEW BUSINESS

NEW PROTOCOL REVIEW

B04-314 - HOST RESPONSE TO P. CARINII IN NEONATAL MICE

The committee decided to send the protocol back to the researcher for further revisions and additions. The following issues need to be addressed:

1. Will *P. carinii* f. sp. hominis to be used in project?
2. Clarify which procedures are carried out in the ' ...'
3. Provide details on in vitro work in ' ...'
4. Type of transgenic mice used.
5. This work should be done at ' ...'

B04-322 - EVALUATION OF BACTERIAL ENDOPHYTES OF GRASS- AND LEGUME-FORAGES AS EMERGING CAUSES OF REPRODUCTIVE LOSS DISEASE IN AGRICULTURAL HERBIVORES

The committee decided to send the protocol back to the researcher for further revisions and additions. The following issues need to be addressed:

1. **Background information describing previous work and identification of these bacteria.** Description of the bacterial strains that will be used for the experiments—are these pure-culture isolates already prepared in the laboratory? Are they mixed cultures from natural materials, with potential for unknown components? Characterize the strains to be used. If the strains are largely uncharacterized, address the biosafety problems that could occur.
2. **Describe animal carcass transport.** Please describe handling and final disposal of the carcasses.
3. **Quantify and identify the oral inoculum.**
4. **Describe whether and how the agent may be spread.** Describe decontamination of animal waste and also decontamination of the infected animal facility.

5. The PI should complete training in the following areas:

Blood-borne pathogen
Lab specific safety training
Hazardous Materials
DOT/IATA Shipping

B04-323

– role of intraspinal plasticity in autonomic dysreflexia

The committee decided to send the protocol back to the researcher for further revisions and additions. The following issues need to be addressed:

1. A letter from Dr. George Smith in support of this project.
2. Details about how the pseudorabies will be perpetuated in the lab and in which lab this work will be done.
3. Maps of the vector if it is a derivative of Ad-Easy (commercial) or a clear description (p. 15).
4. A paragraph or more on pseudorabies as it pertains to this work.
5. Change the protocol to reflect that the vector is able to alter cell cycle.

B04- 324

– MOLECULAR GENETICS OF THE PHYTOPATHIC FUNGUS

MAGNAPORTHE GRISEA

Mark Farman attended the IBC meeting to discuss his submission and prior work with M. grisea. The committee decided to send the protocol back to the researcher and requests resubmission as at least two separate protocols.

COMMITTEE BUSINESS

Non-disclosure/confidentiality statement

IBC decided postpone a decision until Katherine Adams can provide further explanation.

Action item: BSO will invite K. Adams to next IBC meeting for clarification.

BSO UPDATE ON PROTOCOLS

PROTOCOLS MEETING FULL APPROVAL REQUIREMENTS

B020620206-M-4 KTRDC Field Trial Modification

, **B020620206-M-5** KTRDC Field Trial Modification

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B04-321-BBP CAM Drugs for the Treatment of Cancer

B04-320-FT Benefits of the Roundup Ready Alfalfa Weed Control System 2004

B03-298 - Somatic cell transformation of insect cells and larvae

B04-318 – Neural mechanisms of resetting of the aged circadian pacemaker

B04-325 – Evaluation of transgenic corn for southwestern corn borer resistance

Motion to adjourn was made by Robert Jacob and seconded by Kelly Breeding. The vote was unanimous. The meeting was adjourned at 2:15 pm.

Discussion/Review of protocols B010724167-Advanced Genetic Technologies and B98021966- Molecular Biology of Phytopathogenic Fungi.

After a brief discussion, the committee asked Tom Chambers to send a memo to Wendy Baldwin, Executive Vice President for Research regarding : previous approvals.

Motion to adjourn was made by Eric Smart and seconded by Richard Wheaton. The meeting was adjourned at 12:40pm.

MINUTES

Institutional Biosafety Committee
Wednesday, July 14, 2004
308 Combs Cancer Research Center

Members Present

Thomas Chambers
Nader Hanna
Kenneth Dickey
Marcia Finucane
Glenn Telling
Jack Hiatt
Eric Smart
Robert Jacob
Richard Wheaton
Louis Hersh

Members Absent

Chuck Staben
Anthony Sinai
Peter Nagy
Brian Rymond
Kelly Breeding
Arthur Hunt

COMMITTEE BUSINESS

The meeting was called to order at 12:05 pm by Tom Chambers.
The minutes of June 9, 2004 IBC meeting were unanimously approved. Eric Smart moved.
Louis Hersh seconded.

NEW BUSINESS

NEW PROTOCOL REVIEW

B04-328

- Equine Influenza

Full Approval was granted. Kenneth Dickey moved. Eric Smart seconded. The vote was unanimous.

B04-329

- PANVAC-VF, phase III

Discussion only. No protocol had been submitted. Background documents were provided by Marcia Finucane.

COMMITTEE BUSINESS

Non-disclosure/confidentiality statements were signed by all present members. Copies of signed forms will be sent back to IBC members via campus mail.

Marcia Finucane updated the Committee as to the progress of the autoclave verification program scheduled to be implemented in the fall.

The Committee agreed that the present meeting time, the second Wednesday of every month from 12-2 was acceptable for the coming year.

The Committee agreed that annual/new member training for September should not be an evening event. The September training may be combined with the regular September IBC meeting if the meeting will not last over 1.5 hours. If needed, the training may occur as a separate meeting.

BSO UPDATE

PROTOCOLS MEETING FULL APPROVAL REQUIREMENTS

B04-322 - Evaluation of bacterial endophytes of grass- and legume-forages as emerging causes of reproductive loss disease in agricultural herbivores (horses, cattle and goats)

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B04-327 - Advanced Genetic Technologies

Motion to adjourn was made by Kenneth Dickey. Glenn Telling seconded. The meeting adjourned at 1:10 pm.

MINUTES

Institutional Biosafety Committee
Wednesday, August 11, 2004
308 Combs Cancer Research Center

Members Present

Thomas Chambers
Anthony Sinai
Kenneth Dickey
Marcia Finucane
Peter Nagy
Jack Hiatt
Eric Smart
Robert Jacob
Richard Wheaton
Brian Rymond
Kelly Breeding
Chuck Staben
Arthur Hunt

Members Absent

Louis Hersh
Glenn Telling

COMMITTEE BUSINESS

The meeting was called to order at 12:00 pm by Tom Chambers.

The minutes of July 14, 2004 IBC meeting were unanimously approved. Richard Wheaton moved. Ken Dickey seconded.

NEW BUSINESS

NEW PROTOCOL REVIEW

B04-329 – A phase III randomized, controlled study to evaluate the safety and efficacy of PANVAC™-VF in combination with GM-CSF versus best supportive care or palliative chemotherapy in patients with metastatic (stage IV) adenocarcinoma of the pancreas who have failed a gemcitabine-containing chemotherapy regimen.

attended the meeting for discussion.

The protocol was granted **provisional approval** pending the following conditions be met:
(See attached Recommendations for protocol)

A subcommittee assessed the room choice for the injections immediately following adjournment of this IBC meeting.

Kelly Breeding moved. Robert Jacob seconded. The vote was split 9-3 in favor of approval.

B04-335 – Recombinant adenoviral constructs for the study of calcineurin and brain aging

The protocol was **approved** with the following suggestions:

1. p.10: Paraformaldehyde will be used in the fume hood, not the Biological Safety Cabinet
2. p. 16: List cremation as standard DLAR protocol for carcass disposal

Ken Dickey moved. Peter Nagy seconded. The vote was unanimous

B04-334 – Lipid metabolism in obesity and its related diseases

The protocol was **approved**. Brian Rymond moved. Richard Wheaton seconded. The vote was unanimous.

B04-331

- Mechanism of atherosclerosis and restenosis

The protocol was granted **provisional approval** pending the following conditions be met:

1. A table describing each and every construct to be used be submitted to M. Finucane
- Brian Rymond moved. Eric Smart seconded. The vote was unanimous.

B04-330

- The role of ABC transporters in tumor drug resistance and physiology

The protocol was **provisionally approved** for non-animal work only. The investigator was advised to remove the animal work from this protocol, and resubmit after IACUC approval.

The room air handling system must be adjusted so that it is negative to the hallway. This is standard for laboratories and especially important when viral vector work is performed.

Anthony Sinai moved. Peter Nagy seconded. The vote was unanimous.

COMMITTEE BUSINESS

The committee was invited to participate in the NIH Safety Symposium webcast, "Safety Considerations in Recombinant DNA Research with Pathogenic Viruses" September 21-22, 2004.

The newly created "Table of Principal Investigator Requirements" was discussed briefly and will be amended to include plants per Arthur Hunt's request.

BSO UPDATE

PROTOCOL MODIFICATIONS APPROVED

B04-337-

- Mechanisms of pathogenesis and discovery of antimicrobial therapies and vaccines (with aerosol inoculations)

B04-333-M

- Macrophages in atherosclerosis

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B04-332-BSL1

- Molecular analysis of juvenile hormone action in *Heliothis virescens*

B04-336

- Targeting retinoic acid treatment of lung cancer/dissecting the molecular pathology of LAM disease

MINUTES

Institutional Biosafety Committee

Wednesday, September 8, 2004 12:00 P.M.

308 Combs Cancer Research Center

Members Present

Thomas Chambers

Marcia Finucane

Louis Hersh

Glenn Telling

Eric Smart

Robert Jacob

Richard Wheaton

Kelly Breeding

Chuck Staben

Arthur Hunt

Mark Farman

Doug Harrison

Daniel Kenady

Members Absent

Kenneth Dickey

Jack Hiatt

COMMITTEE BUSINESS

The meeting was called to order at 12:01 pm by Tom Chambers.

The minutes of the August 11, 2004 IBC meeting were unanimously approved. Eric Smart moved. Chuck Staben seconded.

New IBC members for the 2004-2005 committee year were welcomed and introduced: Daniel Kenady, General Surgery, Mark Farman, Plant Pathology, and Douglas Harrison, Biological Sciences. They will each serve a three year term, ending August 31, 2007.

NEW BUSINESS

NEW PROTOCOL REVIEW

B04-341

- Glycosylation mutants of Leishmania

The protocol was granted provisional approval pending the following conditions being met:

1. A description of the vector must be provided to the committee, to include the name of the vector and a diagram of the vector used to transfect the *Leishmania* with the gene of choice
2. Clarify the location of the experiments. Explicitly state which procedures will be done at which will be done in Are the gene knockouts and transfections done in
3. On page 7, there is confusion about the concentration of the bleach/hypochlorite used to disinfect glassware. Since the MSDS on this organism recommends 1% sodium hypochlorite, use this for hard surfaces and glassware.
4. On page 10, wording change: remove "non-infective" from "non-infective promastigote"

Tom Chambers moved. Kelly Breeding seconded. The vote was unanimous.

B04- 342

- Retrovirally Mediated Suicide Gene therapy using the enhancer region of

The protocol was approved with the following modification:

Replication competence will be monitored using the M. dunn test as described by Forestell, et al. 1996. Improved detection of replication-competent retrovirus. *J Virol Methods* 60:171-178.

Glen Telling moved. Chuck Staben seconded The vote was unanimous.

B04-340

- Retroviral Transduction of Stem Cells in Young and Old Mice

The protocol was provisionally approved pending the following condition met:

Completion of the laboratory audit by the Biological Safety Officer, and negative airflow into the laboratory from the hallway.

Chuck Staben moved. Robert Jacob seconded. The vote was unanimous.

COMMITTEE BUSINESS

- During the course of reviewing **B04- 342** - Retrovirally Mediated Suicide Gene therapy using the enhancer region of PDGF, the committee discussed the necessity of testing for replication competence of retroviral/lentiviral vectors. The committee voted to require investigators using retroviral or lentiviral vectors to use the M. dunni test, or PCR to test for replication competence prior to injecting the vector for in vivo testing, regardless of the source of the vector system. In vitro experiments do not require this testing. Chuck Staben moved, Louis Hersh seconded. The vote was split 10-3.
- Marcia Finucane updated the group on several issues:
 - The Central Kentucky Blood Center will notify M. Finucane when investigators from UK purchase blood. She will make sure the investigator has a current IBC approval for working with human blood. If the investigator does not have approval, the request for purchase will be denied. This measure was implemented following an investigation in RGAN of an engineering lab using human blood without bloodborne pathogens training, IBC registration, or proper PPE.
 - Marcia Finucane, Ed McClure, and Dave Hibbard have negotiated with state and local authorities concerning acceptance of autoclaved waste at the landfill. The state has given formal notice that there is no requirement for the autoclaved waste to be hauled separately or the transfer station to register as a medical waste hauler. The transfer station and the city had previously proposed an additional charge (~\$45,000/year) to haul autoclaved waste to a different landfill site. Finucane, McCormick, and Hibbard have lobbied for this charge to be dropped, and are awaiting word from the city and transfer station.
 - M. Finucane has provided guidance to the Occupational Health Service regarding a new program providing vaccinia vaccinations to employees who may be potentially exposed to vaccinia virus. A final draft was not available in time for this meeting. She will forward the final draft to committee members via email for comments and vote when available.
 - M. Finucane proposed adding a new IBC member from Microbiology & Immunology since two members from this department will leave the committee next year. Committee members suggested George Luo as a candidate.
 - An adverse event report was distributed to the committee concerning IBC protocol **B04-316**:
The safety, tolerability, and immunogenicity of three dose levels of ACAM3000 modified vaccinia ankaara (MVA) smallpox vaccine in adults without previous smallpox vaccination: A Double-blind, Placebo-controlled, Dose-Ranging, Phase I Study Followed by a Challenge with Dryvax® Smallpox Vaccine.
 - The protocol initially reviewed and provisionally approved at the August 11, 2004 IBC meeting: **B04-329**
– "A phase III randomized, controlled study to evaluate the safety and efficacy of PANVAC™-VF in combination with GM-CSF versus best supportive care or palliative chemotherapy in patients with metastatic (stage IV) adenocarcinoma of the pancreas who have failed a gemcitabine-containing chemotherapy regimen," has not met the approval requirements. M. Finucane will meet with the protocol representatives to facilitate proper completion of the application. A subcommittee (K. Breeding, T. Chambers, R. Jacobs, D. Kenady, and M. Finucane) will meet with to review the training presentation, date TBD)
 - M. Finucane advised the committee that the biological safety office will be focusing on preventing explosions or fires in the Biological Safety Cabinet by urging investigators to replace traditional Bunsen burners with "Touch-o-matic" bunsen burners. M. Farman suggested the Fireboy burners would also be good alternative to traditional bunsen burners as they have a foot pedal and no pilot light. Both will be recommended to investigators who insist on using flames in the Biological Safety Cabinets.

