Minutes
Institutional Biosafety Committee
February 23, 2006, 2:00PM, Ray Butler Conference Room

Present: Mikhail Alexeyev (Vice-Chair), Elliot Carter, William Guess, Jingfang Ju, Dusty Layton, Lalita Samant, Michele Schuler, David Wiik and David Wood

Absent: Joseph Coggin (Chair), Judy Miller, Brenda Jackson, Prakash Rao, Thomasina Sharpe, Samuel Strada, Cathy Tuck-Muller and Walt Dickerson

I Approval of minutes

The minutes of October 13, 2005 were approved.

II Information/Education

Topics for biosafety seminars were addressed. Plans are to offer these seminars on a bi-annual basis. Ultimately, these seminars are designed to stimulate a stronger presence of biosafety concerns within the institution and to create an open forum for questions/answers.

III New Registrations

0601
Investigator: Troy Stevens, Ph.D.
Role of pulmonary progenitor endothelial cells in barrier restoration during Pseudomonas-aeruginosa-induced lung injury

The goal of the project is the evaluate the impact of Pseudomonas-aeruginosa in the alevolar capillary barrier in rats and to examine if microvascular pulmonary endothelial progenitor cells engraft to the site. Agent involves the virulent P. aeruginosa strain PA103 (instilled via tracheostomy). Retroviral transfection of enhanced green fluorescent protein tagged endothelial progenitors is performed and the cells injected into a tail vein of control and P. aeurigonsa-infected rats. Animals will be confined to a designated room in the Biological Research Laboratory. Personal protective equipment will be worn during tracheostomy. Animals with signs of respiratory infection are to be handled in a biological hood. The committee requested the following be addressed: no eye contacts be worn, confirmation that goggles/face shield will be worn during tracheostomy and that the IACUC office be notified that the biosafety registration indicates this is a LC25 study. This information was not included in the animal protocol which is currently pending approval.

Action: The recommendation of the committee was approval pending receipt of requested information.

Vote: For: 8 Opposed: 0 Abstain: 0

0602
Investigator: Judy King, M.D., Ph.D.
Metastasis to the Lungs in ALCAM Null Mice

This project will use cultured MDA-MB-231 breast cancer cells to study the role of activated leukocyte cell adhesion molecule on the adhesion of metastatic breast cancer cells to the lung endothelium. The MDA-MB-231 cells will be put into isolated mouse lungs of both wild type and a knockout mouse lacking the adhesion molecule. Following this treatment, lung tissue will be fixed with formalin or glutaraldehyle and examined microscopically. The number of breast cancer cells present in sections of the tissue will be determined. The level of BSL2 and the use of a biological hood are appropriate for the proposed studies. Because of the potential for infectious agents in human tissues, all bloodborne pathogen protocols should be followed and personnel offered available vaccines.

Action: The recommendation of the committee was approval.

Vote: For: 7 Opposed: 0 Abstain: 1

0603
Investigator: Wesley Denny, Ph.D.
Immunoregulatory signaling in cystic fibrosis airway epithelium

The investigator plans to treat epithelial cell lines (that represent cystic fibrosis epithelium and one other normal) with various agents that initiate/suppress immune functions. Standard tissue culture techniques will be used. Cellular extracts will be prepared from these agents using dounce homogenization or sonification and centrifugation. Personal protective equipment will be worn and agents handled in a certified BSL-2 laminar flow hood in accordance with BL-2 requirements. The committee requested that the following be addressed: list immune agents to be used and section 6, questions #4 and #5 need to be modified to acknowledge limitations in the research.

Action: The recommendation of the committee was approval pending receipt of the request information.

Vote: For: 8 Opposed: 0 Abstain: 0

0604
Investigator: Paul Schwarzenberger, M.D.
Affect of Bacillus anthracis on mice with immune system defects

This research involves in vitro cytotoxicity studies with bacterium on various human cancer cell lines. The Bacillus anthracis Sterne 7702 strain is used and cultured on standard media. This strain is avirulent due to loss of the capsule and is excluded from the select agent list. The agent will be handled in a BSL-2 lab and personnel protective equipment used when handling the materials. Immunocompromised individuals and pregnant women will not be allowed to handle this organism. It is also noted that Ciprofloxacin is an effective form of treatment if biological exposure where encountered.

Action: The recommendation of the committee was approval.

Vote: For: 8 Opposed: 0 Abstain: 0

0605
Investigator: John Oakes, Ph.D.
Induction of α-chemokines by varicella-zoster virus

The goal of this project is to determine if one or more alpha chemokines know to chemoattract netrophilis and T-cells into sites of inflammation play a role in the immunopathogenesis of herpes zoster keratitis. The following issues are requested be approval is granted:

- Section 6, question 5 is blank. The known hazards/risk such be included. A copy of the biohazard MSDS on this infectious agent was provided to the investigator
- Section 6, question 3. Zoster immune globin is a good prophylatical measure. However, the investigator should be aware of two drugs, Vidarabin and Acyclovir that are recommended for the treatment of VZV infection.
- Section 4, question #2. If tissue culture is the only biohazardous technique to be used, this registration may not be needed. Describe the virus-related work (e.g., virus propagation, infection of cultured cells, etc.)

Action: The recommendation of the committee was approval pending receipt of the request information.

Vote: For: 7 Opposed: 0 Abstain: 1

IV New Business

A copy of the 2005 annual biosafety inspection report was distributed and discussed.

V. New Business

The recombinant DNA registration form was modified to include additional information in order to provide for a more thorough review. The new items were highlighted and approved for use by the committee.

Ms. Layton presented a brief overview on federal oversight and review requirements for research involving human gene transfer. A guidance document was created to assist investigators in initiating a gene therapy study which serves to inform both federal and local review requirements. The Office of Research Compliance and Assurance will confirm that a protocol is approval by all necessary review committees before the first patient is enrolled. Additionally, a Human Gene Transfer Registration Supplement was developed and will be required for use with all new recombinant DNA registrations.

V For informational purposes

a. Closed Registrations

Protocol #	PI	Close Date
B8641	John Oakes	10/22/2005

b. New/Start-up Lab Reviews

None

The meeting adjourned at 3:10 PM.

Minutes
Institutional Biosafety Committee
October, 13 2005, 2:00PM , LMB Conference Room

Present: Mikhail Alexeyev (Vice-Chair), Elliot Carter, Jingfang Ju, Dusty Layton, Judy Miller, Lalita Samant, Michele Schuler, Samuel Strada, Cathy Tuck-Muller, David Wiik and David Wood

Absent: Joseph Coggin (Chair), Brenda Jackson, Prakash Rao, Thomasina Sharpe and Walt Dickerson

Guest: Ann Foster, Safety and Environmental Compliance

I Approval of minutes

The minutes of July 27, 2005 were approved.

II Information/Education

The new members of the committee were introduced and the committee membership listing for 2005-06 was distributed. Ms. Layton presented a brief update on current registration data. There are 101 active registrations; 60 of those registered for use of infectious agents and 41 registered for research involving recombinant DNA. Risk group classifications by biosafety levels are as follows: BSL-1/10; BSL-2/82 and BSL-3/ 9. There are forty-five investigators registered to work with biohazardous materials, many having multiple registrations.

Ms. Layton prepared powerpoint slides as handouts for reviewing committee responsibilities and regulatory requirements. The committee is mandated by the NIH and is the cornerstone of institutional oversight of recombinant DNA research. Information of items to be assessed by IBC's were reviewed to include containment levels, adequacy of facilities, lab personnel training and institutional/investigator compliance. Moreover, brief information on human gene transfer research was highlighted to include that IBC's must ensure 1) no human subject participant's are enrolled until RAC review, IBC and IRB approval is obtained, 2) issues raised by RAC in public review are considered, 3) final approval occurs only after RAC review, and compliance with surveillance, data reporting and adverse event reporting. The committee members were informed on the NIH, Office of Biotechnology Activities website for additional resources relating to IBC's roles and esponsibilities. Also, it was noted that the Biosafety in Microbiological and Biomedical Laboratories (BMBL) is a international gold standard in providing recommended biosafety standards for specific organisms. The 5th edition is expected to be released in 2006. IBC members will be provided a copy to be used as a reference when reviewing biohazardous registrations. Lastly, current issues were highlighted to include the increase use of recombinant virus vectors for gene therapy, stem cells and dual-use research in the life sciences with is another initiative to enhance biosecurity.