BSO UPDATE

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B04-339

PLP Splicing: In vivo analysis in a mouse model

Chuck Staben made the motion to adjourn. Richard Wheaton seconded. The meeting was adjourned at 1:35 pm.

MINUTES
Institutional Biosafety Committee
Wednesday, October 13, 2004 12:00 P.M.
308 Combs Cancer Research Center

Members Present

**Thomas Chambers
Marcia Finucane
Louis Hersh
Glenn Telling
Kenneth Dickey
Richard Wheaton
Kelly Breeding
Chuck Staben
Arthur Hunt
Mark Farman
Doug Harrison
Daniel Kenady**

Members Absent

Robert Jacob
Jack Hiatt
Eric Smart

COMMITTEE BUSINESS

The meeting was called to order at 12:05 pm by Thomas Chambers.

Vote to accept the minutes of the September 8, 2004 meeting was postponed pending corrections and additions as discussed by the Committee. Revisions will be sent to IBC members via email for consideration and email vote.

NEW BUSINESS

MODIFICATION

B04-341 **Glycosylation mutants of Leishmania**

The protocol was granted provisional approval pending the following conditions be met:

1. The first page of the original application is amended to reflect animal work, noting IACUC protocol number
2. Acceptable transport of infectious agent and animal specimens is incorporated into the SOP. Tom Chambers will send a letter to the investigator describing acceptable transport.

Ken Dickey moved. Arthur Hunt seconded. The vote was unanimous.

NEW PROTOCOL REVIEW

B04-346 Strategies for Calpain Inhibition

The protocol was granted provisional approval pending the following conditions are met:

1. On page 12, amend application to reflect that up to 1 liter of culture may be produced
2. A summary or citation of the PCR procedure (see page 16) to test for replication competence is submitted to the committee.

Glenn Telling moved. Douglas Harrison seconded. The vote was unanimous.

B04-349 Influence of rat cytomegalovirus (RCMV) on *Porphyromonas gingivalis* induced periodontitis in rats.

The protocol was granted **provisional approval** pending the following conditions are met:

1. Attachment A is submitted for for the CMV and *Porphyromonas gingivalis*
2. Clarify the location of the second lab
3. Transport of infectious agents from the lab to _____ and of animal specimens from _____ to reflect standard procedures(see attachment).

Chuck Staben moved. Daniel Kenady seconded. The vote was unanimous.

B04-347 Production of antibodies to equine cytokines

The protocol was returned to the investigator with the recommendation that he resubmit the protocol pending the following changes:

1. A paragraph is added to the application to describe the function of equine cytokines and a statement as to the need for the research.
2. A paragraph or more describing the rationale for use of adenovirus for antibody production rather than traditional methods for production of hybridomas.
3. The investigator must complete the UK specific training courses for lab safety & bloodborne pathogens, available on-line at [HTTP://EHS.UKY.EDU/CLASSES.HTML](http://EHS.UKY.EDU/CLASSES.HTML)
4. Dates of personnel training should be included in the application (page 5)
5. Adenovirus should be tested for replication competence because it is going into live animals; give method or citation
6. A description of safety precautions used during virus harvesting from the gradient should be included.
7. Bleach concentrations should be standardized throughout the application to 0.5% NaOCI
8. On page 2, George Allen, not Roy Leach is responsible for the autoclaves; no validation methods are in use at this time, chemical Integrators and biological spore testing will be used soon.
9. Transport of agents should be described; both infectious agents to and specimens returning to the laboratory should be addressed (see attachment). Describe method of transport (on foot, state owned vehicle, etc.)
10. Attachment TC should be completed for Vero cells.
12. BBP attachment, the person responsible for lab safety and for the BSC certification must be someone in the lab, not the business manager for the department.
13. Change expiration of BSC certification to 2005,
14. Property tag numbers should be added to the protocol where listed (page 2, 2nd centrifuge)
15. If mixed biohazardous and radioactive materials will be generated, please describe how spills and waste of these materials will be handled (page 13, Section H)

Mark Farman moved. Glenn Telling seconded. The vote was unanimous.

B04-343 A Phase I/II Clinical Trial Evaluating the safety and immunogenicity of LC16m8, A modified vaccinia vaccine, in health volunteers

The protocol was granted full approval.

Chuck Staben moved. Louis Hersh seconded. 4 committee members abstained from voting, 7 members voted in favor of approval.

B04-348 Transcriptional Regulation of Osteoclasts by Mif

The protocol was granted provisional approval pending the following changes:

1. Name of personnel and training should be listed on page 2.
2. Clarify the maximum amount of paraformaldehyde to be present in the BSC. It should be less than 5ml to meet the CDC guidelines for use of volatile chemicals in BSCs.
3. On page 7, check "vacuum" and "inoculation of culture media" as procedures to be done in the BSC.
4. A double trap vacuum line with inline HEPA/hydrophobic filter should be used, see CDC guidelines for BSC at [HTTP://WWW.CDC.GOV/OD/OHS/BIOSFTY/BSC/BSC.HTM](http://WWW.CDC.GOV/OD/OHS/BIOSFTY/BSC/BSC.HTM)
5. Attachment A: symptoms of exposure: replace "not being reported" with "unknown" and list symptoms of exposure to those of wild type virus.
6. Attachment R: Please refer to vendor specifications regarding probability of generating replication competent viruses. Probability is very low.
7. Attachment R: State that the source of the envelope protein is VSV.
8. Attachment R: Expand description of genes listed to describe purpose of each for this experiment (expressed, probe, etc)
9. Attachment R: Recombinant cell lines will be produced.

B04-329 . A phase III randomized, controlled study to evaluate the safety and efficacy of PANVAC TM-VF in combination with GM-CSF versus best supportive care or palliative chemotherapy in patients with metastatic (stage IV) adenocarcinoma of the pancreas who have failed a gemcitabine-containing chemotherapy regimen. (UPDATE)

The committee voted to review Human Gene Transfer Trial protocols prior to IRB review. The consent form will be reviewed as part of the risk assessment.

Kelly Breeding moved. Richard Wheaton seconded. The vote was unanimous.

The committee voted to require Human Gene Transfer Trial protocols to meet applicable Scientific Review Committee requirements prior to consideration by the Institutional Biosafety Committee.

Louis Hersh moved. Chuck Staben seconded. The vote was unanimous.

BSO UPDATE

M. Finucane reported on discussions with the UK IRB on the sequence of approvals for human gene transfer clinical trials. The recommended sequence is: 1) Medical/Scientific Review Board approval, then 2) IBC: require SRB approval, review and approve of risk assessment & exposure control plan, provisional approval until IRB review 3) IRB requires IBC provisional approval and IBC approved risk assessment/exposure control plan; IRB reviews and approves consent document, etc.; approval granted 4) IBC final approval granted after receiving copy of IRB approved consent form, patient information materials, & approval letter. The IBC voted to approve this procedure.

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B04-345

Structural characteristics of pancreatic polypeptide

MINUTES
Institutional Biosafety Committee Open Meeting
Wednesday, November 10, 2004 12:00 P.M.
308 Combs Cancer Research Center

Members Present

Thomas Chambers
Marcia Finucane
Louis Hersh
Glenn Telling
Kenneth Dickey
Richard Wheaton
Jack Hiatt
Chuck Staben
Arthur Hunt
Mark Farman
Doug Harrison
Daniel Kenady
Robert Jacob
Eric Smart

Members Absent

Kelly Breeding

The meeting was called to order at 12:07 pm by Thomas Chambers.

The minutes of the September 8, 2004 IBC meeting were unanimously approved. Glenn Telling moved. Eric Smart seconded.

The minutes of the October 14, 2004 meeting were unanimously approved. Glenn Telling moved. Daniel Kenady seconded.

NEW BUSINESS

NEW PROTOCOL REVIEW

B04-347 : Production of antibodies to equine cytokines

The committee discussed use of ^3H -thymidine in the biosafety cabinet (page 8). It was determined that the Radiation Safety Committee would make determinations as to the safety of this work. A phone call to the investigator confirmed he had Radiation Safety Committee approval for this work, he will fax a copy of the approval letter and verification that the BSCs have been certified to the Biological Safety Officer. The **protocol was approved**. Richard Wheaton moved. Mark Farman seconded. The vote was unanimous.

B04-351 Beta-catenin effects on skeletal muscle growth

The protocol was **provisionally approved** pending the following changes:

1. Paraformaldehyde will not be used in the biological safety cabinet.
2. will be added as personnel handling agents in Part 5 of the application.
3. The povidone iodine solution (Betadine) listed in the spill procedure is the scrub formulation, not the surgical prep.
4. The investigator clarifies procedure for examining animal urine and feces for adenovirus contamination as mentioned in the scientific summary. Appropriate attachments should be included for this work.

Chuck Staben moved. Daniel Kenady seconded. The vote was unanimous.

B04-353 Molecular mechanisms of obesity and type 2 diabetes

The protocol was granted **provisional approval** pending the following changes:

1. C/EBP β is added to attachment A and Attachment R.
 2. Page 9: Do not spray pipet tips with bleach.
 3. p. 10: Check infected animal carcass as biohazardous waste generated
 4. Send a copy of the IACUC form and IACUC approval letter to the Biological Safety Officer.
- Robert Jacob moved. Louis Hersh seconded. The vote was unanimous.

B04-356 Gene expression predictors of lung cancer

The committee **declined to vote** on this protocol. The investigator is urged to resubmit after completing the forms with enough detail that the committee may assess the biosafety of the work.

B04-357 Functional activity of Rb family members p107 and p130

The committee **declined to vote** on this protocol. The investigator is urged to resubmit after completing all the forms with enough detail that the committee may assess the biosafety of the work.

COMMITTEE BUSINESS

- Marcia Finucane requested the committee consider adding Randy Dinkins from USDA labs as an Ex Officio member. M. Finucane recommended Dinkins for his plant forage expertise and Arthur Hunt also cited his animal work as possibly an asset to the committee. Jim Strickland and Randy Dinkins will be invited to the next meeting to explain the mission of the USDA labs on campus and the research which will be conducted there. The committee will decide after this presentation whether M. Finucane should request that president Lee Todd appoint Dinkins to the committee.
- Marcia Finucane announced that she will be a guest lecturer in Wermeling spring '05 course **PHR 760 008: Topics in Pharmaceutical Science: Drug Development, Regulation, and Clinical Research**
- Marcia Finucane asked the committee if she should complete forms for investigators who refused for various reasons and whether different projects which are quite similar and involve the same organisms, could be consolidated into one application. The committee assured M. Finucane that it is the investigator's responsibility to complete the forms, not hers. The committee also agreed to the consolidation of projects into one application if the various projects are outlined as to aims, procedures and personnel. The committee also referred her to appropriate personnel regarding a specific investigator group.

BSO UPDATE

PROTOCOLS MEETING REGISTRATION REQUIREMENTS

B04-348 Transcriptional Regulation of Osteoclasts by Mif

B04-346 Strategies for Calpain Inhibition

B04-341 Glycosylation mutants of Leishmania

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B04-354 Regulation of adipocyte differentiation by angiotensin II

B04-344 Steroid/thyroid hormone action in the ovary

Motion to adjourn was made by Glenn Telling. Richard Wheaton seconded. The vote was unanimous. The meeting adjourned at 1:05 pm.

MINUTES
Institutional Biosafety Committee Open Meeting
Wednesday, December 8, 2004 12:00 P.M.
208 Combs Cancer Research Center

Members Present

Thomas Chambers
Marcia Finucane
Louis Hersh
Kenneth Dickey
Richard Wheaton
Kelly Breeding
Chuck Staben
Arthur Hunt
Mark Farman
Doug Harrison
Daniel Kenady
Robert Jacob
Eric Smart

Members Absent

Glenn Telling
Jack Hiatt

The meeting was called to order at 12:10 pm by Thomas Chambers.

The minutes of the November 10, 2004 IBC meeting were unanimously approved. Chuck Staben moved. Richard Wheaton seconded.

NEW BUSINESS

NEW PROTOCOL REVIEW

B04-360

Nanoparticle formulations for improved tumor uptake and targeting

The protocol was **provisionally approved** pending the following changes:

1. Strike BSL-1 references pertaining to human cell lines from the protocol. The Institutional Safety Committee and the BMBL recognize human cell lines and human tumorigenic cell lines as BSL-2 agents, and all personnel working with such are covered under the OSHA Bloodborne Pathogens Standard (29 CFR Part 1910.1030).

2. The current IACUC approval does not include the use of plasmid DNA. Please modify the IACUC application and submit a copy of the IACUC approval letter to Marcia Finucane. Completion of the laboratory audit with Marcia Finucane.

Robert Jacob moved. Eric Smart seconded. The vote was unanimous

B04-356

Gene expression predictors of lung cancer

The protocol was **provisionally approved** pending completion and the following modifications:

1. The investigator should wear a fit-tested respirator when manipulating constructs outside of biological safety cabinet and when cleaning a spill.

2. Page 13 should be completed.

3. Completion of laboratory audit.

Richard Wheaton moved. Mark Farman seconded. The vote was unanimous.

B04-357

Functional activity of Rb family members p107 and p130.

The protocol was **provisionally approved** pending completion and the following modifications:

1. Clorox should not be placed in the autoclave. Autoclaving is an acceptable means of decontaminating the waste mentioned on page 8. Please do not disinfect with Clorox and then autoclave any materials.

2. Fit-tested respirator does not have to be worn when just moving stocks from freezer to biological safety cabinet.

3. Attachment R: Mark that these agents are oncogenes (this is indicated on Part 5, Section C). and make sure the entire form is completed for each.
4. Centrifuging was not indicated as an aerosol generating procedure in Part 5, Section C. Please mark if this is applicable.
5. Change mol to pfu/ml (or other more appropriate concentration for titers).
6. Attachment BBP: please check "preparing or handling primary cell cultures" as a task and procedure.

Eric Smart moved. Douglas Harrison seconded. The vote was unanimous.

B04-364

MHC-Ib restricted T cell responses during bacterial infection

The protocol was **provisionally approved** pending the following minor revisions:

1. Describe homogenization of tissue. This work should be done in the biological safety cabinet.
2. Add a paragraph to elaborate on rDNA constructs and describe knock-out plasmid.
3. Add Homo sapiens and OTCC source.
4. Add a sentence about mice disposal.
5. Send a copy of the IACUC approval letter to Marcia Finucane.
6. Complete laboratory audit.

Arthur Hunt moved. Chuck Staben seconded. The vote was unanimous.