Additionally, a member information sheet was prepared highlighting pertinent topics: 1)what requires IBC approval, 2)risk group classifications, 3)review of registrations, 4) laboratory inspections, 5) renewals and 6) human gene transfer studies and animal use.

The committee was informed that Dr. Mikhail Alexeyev would be presenting a seminar entitled "Biosafety Recommendations for Working With Viral Vectors" on October 18th. All investigators working with viral vectors will be required to attend. In addition, periodic seminars related to biosafety issues will be offered to faculty, staff and students.

III New Registrations

0516
Investigator: Hung Khong, MD
Project Title: A Randomized, Phase II, Study of TNFerade™ Biologic with 5-FU Radiation Therapy for First Line Treatment of Unresectable Locally Advanced Pancreatic Cancer

This research involves patients with unresectable locally advanced pancreatic cancer who will receive standard treatment with radiation and 5-FU followed by gemcitibine. This is a human gene transfer study involving adenovirus, replication deficient. No significant issues were raised by the NIH Recombinant DNA Advisory Committee (RAC) that would warrant urther review by the RAC in a public session. The Investigator will be informed that before study participants are enrolled the following documentation must be submitted to the NIH Office of Biotechnology Activities: 1) IBC approval, 2) IRB approval, 3) IRB approved consent document, 4) biosketch of investigator(s). Documentation of personnel training in practices/techniques required to ensure adequate safety will be requested for IBC records.

Action: The recommendation of the committee was approval.

Vote: For: 10 Opposed: 0 Abstain: 0

IV New Business

All projects registered w/ the IBC are audited by the committee members to evaluate compliance with our COM Biosafety Manual and CDC guidelines. Ms. Layton asked that the members review the audit assignment list indicating group assignments and respective areas for auditing. Each group is assigned a team leader who is responsible for coordinating dates/time of inspections with the team members. Investigators will be notified in advance that inspections will take place during the first week of December (December 1st, 2nd or 5th). The Office of Research Compliance offered to assist the team leaders in coordinating their site visits with respective departments.

V For informational purposes

a. Closed Registrations

Registration#	PI	Closed Date
B0015	Joseph Coggin, Ph.D.	9/16/2005
B0311	Sudhakar Madanagopal, M.D.	8/25/2005
B0105	David McGee, Ph.D.	9/1/2005
B0309	David McGee, Ph.D.	9/1/2005

b. New/Start-up Lab Reviews

None

The meeting adjourned at 3:10 PM.

Minutes
Institutional Biosafety Committee
July 27, 2005, 3:00PM, Multi-Media Conference Room, MSB 1190

Present: Mikhail Alexeyev, Jon Garcia, Jim Gaubatz (Vice-Chair), Jingfang Ju, Dusty Layton, Judy Miller, Lalita Samant, Samuel Strada, Cathy Tuck-Muller, and David Wiik

Absent: Joseph Coggin (Chair), Elliott Carter, Brenda Jackson, Thomasina Sharpe and Walt Dickerson

I Approval of minutes

The minutes of May 20, 2005 were approved with one minor correction.

II Information/Education

None

III New Registrations

0514
Investigator: Dr. James Parker
Project Title: Bacterial clearance of anesthetized mice
BSL: 2

Research Summary: This is a biosafety level 2 experiment involving intratracheal instillation of S. aureus into anesthetized mice prior to mechanical ventilation followed by collection of lung lavage at the termination of the experiment. IACUC approval has been obtained for use of animals.

Action:
The recommendation of the committee was approval pending additional information. The following should be addressed in the biohazardous registration form: Section 6, question 3, penicillin may not be as effective due to drug resistance. Plans for working with resistant strains will be requested. Section 6, question 4, health issues/conditions must be reviewed. Section 7, the registration does not reflect the appropriate dilution of bleach for spill clean-up. The MSDS indicates a 1% bleach solution which will be the recommendation for use in the laboratory. Lastly, the project title "Ventilation of anesthetized mice" does not adequately reflect the research. The title should be changed to better reflect the experiments involved.