COMMITTEE BUSINESS

The Dec. 6, 2004 memo from Amy P. Patterson, M.D., Director of NIH Office of Biotechnology Activities was distributed.

BSO UPDATE

PROTOCOLS MEETING REGISTRATION REQUIREMENTS

B04-351

Beta-catenin effects on skeletal muscle growth

B04-353

Molecular mechanisms of obesity and type 2 diabetes

Ken Dickey moved to adjourn the meeting at 1:15 pm. Mark Farman seconded. The vote was unanimous.

MINUTES

**Institutional Biosafety Committee Open Meeting
Wednesday, January 12, 2005 12:00 P.M.
208 Combs Cancer Research Center**

Members Present

Thomas Chambers
Marcia Finucane
Louis Hersh
Jack Hiatt
Richard Wheaton
Kelly Breeding
Chuck Staben
Arthur Hunt
Doug Harrison
Daniel Kenady
Robert Jacob
Eric Smart

Members Absent

Glenn Telling
Mark Farman
Kenneth Dickey

The meeting was called to order at 12:10 pm by Thomas Chambers.

Jim Strickland, PhD, gave a brief overview of the USDA-Agricultural Research Service.

The minutes of the December 8, 2004, 2004 IBC meeting were unanimously approved. Chuck Staben moved. Daniel Kenady seconded. The vote was unanimous.

NEW BUSINESS

NEW PROTOCOL REVIEW

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until audit is performed, and any inadequacies are corrected as verified by the BSO.

B04-372 *Anaplasma phagocytophilum* pathogenesis

The protocol was granted **provisional approval** pending the following changes:

1. A formal medical exposure plan for exposure to bacterium should be submitted to the Biological Safety Officer. Please refer to attached sample of exposure plan.
2. Revise with a description of procedures using animals in scientific summary..
3. Satisfactory completion of laboratory audit.

Louis Hersh moved. Richard Wheaton seconded. The vote was unanimous.

B04-362 Stretch and mTOR signaling in skeletal muscle

The protocol was granted **provisional approval** with the following minor revisions:

1. All employees should complete lab safety training.
2. Respirators are required for manipulating virus **outside** of the Biological Safety Cabinet **only**.
3. Indicate that rDNA will be used in the secondary lab: _____ where centrifuge is located
4. In part 5: Biosafety Issues, Section B: Biosafety and handling considerations, check aerosol generating procedures as a potential for amplifying the risk of exposure (centrifugation).
5. Include description of use of NIH/3T3 cells.
6. Describe the use of animals in this protocol
7. Satisfactory completion of laboratory audit.

Douglas Harrison moved. Eric Smart seconded. The vote was unanimous.

B04-366 Glucose regulation of metabolism and transcription in the pancreas

The protocol was **approved** pending satisfactory completion of the laboratory audit.

The committee was concerned that the biological safety cabinet certification would expire soon. The Biological Safety Officer will confirm certification at audit.

Robert Jacob moved. Arthur Hunt seconded. The vote was unanimous.

B04-365 SV5 and Hendra F protein

The protocol was granted **provisional approval** pending the following:

1. Clarification as to the strain of vaccinia and whether it requires vaccination of lab personnel manipulating it
2. Staff using HeLa cells added to BBP exposure control plan and obtain BBP training
3. Satisfactory completion of laboratory audit.

Chuck Staben moved. Eric Smart seconded. The vote was unanimous.

B04-363 Pathogenesis Studies

The protocol was granted **provisional approval** pending the following changes:

1. Attachment A completed for all infectious agents used
2. Description (short) of experiments using *Shigella* and *Listeria* included in BSL-2 summary
3. Volumes listed in protocol be corrected (milliliter listed instead of microliter in some places)
4. The investigator completes lab specific safety training
5. At least one employee must complete the DOT/IATA training for shipping infectious agents
6. Satisfactory completion of full laboratory biosafety audit.

Eric Smart moved. Arthur Hunt seconded. The vote was unanimous.

B04-349 Fate and ecological effects of livestock antibiotics in manure-amended soils

The protocol was **approved** pending submission of rDNA form to BSO.

Laboratory audit has been performed.

Arthur Hunt moved. Eric Smart seconded. The vote was unanimous.

COMMITTEE BUSINESS

DLAR request for IBC to recommend ABSL containment levels after introduction of infectious agent was supported by Eric Smart. Official vote postponed until February meeting.

The committee declined to discuss ABSL containment levels for animals infected with third generation Lentiviral vectors pending scientific recommendation from expert investigator not collaborating on protocols. M. Finucane will request recommendation from other experts/journal articles. This will be discussed at February meeting. (see handouts: UK Fact Sheet: Biosafety Level 2+ (Lentiviral/Retroviral Vectors) and CDC information sheet: Agent: Retroviruses, including Human and Simian Immunodeficiency Viruses (HIV and SIV))

The IBC will meet on the first Wednesday in February, and will return to regular schedule (second Wednesday) in March.

Room 308, Combs Cancer Research building is no longer available. Room 208 Combs is reserved for future meetings. Other locations were discussed and M. Finucane will determine if Room 208 will be the best choice for future meetings.

BSO UPDATE

PROTOCOLS MEETING REGISTRATION REQUIREMENTS

B04-360 Nanoparticle formulations for improved tumor uptake and targeting
Laboratory audit was performed, no inadequacies found.

PROTOCOL MODIFICATIONS

B04-351 Beta-catenin effects on skeletal muscle growth

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B04-370 Mechanism of gene regulation by the embryo MADS-factor AGL15, and roles in Glycine max somatic embryogenesis. Laboratory audit was performed, no inadequacies found.

B04-369 Regulation of gene expression by AGL15, an embryo MADS factor

B04-368 Roles of JAK signaling in drosophila
Laboratory audit was performed, no inadequacies found.

Douglas Harrison moved to adjourn the meeting at 1:35 pm. Richard Wheaton seconded. The vote was unanimous.

MINUTES
Institutional Biosafety Committee, Open Meeting
Wednesday, February 2, 2005 12:00 P.M.
208 Combs Cancer Research Center

Members Present
Thomas Chambers
Marcia Finucane
Louis Hersh
Jack Hiatt
Richard Wheaton
Kelly Breeding
Chuck Staben
Arthur Hunt
Doug Harrison
Daniel Kenady
Kenneth Dickey
Eric Smart
Mark Farman
Glenn Telling

Members Absent
Robert Jacob

Tom Chambers called the meeting to order at 12:07 pm.

OLD COMMITTEE BUSINESS

The minutes of January 12, 2005 were unanimously approved. Richard Wheaton moved. Kelly Breeding seconded.

NEW BUSINESS

NEW PROTOCOL REVIEW

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until audit is performed, and any inadequacies are corrected as verified by the BSO or designee.

B05-377

Conditional depletion of macrophages in transgenic mice

The protocol was granted **full approval pending** the following minor modifications:

1. The investigator should update his BBP training (yearly)
2. The vector listed in Attachment R does not contain the elements listed. Correct the form and submit to BSO for approval.

The lab audit was found to be adequate.

Douglas Harrison moved. Eric Smart seconded. The vote was unanimous.

B05-376

Vascular smooth muscle function under normal and diabetic conditions

The protocol was granted **provisional approval pending** the following changes:

1. Include a description of infected tissue disposal in the scientific summary.
2. Explain acronyms of gene names listed in Attachment R.
3. Some corrections indicated in e-mail to _____ dated 1/25/05 were not included in final IBC revision. Please ensure these changes are included in final copy submitted to BSO.
4. Satisfactory completion of lab audit.

Mark Farman moved. Glenn Telling seconded. The vote was unanimous.

COMMITTEE BUSINESS

The committee discussed and agreed that animals should be housed/handled at ABSL-2 following adenoviral vector and lentiviral/retroviral vector exposure. The UK fact sheet, **BIOSAFETY LEVEL 2+ (LENTIVIRAL/RETROVIRAL VECTORS)**² will be updated to reflect that work with third generation lentiviral vectors may safely be conducted at BSL-2, and animals will be housed at BSL-2 following exposure.

IRB/IBC agreement (handout in packet) Richard Wheaton moved to approve the IRB/IBC Standard Operating Procedures signed by Marcia Finucane on January 25, 2005 and Ada Sue Selwitz (signed January 20, 2005). Douglas Harrison seconded. The vote was unanimous.

The proposed IBC Bylaw changes (see attachment) were **approved pending the following changes:**

1. Change wording in section 2.1, Special members: to an individual with plant expertise, etc.
2. Section 1.3: replace "vice-president for Administration" with "the President or his/her designee."
3. Section 8.0 should be renamed as Section 2.7.
4. Delete "private" in section 2.7 (previously Section 8.0).

Eric Smart moved. Kenneth Dickey seconded. The vote was unanimous.

Marcia Finucane provided a brief overview of wildlife trap/count/release program to be developed in conjunction with faculty members of the Biology Department.

Marcia Finucane announced that a job has been posted for a biological safety specialist. In preparation for expanding the department, new policies will be developed to standardize biological safety office protocol review prior to IBC review.

Motion to adjourn was made by Kelly Breeding. Douglas Harrison seconded. The vote was unanimous. The meeting was adjourned at 1:13pm.

BSO UPDATE

PROTOCOLS MEETING REGISTRATION REQUIREMENTS

B04-372	<u>Anaplasma phagocytophilum pathogenesis</u>
B04-382	<u>Stretch and mTOR signaling in skeletal muscle</u>
B04-385	<u>SV5 and Hendra F protein</u>
B04-363	<u>Pathogenesis Studies</u>
B04-349	<u>Fate and ecological effects of livestock antibiotics in manure-amended soils</u>

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B05-371BBP	<u>Subcellular localization of human arginase, arginine metabolism in patients with SIRS, arginine metabolism in abdominal sepsis (mouse model)</u>
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MINUTES
Institutional Biosafety Committee, Open Meeting
Wednesday, March 9, 2005 12:00 P.M.
208 Combs Cancer Research Center

Members Present

Thomas Chambers
Marla Finucane
Louis Hersh
Jack Hiatt
Richard Wheaton
Robert Jacob
Chuck Staben
Arthur Hunt
Doug Harrison
Kenneth Dickey
Eric Smart
Mark Farman
Glenn Telling

Members Absent

Kelly Breeding
Daniel Kenady

Tom Chambers called the meeting to order at 12:08 pm. He noted a quorum was present. Lou Hersh conducted the meeting.

OLD COMMITTEE BUSINESS

The minutes of February 2, 2005 were unanimously approved. Eric Smart moved. Doug Harrison seconded.

NEW BUSINESS

NEW PROTOCOL REVIEW

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until the biosafety audit is performed, and any inadequacies are corrected as verified by the BSO or designee.

B05-384

Non-reproductive actions of estrogen

BBP on file with BSO

Laboratory biosafety audit has been performed and found to be satisfactory

Arthur Hunt and Louis Hersh were primary reviewers for this protocol.

1. noted that relevant human cell lines are used
2. noted no problems with the protocol
3. noted safety procedures are sufficient.

Arthur Hunt moved to grant full approval to the protocol as submitted. Louis Hersh seconded. The vote was unanimous.

B05-375

Equine strangles

Doug Harrison, Kenneth Dickey, and Robert Jacob were primary reviewers for this protocol

1. results of the laboratory biosafety audit were satisfactory
2. noted that no lab employees had taken the bloodborne pathogen (BBP) training
they are not using human cell lines so no BBP training is required
3. the committee questioned about the need to secure the laboratory
it was agreed that this is an important issue.
the investigator indicated that the lab was not locked when personnel not present.
4. the BSO will ensure that the lab is locked when personnel are not present.
5. questioned if *Strep. equi* produces a toxin and if the toxin may be cloned during the experiment.

- the committee discussed that the PI is cloning cell surface proteins not secreted exotoxins
6. it was noted that the PI stated that these procedures carry no risk but that the ATCC classifies *S. equi* to be handled at BSL2
the PI will be required to handle all live cultures with BSL2 procedures
 7. noted that some questions on page eleven were left blank
it was commented that the answer was unknown at this point in the research so the omission was appropriate.
 8. noted there is a new post-doc in the _____ lab who should be added to the personnel list for this protocol.
 9. noted a deficiency in the description of how the proteins will be purified
request the investigator elaborate on sonication methods.
 10. noted the investigator included an IACUC protocol approval letter that covered the rabbit work but did not list the approval number on the form.
request that this number be added to page 1.
 11. the committee agreed that the investigator could send these modifications to BSO for final approval.
- The protocol was granted **provisional approval** pending modifications submitted to the BSO.
Robert Jacob moved. Eric Smart seconded. The vote was unanimous.

B05-378

Molecular studies of neurodegeneration

BBP on file with BSO.

Chuck Staben, Mark Farman, and Tom Chambers were primary reviewers for this protocol.

1. noted that the investigator implied that genes other than the LDLR receptor would be used in the research.
the BSO will call to confirm.
the committee agreed that if other genes are used in the research that they would not represent a biosafety concern since the research is being conducted with BSL2
2. asked whether working with RNA isolates in the fume hood was appropriate containment
noted that the fume hood is appropriate because the chemical hazards supersede the biological hazards
3. requested a new "attachment R" if oncogene was found and used in research.
noted that even if using an oncogene, BSL2 containment would be appropriate.
4. noted on page 11 that the investigator indicated a "neighboring lab" as supplying HEK cells
requested the investigator be more specific as "neighboring lab" is not specific

Louis Hersh moved to grant **full approval** pending minor changes. Eric Smart seconded. The vote was unanimous.

B04-367

PCR 7 ELISA for detection of Leptospira in the Horses

Glenn Telling and Richard Wheaton were primary reviewers on this protocol.

1. The laboratory biosafety audit was satisfactory.
2. noted that BBP training was not necessary since they are not using human body fluids for the protocol.
3. noted that the investigator did not mention "next steps" for the project, but that they would be addressed in future protocol submissions.
4. expressed concerns that the investigator did not list the proteins to be expressed in *E. coli*.
noted attachment R listed the proteins.
the information was found to be acceptable
5. noted the form does not allow an answer of "Not applicable" so leaving the two questions unmarked was acceptable.
6. questioned if the lab needed an exposure control/treatment plan since the agent is readily treated with doxycycline.
7. this is not needed as they are processing diagnostic specimens which are lower exposure risk than culturing in large amounts
8. questioned the use of 1% sodium hypochlorite.
commented that this is not the same as 1% bleach, but would be a stronger concentration that what is usually required.
9. noted a typographical error on page 7
10. requested that 106 cfu/ml and 102 cfu/ml be replaced with 10^6 and 10^2 .