Vote: For: 9 Opposed: 0 Abstain: 0

0515
Investigator: Dr. Paul Schwarzenberger
Project Title: Trial to evaluate the safety of intratumoral VCL followed by electroporation
BSL2

Research Summary: This study is covered by the NIH Guidelines involving human gene transfer. Plasmid DNA will be stored and maintained in a locked freezer located in the LMB trailer 3. VCL-IM01 has couplet human IL-2 cDNA fused to rat insulin II signal peptide. The DNA will be transferred to the MedPulser® device and electroporated into patients at the Mobile Infirmary Oncology Clinic. It is noted that Mobile Infirmary does not have a Institutional Biosafety Committee. The study has been approved by the Western IRB, dated 5/5/2005 and by the National Institutes of Health Recombinant Advisory Committee.

Action: The recommendation of the committee was approval. The approval is for storage of study drug only and transfer into administration device under biosafety cabinet in BSL-2 facility located in the LMB.

Vote: For: 8 Opposed: 0 Abstain: 1

IV For informational purposes

a. Closed registrations - None

b. New/Start-up Lab Reviews - None

The meeting adjourned at 3:45 PM.

Minutes
Institutional Biosafety Committee
May 20, 2005, 2:00 PM, LMB Conference Room

Present: Mikhail Alexeyev, Jim Gaubatz (Vice-Chair), Jingfang Ju, Dusty Layton, Lalita Samant, Thomasina Sharpe, Samuel Strada, Cathy Tuck-Muller, and David Wiik

Absent: Joseph Coggin (Chair), Elliott Carter, Brenda Jackson, Judy Miller and Walt Dickerson

Guest: Ann Foster (Safety and Environmental Compliance)

I Approval of minutes

The minutes of March 18, 2005 were approved.

II Information/Education

Ms. Layton briefly highlighted issues from a article published in Chronicle of Higher Education entitled "Biosafety Committees Come Under Scrutiny". The article discusses the "The Sunshine Project", an international non-profit organization working against the hostile use of biotechnology work on biological weapons. The group requested last winter IBC minutes from ~400 research institutions, as well as information about the use of select agents. In the course of conducting the IBC survey, the Sunshine Project encountered a number of biosafety problems such as conducting business by email which is a violation of NIH guidelines. The article lists some of the universities that were found to be falling short of compliance. The article emphasizes that IBCs in general need to take their jobs seriously and not just "rubbing stamping" approvals.

From a regulatory perspective, biosafety and biosecurity continues to be a area that impacts research. It was mentioned that new federal initiatives to promote biosecurity in life science research has prompted the establishment of a National Science Advisory Board for Biosecurity (NSABB). The new board will recommend specific strategies for the oversight of dual use biological research, to include the development of guidelines for the case-by-case review and approval by Institutional Biosafety Committees. Therefore, IBCs may be expanding to assume a new role in biosecurity in the review of experiments defined for dual-use research (ie, vaccine-resistant microbes, enhance the virulence of a pathogen or weaponize a biological agent/toxin. The NSABB will hold its first meeting on June 30, 2005.

Ms. Layton provided the committee with a update on select agents. The Office of Research Compliance and Assurance (OCRA) distributed a memorandum to all research investigators providing an updated list of select agents for review. The select agent rule published its final ruling on March 18, 2005 and the agent/toxin list was slightly modified. As a result, the OCRA conducted a survey of all research labs to assess inventory of any new select agents and/or toxins which may be stored or used. It was requested that all toxins used under the exempted amount be registered with the IBC to ensure that the total amount of toxin be maintained below the exempt limit.

III New Registrations

0505
Investigator: Dr. Oystein Fodstad
Project Title: Analysis of tissues from the Cancer Research Institute biobank for molecular determinants of tumor progression and metastasis
BSL: 2

Research Summary: The PI will obtain fresh human tissue from the Cancer Research Institute's biobank which will be stained using Hematoxylin and Eosin. The tissue corresponding to "normal", "primary tumor", and "tumor tissue" from distant metastases will be analyzed by immunohistochemistry for the expression of various markers to tumor progression and metastasis. IRB approval has been obtained.

Action:
The recommendation of the committee was approval pending additional information on medical and health risks. Since the PI and lab staff are exposed to human tissues/fluids, information specific to any health issues or conditions that might require monitoring or review before personnel are allowed to word with biohazards will be requested. In addition, identification of any known health risk/hazards in the research will be clarified. It is noted that Biohazardous Agent Registration form, section 6 entitled 'Medical /Health Information", will be revised to clearly define potential health issues and hazards associated with the research.

Vote: For: 8 Opposed: 0 Abstain: 1

0506
Investigator: Lewis Pannell, Ph.D.
Project Title: Identification and determination of total glycosylation in body tissues and fluids
BSL2

Research Summary: Selected human tissue samples obtain from the Cancer Research Institute's biobank will be digested with enzymes and peptide analyses performed by mass spectrometry methods. The aim is to develop a method for total glycosylation analysis on the samples using a combination of sample preparation and computational methods. IRB approval has been obtained.

Action: The recommendation of the committee was approval pending additional information on medical and health risks. Since the PI and lab staff are exposed to human tissues/fluids, information specific to any health issues or conditions that might require monitoring or review before personnel are allowed to word with biohazards will be requested. In addition, identification of any known health risk/hazards in the research will be clarified.

Vote: For: 8 Opposed: 0 Abstain: 1

0507
Investigator: Lalita Samant, Ph.D.
Project Title: Gli1 upregulates osteopontin: a critical determinant of metastatic breast cancer
BSL2

Research Summary: The human tissue samples will be obtained from the Cancer Research Institute's biobank. The tissues will be stained by using Hematoxylin and Eosin. Plasma will be analyzed by ELISA for the expression of OPN. Correlations will be made with the presence of bone metastases. IRB approval has been obtained.

Action: The recommendation of the committee was approval pending additional information on medical and health risks. Since the PI and lab staff are exposed to human tissues/fluids, information specific to any health issues or conditions that might require monitoring or review before personnel are allowed to word with biohazards will be requested. In addition, identification of any known health risk/hazards in the research will be clarified.

Vote: For: 8 Opposed: 0 Abstain: 1

0508
Investigator: Lalita Samant, Ph.D.
Project Title: Gli1 upregulates osteopontin: a critical determinant of metastatic breast cancer - *recombinant DNA*
BSL2

Research Summary: The human tissue samples will be obtained from the Cancer Research Institute's biobank. The tissues will be stained by using Hematoxylin and Eosin. Plasma will be analyzed by ELISA for the expression of OPN. Correlations will be made with the presence of bone metastases. IRB approval has been obtained. The category of experiments covered by NIH guidelines for this rDNA research project is Section III-D, Experiments in which DNA from Risk Group 2, 3, 4 or restricted agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems.

Action: The recommendation of the committee was approval.

Vote: For: 8 Opposed: 0 Abstain: 1

SA

0509
Investigator: David Wood, Ph.D.
Project Title: Genetic analysis of Rickettsia prowazekii - *recombinant DNA*
BSL3

Research Summary: This project involves the transfer of a drug resistance trait to a select agent which is reviewed by a technical advisory committee administered by the Centers for Disease Control (CDC). The Escerichia coli chloramphenicol resistance gene (cat) will be placed behind a strong rickettsial promoter and inserted into both plasmid and transposon vectors. Previously, chloramphenicol was restricted because it was listed as a treatment for rickettisal infections. However, chloramphenicol is no longer a drug of choice for such infections. The investigator provided relevant publications for the committee's review. The category of experiments covered by the NIH guidelines is Section III-A, Experiments that require IBC approval, Research Advisory Committee (RAC) review and NIH Director approval before initiation. Specific instructions were obtained from the CDC regarding submission of this restricted experiment.

Action: The recommendation of the committee is to defer approval. Local IBC approval is contingent upon review, comment and approval by the CDC.

Vote: For: 9 Opposed: 0 Abstain: 0

0510
Investigator: Hung Kung, M.D.
Project Title: In vitro of immune adjuvants in the generation of anti-tumor immunity
BSL2

Research Summary: This research project involves the use of human blood, human tumor cell lines and human cell lines stably transfected with a gene encoding a cytokine or an antigen. Biohazardous techniques used are centrifugation, pipetting and tissue culturing.

Action: The recommendation of the committee was approval.

Vote: For: 9 Opposed: 0 Abstain: 0

0511
Investigator: Hung Kung, M.D.
Project Title: A phase III-randomized, open-label study of CG1940 and CG8711 vs docetaxel and prednisone in patients with metastatic hormone-refractory prostate cancer who are chemotherapy-naive - *recombinant DNA*
BSL2

Research Summary: This is a human gene therapy study involving patients with metastatic prostate cancer who are not responding to hormone therapy. The cancer vaccine used in this study is of recombinant origin. The patients will be vaccinated with intradermal CG1940 and CG8711 or docetaxel or prednisone. The host strain for propagation of the recombinant is a adeno-associated viral vector. There is no infectious virus generated from the viral vector. The category of experiments covered by the NIH guidelines is Section III-C, Experiments that require IBC and IRB, plus NIH Research Advisory Committee (RAC) review before participant enrollment. A copy of the NIH RAC approval letter has been obtained. In addition, IRB approval has been obtained for this clinical trial.