Glenn Telling moved that the protocol be granted full approval, pending correction of the typographical errors. Richard Wheaton seconded. The vote was unanimous.

B05-380 DNA mismatch repair deficiency and leukemia relapse

BBP on file with BSO

Daniel Kenady and Eric Smart were primary reviewers on this protocol.

1. laboratory biosafety audit was satisfactory
2. noted that human cells and human blood would be manipulated at BSL2.
3. no concerns with the protocol
4. all safety precautions were adequately addressed

Eric Smart moved that it be granted full approval as submitted.

Chuck Staben seconded. The vote was unanimous.

COMMITTEE BUSINESS

Minimum guidelines for TAT protein use

Guidelines from IUPUI were included in the IBC packet for review. Marcia Finucane proposed writing similar guidelines for UK. The committee agreed there is a difference between the TAT protein and TAT fusion protein. The TAT fusion protein can penetrate cells and therefore any proteins attached to it may readily enter cells. The recommendation was made to change the title to "Minimum guidelines for TAT Fusion protein use" and to list commercially available TAT fusion proteins in the guidelines.

Biologicals Response Modifiers Advisory Committee Meeting #31 Briefing Document for October 25-26, 2001. Lentivirus Vectors In Gene Transfer Clinical Trials

1. This document was included in the IBC packet for review.
2. BSO explained that it supports statements made to the committee concerning third generation lentiviral work being conducted at BSL2.
3. The committee agreed that there should be no requirement for an assay for the generation of replication competent virus for third generation lentivirus
4. It was noted existing IBC guideline calls for testing for replication competence when the recombinant viral vector is placed into animals
5. It was suggested to post a few "do's/don'ts" on the website for work with lentivirus vectors.
6. It was pointed out that UK already has guidelines on working with Lentivirus posted on the website
7. It will be determined if additional information about third generation lentiviral vectors should be added to the policy.

Institutional Implications of the Boston University Incident

some points were outlined to discuss (they were included in the IBC packet for review) summarized the BU incident.

asked if it would be appropriate to require attenuated strains to be registered

noted that the OSPA Internal Approval form does not distinguish between biological hazards or chemical hazards.

noted that that form will go online sometime next year and that would be a good time to ask to have the form amended.

The committee tabled the issue for future discussion.

A Phase I, Open-Label Clinical Trial of the Safety and Tolerability of Single Escalating Doses of Autologous CD4 T Cells Transduced with VRX496 in HIV Positive Subjects (Powerpoint Presentation)

presentation was passed out

preparation for reviewing

protocol at a future meeting

Motion to adjourn was made by Eric Smart. Chuck Staben seconded. The vote was unanimous. The meeting was adjourned at 1:14pm.

BSO UPDATE

PROTOCOLS MEETING REGISTRATION REQUIREMENTS

B05-377 Conditional depletion of macrophages in transgenic mice

B05-378 Vascular smooth muscle function under normal and diabetic conditions
has completed all requested changes/amendments to her application. Her laboratory is under positive pressure to the hallway and requests have been made to PPD to make it negative to the hallway.

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B05-391P Accessing RNAi as a reverse genetic tool for global analysis of NBS-LRR gene function in *Medicago*
truncatula

MINUTES
Institutional Biosafety Committee, Open Meeting
Wednesday, April 13, 2005 12:00 P.M.
208 Combs Cancer Research Center

Members Present

Kelley Breeding
Thomas Chambers
Kenneth Dickey
Marks Farman
Marcia Finucane
Louis Hersh
Arthur Hunt
Daniel Kenady
Eric Smart
Chuck Staben
Glen Telling
Richard Wheaton

Members Absent

Doug Harrison
Jack Hiatt
Robert Jacob

Tom Chambers called the meeting to order at 12:10pm. Derek Adams was introduced to the committee as the new Biological Safety Specialist.

OLD COMMITTEE BUSINESS

The content of the minutes of March 9, 2005 were unanimously approved with minor modifications. Eric Smart moved. Louis Hersh seconded.

NEW BUSINESS

Marcia Finucane proposed changing the meeting day to Tuesdays or Thursdays for 2005-2006. No decision was made. The suggestion was tabled.

New Protocol Review

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until the biosafety audit is performed, and any inadequacies are corrected as verified by the BSO or designee.

B05-396

Dendritic cell generation in non-small cell lung cancer (NSCLC)

BBP on file with BSO

Laboratory biosafety audit has not been performed, pending renovation of lab space

Thomas Chambers, Chuck Staben, Glenn Telling, Eric Smart, and Kenneth Dickey were primary reviewers.

1. Dendritic cells are injected into patients.
2. The lab has had contamination problems in the past. This is not a biosafety issue; it is due to other lab factors.
3. Pipette disposal should be in a cardboard box or other puncture resistant box, not red trash bags.
4. Red trash bags should only be used for items to be incinerated. This lab should use orange or clear bags and autoclave solid waste.
5. The investigator is conducting two separate projects: clinical and research. rDNA use for each should be clearly indicated, as well as where the rDNA is being used.

The protocol was approved with minor modifications. Kenneth Dickey moved. Eric Smart seconded. The vote was unanimous.

B04-352

Genetic analysis of RNA virus replication (Hepatitis C virus)

Louis Hersh, Doug Harrison, and Arthur Hunt were primary reviewers.

Laboratory biosafety audit was performed and deficiencies have been corrected.

1. It was noted the project possibly involves using concentrated HCV and transgenic models to express HCV or mutated HCV in mice.
2. Part three should be expanded to include description of transgenic mouse model and types of mutants, and properties of mutants, and to identify any hazards with each.

3. Attachment R should be completed separately for each class of construct/mutant
4. The committee discussed the IACUC issue of injection and animal housing.
5. If using concentrated HCV, biosafety level 3 is appropriate.
6. should be added to personnel list.
7. Although no vaccine is available, interferon treatment may be an option for persons exposed/infected with HCV. The committee recommends a medical surveillance plan be adopted and testing offered to personnel potentially exposed to HCV in the course of this research.
8. Several questions were identified by the committee to be answered by the investigator in a revised protocol:
 - a. Describe the mutants and properties they might have.
 - b. Will host range of virus be altered? If yes, please explain the risks involved.
 - c. Describe explicitly any mutational studies with infectious clones.
 - d. When will virus replicate in mouse models? Will it be immediately after injection or later?
 - e. Is virus shed from mouse? Please describe. What is possible transmission route to humans?
 - f. Clarify personnel and tasks (i.e. who is doing what).
 - g. Describe risk attenuation.
 - h. Will virus be used at high concentrations? If so, under what conditions?
 - i. Will the plasmid(s) be infectious?
 - j. Is there a possible biosafety issue with transfers? If not, why not?

The protocol was **returned to the researcher**. Arthur Hunt moved. Louis Hersh seconded. The vote was unanimous.

B05-395

Oxidative Cellular Signaling in EBV-Lymphoproliferation

Daniel Kenady, Robert Jacob, and Kenneth Dickey were primary reviewers.

BBP on file with BSO.

1. Daniel Kenady summarized the research methods. They were found to be well described in the protocol.
2. The question was raised whether the 1% disinfectant concentration referred to bleach or to hypochlorite. 1% sodium hypochlorite (i.e. 20% bleach) is acceptable.
3. A new lay summary should be submitted that is written at a lay level.

The protocol was **approved with modification**. Daniel Kenady moved. Glenn Telling seconded. The vote was unanimous.

B05-382

Biology of coccidian parasites

Mark Farman and Richard Wheaton were primary reviewers.

Laboratory biosafety audit was performed and found to be satisfactory.

1. Bloodborne pathogens training and an exposure plan are required for this research.
2. A statement describing efficacy of the protocol for heat-killing parasites should be included.
3. The Toxoplasma SOP should include information pertaining to the risk associated for immunocompromised individuals working with live organisms.
4. Constructs for the DNA vaccine should be diagrammed and included with the application.

The protocol was **provisionally approved**. Chuck Staben moved. Richard Wheaton seconded. The vote was unanimous.

OTHER ITEMS FOR DISCUSSION

Institutional Implications of the Boston University Incident.

PI's testing of attenuated strain

Article: Inadvertent Laboratory Exposure to Bacillus anthracis---California, 2004

Marcia Finucane referred to the article: "Inadvertent Laboratory Exposure to Bacillus anthracis---California, 2004" and suggested the IBC set policy on testing of attenuated strains to ensure they are indeed attenuated. The IBC asked her to draft a policy for review.

Article: Rules, Regs, and Red Tape (handout at meeting)

Marcia Finucane distributed this article which discusses the implications of the Final Rule for the Select Agent Program.

Intellectual Property (email from Katherine Adams, handout at meeting)

This email was distributed by Marcia Finucane. The committee discussed MTAs at UK.

Kelly Breeding made the motion to adjourn the meeting. Mark Farman seconded. The vote was unanimous. The meeting adjourned at 1:33pm.

BSO UPDATE

PROTOCOLS MEETING REGISTRATION REQUIREMENTS

B05-378 Molecular studies of neurodegeneration

B05-375 Equine strangles

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B05-388 Function of snRNP particles in pre-mRNA splicing

B05-385P Expression of glucocerebrosidase gene in transgenic tobacco

B05-383P Expression of genes in tobacco to enhance seed germination

B05-390 Enhancement of insect expression systems

B05-387P Expression of a synthetic gene encoding xylanase from Clostridium thermocellum in transgenic tobacco plants

B05-389 Selection and optimal expression of insect anti-growth proteins

MINUTES
Institutional Biosafety Committee Open Meeting
Wednesday, May 11, 2005 12:00 P.M.
208 Combs Cancer Research Center

Members Present

Kelley Breeding
Thomas Chambers
Kenneth Dickey
Mark Farman
Marcia Finucane
Louis Hersh
Arthur Hunt
Daniel Kenady
Chuck Staben
Glen Telling
Richard Wheaton
Doug Harrison
Robert Jacob

Members Absent

Eric Smart
Jack Hiatt

Tom Chambers called the meeting to order at 12:09pm. He noted a quorum was present.

OLD COMMITTEE BUSINESS

The minutes from the April 13, 2005 meeting were unanimously approved. Arthur Hunt moved. Kenneth Dickey seconded.

NEW BUSINESS

New Protocol Review

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until the biosafety audit is performed, and any inadequacies are corrected as verified by the BSO or designee.

B04-363M Pathogenesis Studies Modification

Primary Reviewers: Chambers, Harrison, Hunt, Farman, Jacob, Telling, Wheaton, Dickey

Biosafety Audit will be performed 5/13/05.

1. The investigator cited articles that were not attached to the application
2. Please send electronic or hard copies of the articles cited in reference to the vector

description.

The protocol was **provisionally approved** pending completion of the listed items. Robert Jacob moved. Doug Harrison seconded. The vote was unanimous.

B05-401 Borrelia burgdorferi genes and proteins

BBP on file with BSO

Primary Reviewers: Chambers, Hunt, Dickey

The committee was impressed with the description of biosafety precautions/procedures and found them to be acceptable. However, the committee did not find enough information about the actual science of the protocol to evaluate its safety. Therefore, the investigator is asked to resubmit the application with more specific details as follows:

1. Will proteins be expressed?
2. Is there any potential to change the pathogenicity of the organism?
3. Explain gene acronyms listed on rDNA form
4. Please send the lay and scientific summaries from the grant proposals for this work, to give the committee more details about what is proposed
5. Clarify on Attachment TC source of hybridomas (hybridomas are not covered on IACUC protocol)

The investigator was asked to resubmit the protocol with the above information included. Arthur Hunt moved. Mark Farman seconded. The vote was unanimous.

B05-373

Role of Antiangiogenic Agents in Physiological and Pathological Processes

The lab audit has not been completed

BBP on file with BSO

Primary Reviewers: Harrison, Telling, Wheaton

1. A description of eye bank testing should be submitted to BSO.
2. Needs rDNA attachment form submitted describing the transfection procedure.
3. A discussion on the biosafety level of this work determined that BSL2 would be sufficient as these are not high risk CJD or BSE tissues.

The protocol was provisionally approved pending completion of the above items. Glenn Telling moved. Richard Wheaton seconded. The vote was unanimous.

B05-397

Production of Terpenoids in Yeast

The laboratory audit is completed.

Primary Reviewers: Farman, Jacob

1. Attachment R lists different numbers for plasmid. If this is a typographical error, please Correct. If different plasmids are used, provide information for each
2. The autoclaving protocol should be more specific (time, temperature, pressure)
3. Describe specific procedures in place to prevent large spills

The protocol was provisionally approved pending modifications. Robert Jacob moved. Mark Farman seconded. The vote was unanimous.

B05-405 /

A Phase II, Open-Label, Multicenter Study to Evaluate the Safety, Tolerability, and Biological Activity of Repeated Doses of Autologous T Cells Transduced with VRX496 in HIV-Positive Subjects

Primary Reviewers (receive additional information in packet): Smart, Staben, Kenady, Hersh

1. What action the sponsor and investigator will take if VSV-G DNA is confirmed and the follow-up biological RCL assay confirms the presence of a RCL?
2. The IBC also requests that the consent form contain a statement cautioning the patient that even if symptoms improve, the patient may still be infectious for HIV/AIDS and that they should continue to refrain from unprotected sexual relations, sharing of needles, blood donation or any other behavior considered contributing to the transmission of this infection.

The protocol was provisionally approval pending completion of the above items. Chuck Staben moved. Louis Hersh seconded. The vote was unanimous.

OTHER ITEMS FOR DISCUSSION

Minors in the Lab Policy and Registration Forms

For IBC review and Approval

Committee will individually review again and submit suggestions for changes by May 16.

Article: Heightened security after flu scare sparks biosafety debate (In packet)

Time did not allow for discussion of the article.

Article: Ethical Guidelines for embryonic stem cell research: A newsmaker interview with Richard O. Hynes. PhD, FRS

Time did not allow for discussion of this article.

The meeting was adjourned at 2:15pm. Louis Hersh moved. Mark Farman seconded. The vote was unanimous.

BSO UPDATE

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B04-320-FT-M

Benefits of the roundup ready alfalfa weed control program 2004

B03-248-M
Virus(modification)

Studies of Social and Reproductive Behavior in House Sparrows Carrying West Nile

B04-325-FT-M

Evaluation of Transgenic Corn for Southwestern Corn Borer Resistance

MINUTES

Institutional Biosafety Committee Open Meeting Wednesday, June 8, 2005 12:00 P.M. 208 Combs Cancer Research Center

Members Present

Kelley Breeding
Thomas Chambers
Kenneth Dickey
Mark Farman
Marcia Finucane
Doug Harrison
Louis Hersh
Jack Hiatt
Daniel Kenady
Robert Jacob
Glen Telling

Members Absent

Eric Smart
Arthur Hunt
Chuck Staben
Richard Wheaton

Tom Chambers called the meeting to order at 12:05pm. He noted a quorum was present.