Action: The recommendation of the committee was approval. The investigator is requested to submit the following documents to the NIH Office of Biotechnology Activities before study participants are enrolled: 1) local IBC approval, 2) IRB approval, 3) IRB approved consent document and 4) PI(s) biosketch.

Vote: For: 9 Opposed: 0 Abstain: 0

0512
'nvestigator: David Wood, Ph.D.
.Project Title: Genetic analysis of rickettsia - *recombinant DNA*
BSL3

Research Summary: Research to study the obligate intracellular parasite *Rickettsia prowazekii.* The research would involve fragments of rickettsial chromosomal DNA to be cloned into a *Saccharomyces cerevisease* recipient to identify genes that affect the growth of the yeast recipient. This category of experiments covered by the NIH guidelines is Section III-D, Experiments that require only IBC approval before initiation. These experiments involve DNA from Risk Group 2, 3, or 4 or restricted agents cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems.

Action: The recommendation of the committee was approval.

Vote: For: 9 Opposed: 0 Abstain: 0

0513
Investigator: James Parker, Ph.D.
Project Title: Toxocara canis infection and electroporation in rats
BSL2

Research Summary: Research involves eggs of toxocara canis that will be introduced into the stomach of rats via a catheter. Rats will be anesthetized with Ketamine and xylazine. It is noted that Institutional Animal Care and Use approval has been obtained for this research study. The infected animals will be isolated from other animals. There is no airborne infection associated with the biohazardous agent. Gloves and mask will be provided to personnel for safety precautions.

Action: The recommendation of the committee was approval pending additional information on medical and health risks. Health issues or conditions that might require monitoring or review before personnel are allowed to word with biohazards will be requested, as well as identification of any known health risk/hazards in the research.

Additionally, the Office of Research Compliance and Assurance has requested that the investigator enroll in the Occupational Health Program (OHP) for Animal Handlers as a Category D, defined as "those who are working or handling animals or tissues from animals experimentally infected with pathogens", as the research involves the use of Toxocara canis eggs to be introduced into the stomach of rats. The investigator will be asked to complete a OHP health questionnaire for review, assessment and consultation by the OHP physician.

Vote: For: 9 Opposed: 0 Abstain: 0

IV For informational purposes

a. Closed registrations - None

b. New/Start-up Lab Reviews - None

The meeting adjourned at 3:15PM.

Minutes
Institutional Biosafety Committee
March 18, 2005, 1:00 PM, LMB Conference Room

Present: Joseph Coggin (Chair), Mikhail Alexeyev, Jim Gaubatz, Bill Guess, Jingfang Ju, Dusty Layton, Judy Miller, Samuel Strada, Cathy Tuck-Muller, and David Wiik

Absent: Elliott Carter, Brenda Jackson, Lalita Samant, Thomasina Sharpe and Walt Dickerson

I Approval of minutes

The minutes of October 27, 2004 were approved.

II Information/Education

Ms. Layton announced that on December 16, 2004 all registered IBCs received a compliance memorandum from NIH, Office of Biotechnology Activities regarding the importance of biosafety review and oversight of research involving recombinant DNA. In addition, the committee was informed that NIH has stated they will be conducting site visits at selected institutions. It can be anticipated that these inspections are due to the undertaking of new programs of research related to biodefense and emerging infectious disease threats that frequently involve recombinant DNA work. As such, Dr. Alexeyev who has expertise in rDNA technologies/viral vectors and Ms. Layton met regarding review of educational/guidance information for faculty. It was identified that additional information needs to be provided to investigators as a resource to assist in preparation of registration materials and understanding of regulatory requirements. As a beginning, two documents were modeled from other institutions in order to compose a frequently asked questions involving recombinant DNA guide and information on the NIH rDNA guidelines. Dr. Gaubatz stated that this information should be provided to new faculty submitting registrations for biosafety approval. This information will be included as part of a packet to include the Biosafety Manual for new faculty and registered laboratories.

Furthermore, Ms. Layton stated that Dr. Alexeyev has agreed to provide a educational seminar in the fall for faculty on viral vectors and safety issues. Information on commonly used viral vectors and recombinant DNA technologies will help lend guidance to investigators using these materials in their research and to promote safe conduct and ensure compliance with NIH guidelines.

III New Registrations

0501
Investigator: David McGee, Ph.D.
Project Title: Affect of *Bacillus anthracis* on mice with immune system defects
BSL: 2

In review of this registration it was determined that no experiments would be conducted under this proposed registration except for growing the organisms and supplying a frozen stock to Dr. Paul Schwarzenberger at Louisiana State University. Dr. Schwarzenberger will be determining the affects of this organism on outcomes in mice that have various defects in the immune system, such as IL-17. Dr. McGee has already obtained IBC approval (6/30/03) to work with *Bacillus anthracis* (Sterne 7702 strain), therefore it was recommended that the information submitted in the proposed registration be filed as an amendment to his active registration B0309. It was noted that this strain is exempt from the select agent regulation.

Action: The recommendation of the committee was approval pending receipt of biosafety approval from Louisiana State University and plans for packaging and shipping the materials.
Vote: For: 8 Opposed: 0 Abstain: 1

0502
Investigator: Paul Schwarzenberger, MD
Project Title: Phase II study of a TGF beta gene modified allogeneic tumor cell vaccine in patients with stages II-IV non small cell lung cancer.

Action: The recommendation of the committee was approval pending clarification of the following items: 1) the section entitled "location of experiments" on page 1 on the biohazardous agent registration form should be changed to LMB to identify the

room/area of location; 2) It was noted that Drs. Barsoum and Rohrer will observe and monitor required safety practices in the laboratory and should be listed as personnel on the registration form; 3) IRB documentation/approval is requested, as patient/subject recruitment and study procedures are carried out at Mobile Infirmary; and 4) Dr. Coggin, Chair of Microbiology and Immunology, provided the IBC with some comments relative to your proposed registration containing explicit information about the storage and potential use of the frozen cells and preparation of vaccine. Due to a conflict of interest, the committee requests that a letter be addressed and submitted by the principal investigator.

Vote: For: 8 Opposed: 0 Abstain: 1

0503
Investigator: Paul Schwarzenberger, MD
Project Title: Phase II study of a TGF beta gene modified allogeneic tumor cell vaccine in patients with stages II-IV non small cell lung cancer - *recombinant DNA research.*

Action: The recommendation of the committee was approval pending clarification of the following items: 1) the section entitled "location of experiments" on page 1 on the biohazardous agent registration form should be changed to LMB to identify the room/area of location; 2) It was noted that Drs. Barsoum and Rohrer will observe and monitor required safety practices in the laboratory and should be listed as personnel on the registration form; 3) IRB documentation/approval is requested, as patient/subject recruitment and study procedures are carried out at Mobile Infirmary; 4) NIH recombinant DNA documentation/approval is requested, as this work involves the transfer of recombinant DNA into human research participants and is regulated by NIH guidelines, Section III-C-1. These experiments require the review/approval by the NIH recombinant DNA advisory committee and 5) Dr. Coggin, Chair of Microbiology and Immunology, provided the IBC with some comments relative to your proposed registration containing explicit information about the storage and potential use of the frozen cells and preparation of vaccine. Due to a conflict of interest, the committee requests that a letter be addressed and submitted by the principal investigator.

Vote: For: 8 Opposed: 0 Abstain: 1

0504
Investigator: Hung Khong, M.D.
Project Title: Clinical study of vaccine versus best supportive care or palliative chemotherapy in patients with metastatic pancreatic cancer who have failed a gemcitabine-containing chemotherapy regine