OLD COMMITTEE BUSINESS

The minutes from the May 11, 2005 meeting were unanimously approved. Kelly Breeding moved. Mark Farman seconded.

NEW BUSINESS

New Protocol Review

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until the biosafety audit is performed, and any inadequacies are corrected as verified by the BSO or designee.

B05-410 Equine Infectious Anemia

Attachment BBP on file with BSO

Primary Reviewers: Tom Chambers, Glenn Telling, Eric Smart, Ken Dickey

Tom Chambers presented the protocol.

1. Respective parts of the protocol must include specific location of "research farm". (i.e.
2. Issue of the stall mucking must be addressed. Who and when?
3. Discuss the precise protocol used for transporting animal carcasses if necessary.
4. Is the Adenovirus tested for replication competency? Explain. Adenovirus constructs should be tested for replication competent adenovirus prior to inoculating animals. Please include in protocol.
5. The Biological Safety Cabinet in should be added to the protocol.

The protocol was **provisionally approved pending revisions**. Ken Dickey moved. Glen Telling seconded. Tom Chambers abstained. The vote was unanimous.

B05-414 Virulence and immunity of equine arteritis virus

Primary Reviewers: Tom Chambers, Doug Harrison, Eric Smart, Ken Dickey

Tom Chambers presented the protocol.

1. Respective parts of the protocol must include specific location of "research farm". (i.e.
2. Discuss the precise protocol used for transporting animal carcasses if necessary.
3. Rocal must be listed on the disinfectant list with the appropriate dilution.
4. Does virus modification and passage through HeLA cells change the host range? Are these viruses pathogenic to humans?

The protocol was **provisionally approved pending revisions**. Doug Harrison moved. Mark Farman seconded. Tom Chambers abstained. The vote was unanimous.

B05-408 Role of drug and vitamin transport genes in cancer etiology and treatment
BBP on file with BSO

Primary Reviewers: Doug Harrison, Robert Jacob

Doug Harrison presented the protocol.

1. An elaboration is needed on the transporter genes being used. More description of the specific functions is needed.
2. Consistency on Section 2 – B, rDNA will be used in room if DNA cloning will be performed.
3. The certification of the Biological Safety Cabinet is out-of-date. Documentation of the certification is required. It may be faxed to 257-8787, Attn: Marcia Finucane, BSO.
4. On Attachment TC: An explanation is needed regarding the origin of the cancer cells. Describe cell line origin and give name of commercial source, etc.
5. Describe how many and details of plasmids on Attachment R.
6. Personnel must complete Bloodborne Pathogen Training.

The protocol was **provisionally approved pending revisions**. Robert Jacob moved. Doug Harrison seconded. The vote was unanimous.

B05-409 Regulation of Na⁺ channel gene expression and Calcium regulation in brain aging and Alzheimer's disease (3 year renewal)
BBP on file with BSO

Primary Reviewers: Robert Jacob and Glenn Telling

Robert Jacob presented the protocol.

1. While the investigator supplied adequate details of standard biosafety procedures (for example spill procedures, the use of personal protective clothing etc.), the protocol in its current form lacks sufficient scientific context to enable the committee to adequately assess the potential for biosafety-related issues. The investigator therefore needs to supply more details of the proposed experiments (but not the detailed SOP or entire grant request).
2. More details of the AAV system and its planned use must be supplied if the investigator really plans to use this as a delivery system.
3. Where and when will the SA toxins be used? Describe use of saxitoxin and tetrodotoxin in this protocol.
4. What animals will be used? Will animal use include only uninfected tissue harvest? Please explain.

The investigator was asked to **resubmit the protocol** with the above information included. Kelly Breeding moved. Glenn Telling seconded. The vote was unanimous.

B05-415 04-ID-168: A multicenter, open-label phase I/II study to evaluate safety and immunogenicity of MVA-BN[®] smallpox vaccine in HIV infected subjects (CD4 counts >350 / µl) and healthy subjects with and without previous smallpox vaccination - POX-MVA-010

Primary Reviewers: Louis Hersh, Chuck Staben, Daniel Kennady

Louis Hersh presented the protocol.

Overall, the committee members were satisfied and deemed the protocol reasonably safe.

The protocol was **approved**. Louis Hersh moved. Mark Farman seconded. The vote was unanimous.

B05-412 A Double-Blind, Placebo-Controlled, Dose-Finding, Phase 2 Study to Assess the Safety, Tolerability, and Immunogenicity of Three Dose Levels of ACAM3000 Modified Vaccinia Ankara (MVA) Smallpox Vaccine in Adults With and Without Previous Smallpox Vaccination

Primary Reviewers: Lou Hersh, Chuck Staben, Daniel Kennady, Marcia Finucane

1. A spill protocol should be included in the application.

Overall, the committee members were satisfied and deemed the protocol reasonably safe. The protocol was **approved pending revisions**. Louis Hersh moved. Mark Farman seconded. The vote was unanimous.

B05-407P Sudden Oak Death Kentucky Forest Survey

Primary Reviewers: Farman, Hunt

Mark Farman presented the protocol.

1. Training date for is supplied.
2. A list of disinfectants to be used is supplied.

3. Information on the location and certification of the Biological Safety Cabinet should be included in application. (Certifying company and date)
4. The scientific summary should include information about the DNA extractions/manipulations being performed in a biological safety cabinet.

The protocol was provisionally approved pending revisions. Mark Farman moved. Glenn Telling seconded. The vote was unanimous.

B05-416 . Characterization and isolation of disease resistance genes from Nicotiana

Primary Reviewers: Arthur Hunt, Mark Farman

Mark Farman presented the protocol.

1. Your proposed use of ethanol for decontaminating sporangia needs to be clarified. If this is a standard, effective method in decontaminating blue mold sporangia and spores, please supply a standard reference. If that is not available, the committee would accept 10% bleach as a generally effective decontaminant.
If no standard reference is available regarding ethanol, and bleach is not appropriate in your protocol, please supply the committee data that demonstrate the effectiveness of your decontamination procedure. These should include time and effectiveness data with sufficient numbers of sporangia and spores as well as a range of exposure times and concentrations to evaluate effectiveness.
2. Clarify the rDNA work: What are the plans if resistant plants are found? If plant transformations are planned for later experiments, they should be explained in this protocol or added as a modification at a later date.
3. HEPA filters in the growth chamber should be routinely checked and certified.
4. How will the effectiveness of the containment procedures be tested? Will proper PPE be used? Please describe in detail.
5. Work with plant pathogens which could affect crops in KY is considered at least BSL2-P, not hazardous to human but to plants.

The protocol was provisionally approved pending revisions. Mark Farman moved. Lou Hersh seconded. The vote was unanimous.

B05-417 . Serum Amyloid A and vascular proteoglycans in atherosclerosis

Primary reviewers were not assigned. The protocol was emailed to the committee for review on 6/8/05.

Marcia Finucane presented the protocol.

1. Attachment R: rDNA should be completed for the construct proposed.
2. Information about personnel training should be included in protocol.
3. Rooms should be described.
4. Prior to injection into animals, the adenovirus should be assayed for replication competent virus. This should be described in the protocol.

The protocol was provisionally approved pending revisions. Marcia Finucane moved. Glenn Telling seconded. The vote was unanimous.

OTHER ITEMS FOR DISCUSSION

was approved to attend the next IBC meeting to answer questions.

Minors in lab policy (vote)

The policy was discussed and changes were suggested. The committee declined to vote on the policy pending revisions. The Minors in Research Proposal will include Dr. Farman's comments. The

Biosafety

department will also incorporate any suggestions from the committee submitted by June 15th. The draft policy will be emailed to IBC members for review and vote.

Non-voting administrators on the IBC. Marcia Finucane suggested amending the by-laws to state that administrators may serve on the IBC but may not vote.

Ken Dickey suggested amending the by-laws to name current ex-officio members (Ken Dickey, Marcia Finucane, and Martin Evans) as standing members to avoid confusion as to their voting status.

ASM News magazine letters: Another Leukemia case tied to viral vectors in French gene therapy trial; Nanoemulsions destroy pathogens, deliver vaccines; Elusive Hepatitis C virus propagated in vitro. These articles were not discussed.

The meeting was adjourned at 2:03 pm. Glenn Telling moved. Mark Farman seconded. The vote was unanimous.

BSO UPDATE

PROTOCOLS MEETING REGISTRATION REQUIREMENTS

B04-383M	<u>Pathogenesis Studies Modification</u>
B05-401	<u>Borrelia burgdorferi genes and proteins</u>
B05-395 I	<u>Oxidative Cellular Signaling in EBV-Lymphoproliferation</u>
B05-398BBP	<u>Production of Terpenoids in Yeast</u>
B05-373 I	<u>Role of antiangiogenic agents in physiological and pathological processes</u>

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B05-413	<u>Molecular Mechanisms of Nutrient Absorption and Metabolism</u>
B05-388	<u>Microsomal prostaglandin E synthase-1 in rheumatoid arthritis</u>
B05-402FT I	<u>Studies of cadmium accumulation in plants</u>
B05-403 I	<u>Studies of plant trichome secretion</u>

MINUTES
Institutional Biosafety Committee Open Meeting
Wednesday, July 13, 2005 12:00 P.M.
208 Combs Cancer Research Center

Members Present

Kelley Breeding
Thomas Chambers
Marcia Finucane
Eric Smart
Richard Wheaton
Doug Harrison
Louis Hersh
Jack Hiatt
Daniel Kenady
Robert Jacob
Arthur Hunt

Members Absent

Glen Telling
Kenneth Dickey
Chuck Staben
Mark Farman

Tom Chambers called the meeting to order at 12:05pm. He noted a quorum was present.

OLD COMMITTEE BUSINESS

The minutes from the June 8, 2005 meeting were unanimously approved. Arthur Hunt moved. Robert Jacob seconded.

NEW BUSINESS

New Protocol Review

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until the biosafety audit is performed, and any inadequacies are corrected as verified by the BSO or designee.

*****B04-352**

Genetic analysis of RNA virus replication (Hepatitis C virus)

Attachment BBP on file with BSO

Primary reviewers: Hersh, Hunt, Harrison, Kenady, Jacob

Protocol was initially reviewed at the April 13, 2005 IBC Meeting.

attended the meeting to address questions and concerns from the committee. New issues were raised which questioned compliance with the NIH Guidelines. The final decision was to issue a "Cease and Desist" memorandum from the IBC for to suspend work on infectious HCV virus until all biosafety and regulatory issues are resolved. The research will be approved, and the lab will be reinstated to full IBC registration immediately following clarification of the issues and full compliance to NIH and IBC policies. The IBC members will be sent responses and revisions via e-mail and polled as to the acceptance of the revisions. (Acceptable revisions were received by July 25, 2005).

B05-423

Ca²⁺ permeable Na channels and cardiac cell and mechanisms of E-C coupling in

atrial cells

BBP on file with BSO

Primary reviewer: Wheaton

New investigator: not yet on campus.

Richard Wheaton presented the protocol.

Overall, the committee members were satisfied and deemed the protocol reasonably safe. However, verbal notice that the perfusions were not going to be performed in a animal procedure room in rather they would be in the open lab on the benchtop.

1. Issue regarding murine heart surgery and perfusion in an open lab has not been resolved.
2. Issue regarding the mice shedding adeno-virus has not been resolved.

The protocol was tabled due to concerns with the proposed procedures with the adeno-virus on the benchtop in the open lab. Richard Wheaton moved. Lou Hersh seconded. The vote was unanimous.

Members were amenable to voting for a full approval if these issues were resolved promptly to their satisfaction. (Acceptable facilities in were found the next day for the perfusion and acceptable shedding studies were described. The IBC was polled and found these revisions acceptable, full approval granted.)

B05-422 American heart association national center scientist development grant and Ca²⁺ and calmodulin signaling in the cardiac myocyte under hypertensive stress

BBP on file with BSO

Primary reviewer: Wheaton

New investigator: not yet on campus.

Richard Wheaton presented the protocol.

Overall, the committee members were satisfied and deemed the protocol reasonably safe. However, verbal notice that the perfusions were not going to be performed in a animal procedure room in _____ rather they would be in the open lab on the benchtop.

3. Issue regarding murine heart surgery and perfusion in an open lab has not been resolved.
4. Issue regarding the mice shedding adeno-virus has not been resolved.

The protocol was tabled due to concerns with the proposed procedures with the adeno-virus on the benchtop in the open lab. Richard Wheaton moved. Lou Hersh seconded. The vote was unanimous.

Members were amenable to voting for a full approval if these issues were resolved promptly to their satisfaction. (Acceptable facilities in _____ were found the next day for the perfusion and acceptable shedding studies were described. The IBC was polled and found these revisions acceptable, full approval granted.)

B04-355 Periodontal Pathogens: Animal Models and Infection

Primary reviewer: Jacob

Robert Jacob presented the protocol.

1. On page 10, removal of the statement "To our knowledge, all the oral bacteria are neither infectious nor contagious." The bacteria named in your summary are considered infectious by this definition: "Infection denotes the establishment and proliferation of a microorganism within a host"; Infectivity indicates the ability of the agent to enter, survive and multiply in the host, disease may or may not be the result.
2. Complete Attachment A for each microorganism named in your scientific summary (*Porphyromonas gingivalis*, *Tannerella forsythia* (do you mean *Tannerella forsythensis*?), and *Treponema denticola*) (see attachment or http://ehs.uky.edu/biosafety/forms/ATTACHMENT_A.rtf) You may e-mail the completed forms to the BSO.
3. Page 7, complete the information about the biological safety cabinet
4. Page 7, change the designation of the procedures to BSL2 (per ATCC classification for *Tannerella forsythensis* & *Porphyromonas gingivalis*)

The protocol was provisionally approved pending revisions and written clarification of the comments made by the IBC. After submission of revisions and IBC acceptance, Kesavalu will be fully approved. Eric Smart moved. Lou Hersh seconded. The vote was unanimous.

B05-425 GV-001.004 A Randomized, Phase II, Study of TNFerade™ Biologic with 5-FU and Radiation Therapy of Unresectable Locally Advanced Pancreatic Cancer.

Primary reviewers: Smart, Harrison, Hersh, Chambers

Renewal Protocol

Eric Smart and Lou Hersh summarized the protocol.

1. Exposure control plan must be completed and submitted to the BSO.

The protocol was provisionally approved pending revisions. Eric Smart moved. Tom Chambers seconded. The vote was unanimous.

B05-426 Domains of the gD receptor nectin-1 involved in viral spread

BBP on file with BSO

Primary reviewers: Kenady, Hunt

Four research protocol descriptions are provided. Three of these are methods, and none of the descriptions exhibit a clear statement of the problem(s) or rationale(s) for the project given.

1. The protocol should contain a summary of the first project – NOT methods, but a description of the viral constructs, as well as a rationale for their use, and for the choice of cell lines.
2. For the second project, please spell out just what is to be done – what is the nature of the virus(es) to be used, what is the rationale for cell line choice, what will be expressed in which cell lines? Please do not attach a description of experimental methods.
3. Those items in Parts 3 of the protocol that address safety issues regarding HSV studies are appropriate, and should not be deleted.
4. Attachments A – it is not clear what will be done with bovine herpesvirus type 1, HSV-2, or pseudorabies virus. Please spell out, clearly, in Part 3 just what is being done with these (NOT procedures for using them, but what they are being used for, and why).

5. On pp. 21-22, a much better description is needed. It is especially confusing in the section "Expression of Recombinant DNA in Cell Culture". Are intentions to express gD, gB, gH, or gL transiently using mammalian expression vectors? Also, maps and other information regarding pPEP98-101 are needed.
6. On p. 24, some description of the recombinant virus(es) and mutants is needed. Especially important is some statement as to the probability of generating recombinant infectious virus, and what steps may be taken to assess the risk (if any).
7. Attachments C – what will be done with vero, 293, and MDCK cells?
8. Page 27 should clarify the indication that the 78H1 cell lines will not be recombinant. This is contradictory to part 3.

The investigator was asked to resubmit the protocol with the above information included. Eric Smart moved. Lou Hersh Seconded. The vote was unanimous.

B05-429 Adiponectin in inflammatory bowel disease

Primary reviewers: Chambers, Smart

1. Fax a copy of the IACUC approval to the Biosafety Officer when approval is granted.
2. Training dates, and proof if necessary, are needed for each person listed as handling agents.
3. Need certification expiration date for the Biological Safety cabinet in room
4. Part 4, section C – please indicate the disposal methods for the infected mice.
5. Page 11, line 2 – This line must be more specific. "...but not limited to" is too general.
6. Attachment A needs to include the name of the agent, in conjunction with the source.
7. Attachment R must include a description of the vector construct. A diagram is acceptable.
8. Need to schedule a lab audit with Biological Safety.

The protocol was provisionally approved pending revisions. Tom Chambers moved. Kelly Breeding seconded. The vote was unanimous.

B05-410 Equine Infectious Anemia

Primary Reviewers: Tom Chambers, Glenn Telling, Eric Smart, Ken Dickey

Protocol was initially reviewed at the June 8, 2005 IBC Meeting. Provisional approval pending revisions was granted. Review of the revisions was necessary for full approval.

1. Containment of animal waste is still a concern. Please revise the containment to incorporate composting the bedding.

The protocol was again provisionally approved pending revisions. Eric Smart moved. Lou Hersh seconded. Tom Chambers abstained. The vote was unanimous.

Modifications of the by-laws were made. Committee approval will be made via email voting.

The meeting was adjourned at 1:55pm. Arthur Hunt moved. Kelly Breeding seconded. The vote was unanimous.

OTHER ITEMS FOR DISCUSSION

Revisions of the IBC by-laws will be discussed and voted upon at the August meeting.

BSO UPDATE

PROTOCOLS MEETING REGISTRATION REQUIREMENTS

B05-408 Role of drug and vitamin transport genes in cancer etiology and treatment
BBP on file with BSO

B05-414 04-ID-188: A multicenter, open-label phase I/II study to evaluate safety and immunogenicity of MVA-BN[®] smallpox vaccine in HIV infected subjects (CD4 counts >350 / μ l) and healthy subjects with and without previous smallpox vaccination - PQX-MVA-010

B05-412 A Double-Blind, Placebo-Controlled, Dose-Finding, Phase 2 Study to Assess the Safety, Tolerability, and Immunogenicity of Three Dose Levels of ACAM3000 Modified Vaccinia Ankara (MVA) Smallpox Vaccine in Adults With and Without Previous Smallpox Vaccination

B05-407P Sudden Oak Death Kentucky Forest Survey
B05-414 Virulence and Immunity of equine arteritis virus

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B05-419 : Regulation of Cholesterol Synthesis

PROTOCOL MODIFICATIONS: Location/personnel changes

B04-346M Strategies for Calcipain Inhibition

B03-280M2 Axonal Growth and Guidance for Nervous System Repair

B03-241M2 Gene Therapy for Spinal Cord Regeneration

MINUTES

**Institutional Biosafety Committee Open Meeting
Wednesday, August 10, 2005 12:00 P.M.
208 Combs Cancer Research Center**

Members Present

**Kelley Breeding
Thomas Chambers
Marcia Finucane
Eric Smart
Richard Wheaton
Doug Harrison
Louis Hersh
Jack Hlatt
Mark Farman
Chuck Staben
Arthur Hunt
Glen Telling**

Members Absent

Kenneth Dickey
Robert Jacob
Daniel Kenady

Tom Chambers called the meeting to order at 12:03pm. He noted a quorum was present.

OLD COMMITTEE BUSINESS

The minutes from the July 13, 2005 meeting were unanimously approved. Eric Smart moved, and Kelley Breeding seconded.

NEW BUSINESS

The IBC by-laws were amended to create non-voting status for University administrators who are members of the IBC. This is to avoid any perceived conflict of interest should an appeals process be implemented. "Administrator" is defined by the University as a person whose duties are over 50% administrative. Language was added to describe situations where an e-mail poll of IBC members will be utilized. Doug Harrison moved. Arthur Hunt seconded. The vote was unanimous.

New Protocol Review

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until the biosafety audit is performed, and any inadequacies are corrected as verified by the BSO or designee.

B05-432 Peptidases and AD

Primary Reviewers: Chambers, Hunt, Telling

BBP on file with BSO

The protocol was presented by Thomas Chambers, room for final vote.

was present during discussion, but left the

The protocol was provisionally approved pending the following minor modifications:

1. **should take the on-line safety trainings.**
2. **Viral constructs should be tested for replication competent lentivirus prior to animal injections.**
3. **The lab in which infectious agents are to be stored should be identified.**

Eric Smart moved. Kelly Breeding seconded.

abstained. The vote was unanimous.

B05-427 Prostaglandin E2-EP4 axis and angiotensin II induced abdominal aortic aneurysms
and the role of leptin in development of atherosclerosis

Primary Reviewers: Wheaton, Dickey, Farman, Harrison

The protocol was presented by Doug Harrison.

The protocol was provisionally approved pending the following modifications:

1. **Viral constructs should be tested for replication competent retrovirus prior to animal injections. Please include information describing how this will be done.**
2. **All viral work prior to the RCR testing should be conducted at a BSL-2 level. Please make this clear on page 5.**
3. **Aerosol generation should be marked in Section B: Biosafety and handling considerations (page 7) because centrifugation will be involved in the construction of the virus.**

4. A description of procedures the lab will use to minimize the potential for exposure based on the routes of exposure indicated in Section B: Biosafety and Handling considerations should be included in the protocol (page 7).

Richard Wheaton moved. Mark Farman seconded. The vote was unanimous.

B05-433 05-ID-171: The Safety, Tolerability, and Immunogenicity of ACAM3000 Modified Vaccinia ANKARA (MVA) Smallpox Vaccine in HIV-Seropositive Subjects who are Vaccinia Naïve: A Double-Blind, Placebo-Controlled, Phase 1/2 Study: H-249-004

Primary Reviewers: Hersh, Staben, Smart

The protocol was presented by Chuck Staben.

The protocol was approved as written.

Discussion centered around the risk posed to immune incompetent persons when receiving this attenuated strain, risk of secondary transmission, and pregnancy. The committee found the protocol adequately addresses these issues.

Eric Smart moved. Louis Hersh seconded. The vote was unanimous.

B05-426 Domains of the α D receptor nectin-1 involved in viral spread

Primary reviewers: Kenady, Hunt, Chambers

BBP on file with BSO

The protocol was approved as written

The protocol was presented by Tom Chambers.

This was a resubmission of a protocol submitted at the July 2005 meeting. The committee was pleased that the investigator had adequately clarified the questions returned to the investigator following the July meeting.

Arthur Hunt moved. Eric Smart seconded. The vote was unanimous.

OTHER COMMITTEE BUSINESS

The committee decided to have the annual IBC training at the September 14, 2005 meeting if the caseload permits.

The meeting date will remain on the second Wednesday of every month.

Marcia Finucane will contact the President's Office to request changes to the IBC membership list for 2005-2006.

The meeting adjourned at 1:15 pm. Richard Wheaton moved. Kelly Breeding seconded. The vote was unanimous.

BSO UPDATE

PROTOCOLS MEETING REGISTRATION REQUIREMENTS

B04-352 : Genetic analysis of RNA virus replication (Hepatitis C virus)

B05-423 Ca²⁺ permeable Na channels and cardiac cell and mechanisms of E-C coupling in atrial cells

B05-422 . American heart association national center scientist development grant and Ca²⁺ and calmodulin signaling in the cardiac myocyte under hypertensive stress

B04-355 Periodontal Pathogens: Animal Models and Infection

B05-425 GV-001.004 A Randomized, Phase II, Study of TNFerade™ Biologic with 5-FU and Radiation Therapy of Unresectable Locally Advanced Pancreatic Cancer.

B05-410 Equine Infectious Anemia

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B05-421 Nutrition Toxicology and Endothelial Cell Function

B05-418P Gene Expression Profiles in a Grass-Endophyte Symbiosis

B05-431P Messenger RNA 3' end formation in plants

PROTOCOL MODIFICATIONS

B04-345M Structural characteristics of pancreatic polypeptide and exon 1 of huntingtin

MINUTES
Institutional Biosafety Committee Open Meeting
Wednesday, September 14 12:00 P.M.
208 Combs Cancer Research Center

Members Present

Kelley Breeding	Daniel Kenady
Thomas Chambers	Mark Farman
Marcia Finucane	Chuck Staben
Eric Smart	Arthur Hunt
Robert Harmon	Kenneth Dickey
Richard Wheaton	Carol Pickett
Doug Harrison	Sabire Ozcan
Robert Jacob	Nathan Slovis

Doug Harrison called the meeting to order at 12:10pm. He noted a quorum was present.

OLD COMMITTEE BUSINESS

The minutes from the August 10, 2005 meeting were unanimously approved. Chuck Staben moved, and Mark Farman seconded.

OTHER ITEMS FOR DISCUSSION

Marcia Finucane gave a formal presentation of IBC Training for 2005.

- Role of BSO
- Makeup of IBC
- Role of IBC
- Responsibilities of IBC
- Role of Biosafety Office

NEW BUSINESS

New Protocol Review

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until the biosafety audit is performed, and any inadequacies are corrected as verified by the BSO or designee.

B05-437 : Ras Family G-protein Signaling

Primary Reviewers: Chambers, Harrison, Farman, Dickey

BBP on file with BSO

The protocol was presented by Mark Farman.

The protocol was **provisionally approved** pending the following minor modifications:

1. Reference which specific experimental protocols (numbers are sufficient) will be used in each of the projects.
2. Attachment A: specify the name of the adenoviral vectors received from Dr. Volgestein at Harvard. (If pADTrackCMV is the recombinant vector insert this information into attachment A.)
3. Indicate in the scientific summary where the neuroblastoma cells (SH-SY5Y) will be used in the protocol.
4. Two separate Attachment TC forms should be used to differentiate primary and immortal cell lines.

Mark Farman moved. Eric Smart seconded. The vote was unanimous.

B05-434 Studies on Apoptosis by Par-4
Primary Reviewers: Chambers, Hunt, Jacob, Smart, Dickey
BBP on file with BSO

The protocol was provisionally approved pending the following modifications:
The protocol was presented by Eric Smart.

1. An IRB number is necessary for the primary human cell lines in this protocol. (Any tissue originating from human subjects must be registered with the IRB.)
2. Only the cells which have been listed in the Scientific Summary will be approved for use in this protocol. A modification or notification must be submitted via email to the BSO when a new cell will be introduced into the procedures. If other cells from the spreadsheet are intended for use in current protocol, please include them in the Scientific Summary.

Robert Jacob moved. Arthur Hunt Seconded. The vote was unanimous.

B05-439 Architecture of the thin filament Z-line Structure
Primary Reviewers: Harrison, Staben, Farman, Kenady
BBP on file with BSO

The protocol was presented by Doug Harrison.
The protocol was provisionally approved pending the following modifications and a lab audit:

1. Project 3 must provide a reference for the standard protocols used to test replication competency of the Adenoviral constructs.
2. Each member of the personnel must receive bloodborne pathogen training.
3. Use of infectious agents should be consistently marked on page 1 and page 6.
4. Indicate the security of the refrigerator and barcode number for the BSC.
5. Attachment A: specify the name of the adenoviral vectors received from Dr. Volgestein at Harvard. (If pADTrackCMV is the recombinant vector insert this information into attachment A.)
6. Submit two TC attachments; one for the immortal, and one for the primary. List the cell lines of each respectively.

Mark Farman moved. Arthur Hunt seconded. The vote was unanimous.

B05-440 Innate immune responses involved in prostate cancer progression
Primary Reviewers: Staben, Hunt, Kenady, Jacob, Smart
BBP on file with BSO

The protocol was presented by Chuck Staben.
The protocol was provisionally approved pending the following modifications and a lab audit:

1. Provide a more summarized description, not list, of the SOPs listed in the Scientific Summary. Include work involving the transgenic mice.
2. The IBC emphasizes the use of human tissues with transgenic mice requires universal precautions of BSL2.
3. An IRB number is necessary for the primary human cell lines in this protocol. (Any tissue originating from human subjects must be registered with the IRB.)
4. Incorporate a protocol into scientific summary which tests for replication competency of retro viruses.

Eric Smart moved. Robert Jacob seconded. The vote was unanimous.

The meeting adjourned at 2:10 pm. Eric Smart moved. Kelly Breeding seconded. The vote was unanimous.

BSO UPDATE

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B05-430	<u>Bloodfeeding mosquitoes using chicks and mice</u>
B05-438	<u>Plasmid Construction in E.coli</u>
B05-438P	<u>Biochemical dissection of plant RNAi and miRNA pathways</u>
B05-435	<u>Biomaterials with Rationally Immobilized Growth Factors</u>

PROTOCOL MODIFICATIONS

B05-384M	<u>Non-reproductive actions of estrogen</u>
B04-308M	<u>Signaling Pathway regulating the fate determination of neural stem cells in the adult hippocampal dentate gyrus</u>
B04-346-M2	<u>Strategies for Calpain inhibition</u>

MINUTES
Institutional Biosafety Committee Open Meeting
Wednesday, October 12, 2005 12:00 P.M.
208 Combs Cancer Research Center

Members Present

Daniel Kenady
Thomas Chambers
Mark Farman
Marcia Finucane
Arthur Hunt
Robert Harmon
Kenneth Dickey
Carol Pickett
Doug Harrison
Sabire Ozcan
Nathan Slovis

Members Absent

Eric Smart
Robert Jacob
Richard Wheaton
Kelly Breeding
Chuck Staben

Tom Chambers called the meeting to order at 12:05pm. He noted a quorum was present.

OLD COMMITTEE BUSINESS

Minutes from the September 14, 2005 meeting were unanimously approved. Robert Harmon moved, and Doug Harrison seconded.

- It was noted that new and existing member introductions took place at the September meeting.

NEW BUSINESS

New Protocol Review

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until the biosafety audit is performed, and any inadequacies are corrected as verified by the BSO or designee.

B05-441 Polyamine inhibition in biofilm formation

Primary Reviewers: Chambers, Harrison, Kenady, Jacob, Ozcan, Pickett

The protocol was presented by Doug Harrison.

The protocol was provisionally approved pending the following modifications:

1. Attachment A needs to include more accurate information such as the source of agent
2. Part 4, Section B needs more information such as the volume of culture generated, route of exposure, Section C: explain how potentially biohazardous materials (recombinant bacteria) will be handled for disposal (autoclaving is preferred).

Doug Harrison moved. Daniel Kenady seconded. The vote was unanimous.

B05-442 The role of Pcd4The role of Pcd4 in colon cancer development

Primary Reviewers: Harrison, Staben Harmon, Hunt, Farman, Kenady, Ozcan, Dickey, Pickett

BBP on file with BSO

The protocol was provisionally approved pending the following modifications:

The protocol was presented by Doug Harrison.

1. An IRB number is necessary for this protocol. (Any protocol that uses human subjects or tissue from human subjects, even surgical specimens, must be registered with the IRB.)
2. Complete the TC Attachments by indicating whether the cell lines are oncogenic, transforming, etc.
3. MAPK1 should be added to Attachment R under gene name. (i.e. Pcd4, MAPK1)

Robert Harmon moved. Daniel Kenady Seconded. The vote was unanimous.

B05-443 · Using AAV vector to deliver shRNA into the brain toward a potential treatment for Huntington's Disease

Primary Reviewers: Chambers, Staben, Harmon, Hunt, Farman, Jacob, Dickey

BBP on file with BSO

The protocol was presented by Tom Chambers.

The protocol was provisionally approved pending the following modifications:

1. Include a construction map for the AAV vector from the manufacturer
2. This virus must be tested for replication either by the PI, or by the manufacturer before injection into animals. If the PI will do the test, please include how the test will be completed. If Medtronic, Inc. performs the test, provide information about how this is done. This must be provided before full approval is granted.

Mark Farman moved. Arthur Hunt seconded. The vote was unanimous.

OTHER BUSINESS

After full discussion, the committee decided that the method in which the protocols are distributed will not change. Full, not shortened, versions of the protocols will be included in IBC packets as in the previous months.

Confidentiality agreement contracts were signed and collected by the Biological Safety office.

The meeting adjourned at 1:05 pm. Mark Farman moved. Robert Harmon seconded. The vote was unanimous.

BSO UPDATE

PROTOCOLS MEETING REGISTRATION REQUIREMENTS

B05-400	<u>Analysis of Signal-Specific Complex Formation</u>
B05-429	<u>Adiponectin in inflammatory bowel disease</u>
B05-437	<u>Ras Family G-Protein Signaling</u>

PROTOCOL MODIFICATIONS

B05-365M	<u>SV5 and Hendra F protein</u>
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MINUTES

Institutional Biosafety Committee Open Meeting Wednesday, November 9, 2005 12:00 P.M. 208 Combs Cancer Research Center

Members Present

Kelly Breeding
Arthur Hunt
Richard Wheaton
Robert Harmon
Carol Pickett
Tom Chambers
Marcia Finucane
Sabire Ozcan
Doug Harrison
Mark Farman
Eric Smart
Chuck Staben
Robert Jacob
Daniel Kenady

Members Absent

Ken Dickey
Nathan Slovis

Tom Chambers called the meeting to order at 12:05pm. He noted a quorum was present.

OLD COMMITTEE BUSINESS

The minutes from the October 12, 2005 meeting were unanimously approved. Robert Harmon moved. Arthur Hunt seconded. The vote was unanimous.

NEW BUSINESS

New Protocol Review

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until the biosafety audit is performed, and any inadequacies are corrected as verified by the BSO or designee.

B05-437M

: Ras Family G-Protein Signaling

Primary Reviewers: Chambers, Smart, Wheaton, Harrison, Jacob

BBP on file with BSO

Presented by: Chambers

The modification was fully approved as written. Eric Smart moved. Arthur Hunt seconded. The vote was unanimous.

B05-445

: Immortalization of primary mouse melanocyte cell lines of a variant pigment composition

Primary Reviewers: Chambers, Jacob, Smart, Staben, Kenady, Pickett

Presented by: Chambers

The protocol was provisionally approved pending the following modifications:

1. Identify the combinations of oncogenes that will be used in the research. If all genes will be pooled, please note this in the scientific summary.
2. Indicate the concentration of lentivirus that will be used (PFU).

B05-447P : Using Tobacco Mosaic Virus as a Pathogen to Evaluate Resistance Response in Plants

Primary Reviewers: Harmon, Hunt, Farman, Ozcan, Pickett
Presented by: Harmon

The protocol was provisionally approved pending the following revisions:

1. Completion of a more extensive scientific summary section which will place more of the protocol's emphasis on the transgenic plants being utilized in the research. The current scientific summary details only the safety procedures utilized in the plant containment facility.
2. Explanation of the method by which the transgenic plants were created.
3. Clarification on the exact plant species to be utilized in this protocol.
4. Explanation of the exact location of TMV inoculations. TMV inoculation should occur in the containment facility.
5. Completion of Attachment R in reference to the transgenic plants being utilized not the unmodified TMV. TMV information is located on Attachment A.
6. Revision of Attachment P to reflect transgenic plants to be utilized in research project.
7. Completion of a set of standard operating procedures for working inside the plant containment facility that will be attached to the protocol.

Arthur Hunt moved. Sabire Ozcan seconded. The vote was unanimous.

B05-448P : Using Potato Virus X as a Pathogen to Evaluate Resistance Response in Plants

Primary Reviewers: Harmon, Hunt, Farman, Ozcan, Wheaton
Presented by: Hunt

The protocol was provisionally approved pending the following minor modifications:

1. Completion of a more extensive scientific summary which will provide details on the construction of the PVX vector to be utilized in the research. The current scientific summary details only the safety procedures utilized in the plant containment facility.
2. Completion of Attachment R with more detail on the specific structure of constructs to be utilized in the research.
3. Attachment P, Part 2, Item 1, Part a should have the second box checked stating "DNA from host organism is propagated only in that same organism, no foreign DNA used".
4. Completion of a set of standard operating procedures for working inside the plant containment facility that will be attached to the protocol.

Arthur Hunt moved. Chuck Staben seconded. The vote was unanimous.

B05-449 : Effects of HIV on Macrophage Function

BBP on File with BSO

Primary Reviewers: Harrison, Staben, Kenady, Dickey
Presented by: Harrison

The protocol was fully approved as written. Doug Harrison moved. Daniel Kenady seconded. The vote was unanimous.

OTHER BUSINESS

was up for annual review of his gene therapy protocol number B04-329. No issues were raised during the review. Eric Smart moved. Daniel Kenady seconded. The vote was unanimous to accept the report.

was granted Full Approval after submitting a formal letter from Medtronic, Inc. indicating that the AAV he proposed to use for protocol number B05-443 was replication deficient. Mark Farman moved. Richard Wheaton seconded. The vote was unanimous.

IBC will require specific citation for future replication competency testing. The testing laboratory should provide specific assay procedure, assay controls, and sensitivity of assay.

The meeting adjourned at 1:35 pm. Eric Smart Moved. Mark Farman Seconded. The vote was unanimous

BSO UPDATE

PROTOCOLS MEETING REGISTRATION REQUIREMENTS

B05-421	: <u>Nutrition toxicology and endothelial cell function</u>
B05-439	<u>Architecture of the thin filament Z-line Structure</u>
B05-441	<u>Polyamine inhibition in biofilm formation</u>
B05-442	<u>The role of Pcd4The role of Pcd4 in colon cancer development</u>
B05-444	<u>Bladder Epithelial Cell Culture for Research in Interstitial Cystitis</u>
B05-448BBP	<u>Nanoparticle containing drugs</u>
B05-428	<u>KTRDC Development and Field Testing of Transgenic Nicotiana-2005</u>

PROTOCOL MODIFICATIONS

B04-356M	<u>Gene Expression Predictors of Lung Cancer</u>
B04-357M	<u>Functional Activity of Rb Family Members p107 and p130</u>
B04-323M	<u>Role of Intrasinal plasticity in autonomic dysreflexia</u>

MINUTES

Institutional Biosafety Committee Open Meeting
Wednesday, December 14, 2005 12:00 P.M.
208 Combs Cancer Research Center

Members Present

Kelly Breeding
Arthur Hunt
Richard Wheaton
Robert Harmon
Tom Chambers
Marcia Finucane
Sabire Ozcan
Doug Harrison
Mark Farman
Eric Smart
Chuck Staben
Daniel Kenady

Members Absent

Ken Dickey
Nathan Slovis
Carol Pickett
Robert Jacob

Biosafety Office Staff

Derek Adams
Brandy Nelson
Megan Cormney

Tom Chambers called the meeting to order at 12:15pm. He noted a quorum was present.

OLD COMMITTEE BUSINESS

The minutes from the November 9, 2005 meeting were unanimously approved. Robert Harmon moved. Richard Wheaton seconded. The vote was unanimous.

NEW BUSINESS

New Protocol Review

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until the biosafety audit is performed, and any inadequacies are corrected as verified by the BSO or designee.

B05-453

Adventures in Secretary Mechanisms

BBP on file with BSO

The protocol was provisionally approved pending the following minor modifications.

1. Provide a description of the acronyms used for the table of genes provided in attachment R. A key at the top of the table will be sufficient.
2. Insert the vector names into the "vector technical names" area under the "Vector Description" section of attachment R.
3. The main door used for entering the laboratory area should be labeled with contact information. The contact will either be individual researchers in that area or the department head/chair.

Other comments made by the IBC regarding _____, protocol:

- IRB approval is not necessary because the human blood is commercially acquired.
- The transgenic mice are not a concern because they are not being created by this PI and IACUC has reviewed the protocol and given approval.
- Several members were concerned with the open lab layout of _____ and it was explained that everyone in the open lab follows BSL2 procedures and containment.

Robert Harmon moved. Sabire Ozcan seconded. The vote was unanimous.

B05-457 Immortalize Human Lymph-node B cells from Hepatitis C Virus (HCV) Positive Patients with Epstein-Barr Virus (EBV) to Generate Monoclonal Anti-HCV Antibody for Future Therapeutic and Diagnosis Application
BBP on file with BSO

The protocol was provisionally approved pending the following modifications:

1. Provide more compelling scientific reasoning for why the monoclonal antibodies are going to be produced in this fashion when they are already commercially available.
2. Address the specific use of 3H-Thymidine in the BSC. This information can be provided in the scientific summary or Part 4 where it is listed.
3. Even though is not directly working with the specimens, he should still complete and document training for both lab specific and hazardous materials training.
4. Provide a detailed method of transport for the extracted tissue to be taken from the OR to the research laboratory.
5. Rephrase the name of the agent on attachment A to read "HCV positive tissues from patients of the UK hospital OR".

Other comments made by the IBC regarding protocol:

- Committee discussed if HCV was actually being replicated in the lymphocytes being cultured in the lab and decided it was not. HCV is replicated in hepatocytes.
- The committee agreed to place the preferred method of transport for various samples, including extracted tissue, on the IBC website.

Douglas Harrison moved. Daniel Kenady seconded. The vote was unanimous.

B05-458 Role of drug and vitamin transport genes in cancer etiology and treatment
BBP on file with BSO

The protocol was approved as written with minor adjustments from the Biological Safety Office.

1. Mark the appropriate box for the correct BSC being used in the procedures. A2/B3
2. Include some details on the room which will be used for adenovirus work.

Other comments made by the IBC regarding protocol:

- RCA testing only needs to be addressed if the virus is physically being inserted into animals.

Eric Smart moved. Arthur Hunt seconded. The vote was unanimous.

B05-459 Mechanisms of DNA mismatch repair
BBP on file with BSO
Needs Audit

The protocol was provisionally approved pending the following minor modifications and completion of the biosafety audit:

1. Indicate the volume of *E. coli* that will be cultured in flasks.

Eric Smart moved. Daniel Kenady seconded. The vote was unanimous.

OTHER BUSINESS

Eric Smart recommended that Marcia Finucane inform Wendy Baldwin of deviation from the IBC approved protocol, specifically not wearing respiratory protection in the laboratory. The IBC went on record to indicate that they do not agree with current practices because they are not what the IBC reviewed and approved.

A motion was made for the IBC to send a letter to _____ insisting that he immediately follow the specified safety procedures outlined in his approved IBC protocol. If he does not comply, access to the laboratory will be denied for _____ and his staff. Daniel Kenady moved. Eric Smart seconded. The vote was unanimous.

A second motion was made which stated that the BSO must complete a surprise inspection for PPE following the delivery of the letter. Mark Farman moved. Eric Smart seconded. The vote was unanimous.

It was brought to attention that the "Minors in Labs Policy" had reached its final level of review. It will be submitted to the Committee for Environmental Health and Safety for final approval soon.

The meeting adjourned at 1:25 pm. Eric Smart moved. Mark Farman seconded. The vote was unanimous.

BSO UPDATE

PROTOCOLS MEETING REGISTRATION REQUIREMENTS

B05-434	<u>Studies on Apoptosis by Par-4</u>
B05-437M	<u>Ras Family G-Protein Signaling</u>
B05-440	<u>Innate Immune responses involved in prostate cancer progression</u>
B05-445	<u>Immortalization of primary mouse melanocyte cell lines of a variant pigment composition</u>
B05-449	<u>Effects of HIV on Macrophage Function</u>

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B05-450	<u>Investigation on the Periovulatory process</u>
B05-451	<u>Role of thrombospondin 1 in the development of diabetic renal complications</u>
B05-452	<u>Deciphering the mechanisms underlying the extreme resistance exhibited by transgenic soybean lines transformed with the Bean pod mottle virus capsid polyprotein</u>
B05-456	<u>Enzymes in Eicosanoid Metabolism</u>
B05-460	<u>Molecular Detection of Naturally Occurring Plant Pathogens</u>
B05-545	<u>Salamander Genome Project</u>

MINUTES

**Institutional Biosafety Committee Open Meeting
Wednesday, January 11, 2006 12:00 P.M.
208 Combs Cancer Research Center**

Members Present

Kelly Breeding
Arthur Hunt
Richard Wheaton
Daniel Kenady
Carol Pickett
Tom Chambers
Marcia Finucane
Sabire Ozcan
Doug Harrison
Eric Smart
Janet Rodgers

Members Absent

Chuck Staben
Nathan Slovis
Robert Jacob
Robert Harmon

Biosafety Office Staff

Derek Adams
Brandy Nelson

Tom Chambers called the meeting to order at 12:08pm. He noted a quorum was present.

OLD COMMITTEE BUSINESS

The minutes from the December 14, 2005 meeting were unanimously approved. Doug Harrison moved. Kelly Breeding seconded. The vote was unanimous.

NEW BUSINESS

New Protocol Review

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until the biosafety audit is performed, and any inadequacies are corrected as verified by the BSO or designee.

B05-461 Effect of human herpes virus-8 on blood-brain barrier disruption
in human immunodeficiency virus type-1
BBP on file with BSO

The protocol was provisionally approved pending the following minor modifications and an acceptable laboratory audit.

1. Scientific summary is not adequate in current form. The summary should present a summary of the full research plan. The summary should also include how all proteins and cell lines mentioned in the attachments will be utilized in the research.
2. The use of the terms "approved solutions" and "approved disinfectant" in Part 4-C of the protocol should be changed to "0.5% sodium hypochlorite" or another disinfectant tested for efficacy against HIV and HHV-8. A good choice would be Vindicator available through UK Stores, catalog number 6840-0184. Sodium hypochlorite use should be at 0.5% as opposed to 1% in the table summarizing disinfectant use in the lab.
3. must complete training, including Blood-Borne Pathogen, Lab Specific Safety, and Hazardous Materials Training.

Other comments made by the IBC regarding

protocol:

- A concern was raised regarding the laboratory's ability to function at BSL-2+ and if BSL-2+ is adequate for HIV. The Department of Biological Safety assured the committee that this is the appropriate biosafety level and that training has been provided to the laboratory regarding all the practices and procedures to be followed for BSL-2+ containment.
- Eye protection worn in the lab was questioned by the committee and it was mentioned that all activities involving the infectious agent will be performed in a biological safety cabinet thus eliminating the need for eye protection.
- Storage of paraformaldehyde in the biological safety cabinet was questioned by the committee and it was stated that lab has been instructed not to store any items in the biological safety cabinet. Chemicals will be stored in the chemical fume hood.

B06-467 05-ID172 Randomized, Double-blind, Placebo-controlled Phase II Trial of the Safety, Tolerability and Immunogenicity of Lyophilized ChimerivaxTM-WN02 West Nile Vaccine in Healthy Adults H-244-003
BBP on file with BSO

The protocol was approved as written.

Other comments made by the IBC regarding ' protocol:

- Lack of specific training is not an issue due to the nature of the work. The only required training for group is Bloodborne Pathogens Training. All other training is beneficial but optional.
- A concern for environmental and community risk was addressed. The committee accepted the sponsor's risk assessment (in the Investigator's Brochure) on the issue.

Doug Harrison moved. Daniel Kenady seconded. The vote was unanimous.

B05-434M Studies on Apoptosis by Par-4
BBP on file with BSO

The protocol was provisionally approved pending the following minor modifications.

1. Provide a reference for the proposed competency testing methods.
2. Indicate the specific area where the animal work with lentivirus will be conducted. Is it the same area as where adenovirus work is completed?

Other comments made by the IBC regarding ' protocol:

- has recently been approved for similar work involving adenovirus. No major changes are necessary for this modification.

OTHER BUSINESS

updated the committee on issues relating to

Tom Chambers
which were discussed in the last

IBC meeting. As the committee requested in the December meeting, a letter was sent to regarding use of respirators in his laboratory. A meeting attended by Tom Chambers, Marcia Finucane, David Hibbard, Chuck Staben, Alan Kaplan, Sue Straley, and resulted in agreement to use N-95 respirators or PAPRs in the facility. The committee had also requested a surprise inspection of lab be completed by Marcia Finucane. This has yet to be accomplished due to difficulty in knowing the work schedule of the lab. Eric Smart again expressed concern about the liability of the committee and the University in relation to noncompliance of Eric Smart and Daniel Kenady suggested that lab be requested to give an anticipated to schedule of work to Marcia Finucane in order to facilitate an inspection. Marcia Finucane also related to the committee an incident involving exhaust system failure in the facility on January 3rd, 2006 and information on future improvements to the facility.

modification was approved by a majority via email voting.

The meeting adjourned at 1:03 pm. Daniel Kenady moved. Arthur Hunt seconded. The vote was unanimous.

BSO UPDATE PROTOCOLS MEETING REGISTRATION REQUIREMENTS

- B05-453** Adventures In Secretory Mechanisms
B05-458 Role of drug and vitamin transport genes in cancer etiology and treatment

PROTOCOLS ISSUED REGISTRATION NUMBERS (These protocols do not require review by IBC and are registered with the BSO)

- B05-447P** Using Tobacco mosaic virus as a pathogen to evaluate resistance response in plants
B05-448P Using Potato Virus X as a pathogen to evaluate resistance response in plants
B05-462 Novel Tissue Engineering Scaffold for Treatment of Chronic Osteomyelitis
B05-463 Molecular Biology of Olfaction
B05-466BBP Catheter Flow Rate Study Utilizing Human PRBC

PROTOCOL MODIFICATIONS

- B04-355M** Periodontal pathogens: Animal models and infection
B05-272M Group V sPLA2 and Atherosclerosis Macrophage-Derived GQ Secretory Phospholipase AA2 and Atherosclerosis
B05-443M Using AAV Vector to deliver shRNA into the brain toward a potential treatment for Huntington's Disease
B04-365M2 SV5 and Hendra F promoted membrane fusion

MINUTES

Institutional Biosafety Committee Open Meeting
Wednesday, February 8, 2006 12:00 P.M.
208 Combs Cancer Research Center

Members Present

Thomas Chambers
Marcia Finucane
Richard Wheaton
Daniel Kenady
Carol Pickett
Sabire Ozcan
Doug Harrison
Eric Smart
Janet Rodgers
Nathan Slovis
Chuck Staben
Robert Jacob
Arthur Hunt

Members Absent

Kelly Breeding

Biosafety Office Staff

Derek Adams
Brandy Nelson

Tom Chambers called the meeting to order at 12:07pm. He noted a quorum was present.

OLD COMMITTEE BUSINESS

The minutes from the January 11, 2006 meeting were unanimously approved. Richard Wheaton moved. Eric Smart seconded. The vote was unanimous.

NEW BUSINESS

New Protocol Review

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until the biosafety audit is performed, and any inadequacies are corrected as verified by the BSO or designee.

B06-468

Biology of Relapsing Fever in *Borrelia* Species

BBP on file with BSO

The protocol was provisionally approved pending the following minor modification.

1. The scientific summary should be modified to include more information about the use of recombinant proteins. Specifically, the IBC needs to be informed if any of the recombinant proteins confer pathogenicity to *E. coli*, are to be injected into mice, and how exactly they will be utilized in the protocol.
2. Sharps disposal procedures discussed on Page 8 need to be modified. Sharps should not be autoclaved prior to disposal. Sharps should be placed in sharps disposal container after use and picked up by housekeeping when full for incineration.

Other comments made by the IBC regarding _____ protocol:

- The protocol indicates the BSC and centrifuge are in different rooms. The Department of Biological Safety has inspected the laboratory for a previous approval and transport is completed in a safe manner between these spaces.

Arthur Hunt moved. Carol Pickett seconded. The vote was unanimous.

B06-470

combined exposure
BBP on file with BSO

Immunotoxicity of zidovudine and sulfamethoxazole-trimethoprim

The protocol was provisionally approved pending the following minor modifications.

1. Due to outdoor transport utilized in protocol the IBC would like spill procedures to include notification of Hazardous Materials (Environmental Management @ 257-3285) in the event of a spill outside the laboratory.

Other comments made by the IBC regarding protocol:

- Due to the utilization of FDA-approved vaccines the IBC does not need additional information of infectious agent forms for this protocol.
- IRB and IACUC approvals must be in place for this protocol. It should be indicated on the first page of the protocol that this protocol is a clinical trial.
- FACS analysis of potentially infectious materials was an area of concern for the IBC. Discussion of the subject was resolved as samples will contain 1% paraformaldehyde which is adequate to inactivate HIV.
- The IBC expressed concern over the safety of personnel in handling infected materials. Clinic and laboratory personnel have received training in proper blood-borne pathogen procedures and have been offered Hepatitis B vaccines.

Robert Jacob moved. Eric Smart seconded. The vote was unanimous.

B06-472

transformation
BBP on file with BSO

The role of maturation-promoting factor in Ras-induced

The protocol was provisionally approved pending the following minor modifications and a satisfactory laboratory audit.

1. The use of animals in this protocol needs clarification. The IBC needs to know if animals will be used for isolation of cells or will be injected with viral vectors. The scientific summary should contain specific information regarding animal use in this protocol.
2. The submitted forms contain multiple instances of improperly checked boxes. Part 1, Page 1 of the IBC form should indicate the use of infectious agents in this protocol. Part 3, Page 7 of the IBC form contains conflicting information regarding training of personnel.
3. The protocol indicates the use of radioactive materials in conjunction with biohazardous agents. Specific information regarding how radioactivity will be utilized in the protocol should be included in the scientific summary. Disposal procedures for waste generated should be included as well.
4. The IBC was unsure if murine retroviruses were classified as Risk Group 1 organisms and if they would still be classified as RG1 after the addition of Ras. This information should be provided on Attachment A.
5. Several cell lines listed on Attachments TC 5-10 are listed as "not to be used in the proposed rDNA experiments". Cell lines not actively involved in the protocol do not need to be included on the forms. Cell lines which will be utilized in this protocol should be included in the scientific summary as well as on Attachment TC.

Other comments made by the IBC regarding _____ protocol:

- The IBC was impressed with the scientific summary, amount of information included, and the safety procedures discussed in the protocol.
- Because the use of animals in the protocol was unclear a discussion of acceptable use of ecotrophic retroviruses was held. The IBC felt it acceptable to place the viruses into cells isolated from mice but not into live mice at the biosafety level indicated in the protocol.

Doug Harrison moved. Eric Smart seconded. The vote was unanimous.

B06-473 _____ Tumor Immunology

BBP on file with BSO

The protocol was provisionally approved pending the following minor modifications and a satisfactory laboratory audit.

1. Adenovirus work needs to be clarified in the scientific summary. Specifically, the lay summary contains information about intranasal adenoviral inoculation that is not mentioned elsewhere in the protocol. The IBC needs to know if stocks of adenovirus will be produced and where this will occur. Also, the IBC needs to know where animal inoculations will occur.
2. An attachment TC must be completed for mouse bone marrow cells to be utilized in the protocol.
3. A letter of collaboration with _____ must be on file with the Department of Biological Safety. The IBC must know specific personnel in _____ lab who will be performing viral in order to verify proper training has been received.
4. The IBC suggests the researcher evaluate the use of the PCR method of determining replication competency instead of the plaque assay. A reference to the PCR method for determining replication competency can be found on-line at http://www.safety.duke.edu/LabSafety/Docs/RCV_ScreeningMethods_final.doc.

Other comments made by the IBC regarding _____ protocol:

- The committee discussed the fact that the plaque assay may not be the most sensitive method for the detection of replication competent viruses. The IBC feels the PCR method is more sensitive and faster than the plaque assay method. The PCR method is the recommended method for determination of replication competency.
- The IBC generally requires testing for replication competency or viral vectors if they are to be placed in animals. Testing prior to infection of bone marrow cells which will be subsequently injected into mice is acceptable.

Doug Harrison moved. Eric Smart seconded. The vote was unanimous.

B06-474P _____ The molecular mechanisms underlying interactions of plants with hemibiotrophic pathogens

The protocol was provisionally approved pending the following minor modification.

1. Section B: Location of Experiments, Page 7, needs to be revised. Boxes need to be checked to indicate the use of infectious agents in the protocol.

Other comments made by the IBC regarding _____ protocol:

- The committee discussed the fact that this exotic agent is a fairly low risk due to origination in Western Hemisphere. BL2 precautions are completely adequate for this work.
- The Department of Biological Safety confirmed that a collaboration letter for work with _____ is on file.

Arthur Hunt moved. Richard Wheaton seconded. The vote was unanimous.

OTHER BUSINESS

_____ has not been performing any animal experiments recently; therefore an observation of laboratory practices by the BSO has yet to occur. _____ has agreed to notify the BSO when animal experiments resume.

Marcia Finucane discussed the Lab Exit Checklist, available on-line at <http://ehs.uky.edu/ehs/exit.html>. All researchers leaving the University should be encouraged to follow these procedures.

The meeting adjourned at 1:10 pm. Eric Smart moved. Arthur Hunt seconded. The vote was unanimous.

BSO UPDATE

PROTOCOLS MEETING REGISTRATION REQUIREMENTS

B06-467 05-ID172 Randomized, Double-blind, Placebo-controlled Phase II Trial of the Safety, Tolerability and Immunogenicity of Lyophilized Chimerivax™-WN02 West Nile Vaccine in Healthy Adults H-244-003

B05-434M Studies on Apoptosis by Par-4

B05-409 Regulation of Na⁺ channel gene expression and Calcium regulation in brain aging and Alzheimer's disease

B05-459 Mechanisms of DNA mismatch repair

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B05-438 Plasmid construction in E. coli

B06-469 Gene Expression in cells and transgenic mice

B06-471P Functional Genomics of Cytochrome P450s

PROTOCOL MODIFICATIONS

B04-365M2 SV5 and Hendra F Promoted Membrane Fusion

B03-245M Novel Aureolic Acid Type Antitumor Agents/Angucycline-Derived Antitumor Drugs