Action: The recommendation of the committee was approval pending several administrative actions. This is a clinical research study involving Vaccinia which is classified as a biosafety level 2 agent. This study involves patients with metastatic pancreatic cancer who failed standard chemotherapy and vaccinated subcutaneously with viral vector (vaccinia and fowlpox) carrying tumor antigens. The viral based cancer vaccines are stored in closed vials. The vial is vortexed, then the contents are drawn into syringes and injected into patients. Areas of biosafety precautions include handling of vaccine/exposure to papular/pustular lesions until scab separates. Appropriate personnel protective gear must be utilized and vaccination of involved personnel may be considered. IRB approval (12/14/04) has been obtained for this study. All study procedures will take place at the Medical Oncology Clinic at Knollwood Hospital. The study sponsor, Therion Biologics, will provide the appropriate biosafety/bloodborne pathogen training to all involved personnel. Therefore, the committee agreed that our institutional bloodborne pathogen training program via Complynow® would not be required. A copy of the training log will be requested from the investigator. This research study was inadvertently submitted on a biohazard agent registration form. The committee requested submission of a recombinant DNA registration for use with these recombinant viral vectors. Ms. Layton contacted Mr. Allan Shipp at NIH, Office of Biotechnology Activities regarding registering these viral based cancer vaccines with NIH for review/approval by the Recombinant DNA Advisory Committee (RAC). It was learned that the study has been reviewed by the RAC and documentation provided for the study file. However, Ms. Layton informed the investigator that the study needs to be registered with NIH as an additional clinical trials site (per NIH guidelines, Appendix M-I-C-2) before subject enrollment. This includes submitting IBC approval, IRB approval, IRB approved consent and a curriculum vitae of the investigator(s).

Vote: For: 8 Opposed: 0 Abstain: 1

IV 2004 Biosafety Inspections

The 2004 biosafety audit report was distributed to the committee. A total of forty-six labs were inspected, with 35% attaining full compliance as compared to 18% in the previous year. A audit summary of minor deficiencies identified during the inspections were provided in the audit report. No major deficiencies were noted. The inspection team of the Biomechanical Engineering lab noted in their report that the lab was very tidy and organized. The inspection team made a recommendation to lift the "unannounced" inspections since there had not been any major deficiencies noted during the last two periodic visits. The investigators were notified that the laboratory was no longer subject to "unannounced" inspections, as their compliance status with institutional biosafety policies had been achieved. For the year 2004, the committee reviewed/approved 30 new registrations compared to 18 new projects in year 2003. There was one known biosafety related injury report involving human blood. This exposure was evaluated and treated by Dr. Sharpe.

V For Informational purposes

a. New approvals - Vote by mail review

B0430 Dr. Jian Yang
Develop mouse models for basic research and drug development for obesity and/or diabetes
BL2
Recombinant DNA
Approved: January 11, 2005

b. Closed Registrations - None

c. New/Start-up Lab reviews

Registration #	PI	Date Inspected	Inspectors
B0428/DNA0429	Brian Fouty, MD	12/15/04	J. Gaubatz, J. Miller

The meeting adjourned at 2:00PM.

Minutes
Institutional Biosafety Committee
October 27, 2004, 9:00 AM, LMB Conference Room

Present: Joseph Coggin (Chair), Mikhail Alexeyev, Elliot Carter, Jim Gaubatz, Bill Guess, Jingfang Ju, Dusty Layton, Judy Miller, Lalita Samant, Samuel Strada, Cathy Tuck-Muller, and David Wiik

Absent: Brenda Jackson, Thomasina Sharpe and Walt Dickerson

I Approval of minutes

The minutes of July 23, 2004 were approved.

II Information/Education

The new members of the committee were introduced and the committee membership listing for 2004-05 was distributed. Ms. Layton presented a brief report on current registration data. There are 102 active registrations; 66% involve biohazardous infectious agents and 34% are recombinant DNA registrations. Risk group classifications by biosafety levels are as follows: BSL-1/ 14; BSL-2/ 79 and BSL-3/ 9.

The institution is required to file an annual report with National Institutes of Health, Office of Biotechnology Activities, and provide a roster of all members to ensure compliancy with committee membership requirements. The IBC is required to have certain areas of expertise represented, plus 2 community members. This report was submitted and pending receipt of information from NIH for year 2004 approval.

Ms. Layton informed the committee that Ms. Nims in Safety and Environmental Compliance and the Office of Research Compliance and Assurance conducted three training sessions in April on the handling of biomedical and chemical waste. These sessions will be offered two to three times a year for new hires. In addition, the committee suggested that a one page formation sheet be utilized as a mechanism for the required two year refresher training.

Dr. Coggin briefly discussed the terms commonly used in biosafety and rDNA review process which may be used by new members to assist them in this process. This information was included in the meeting packets for review by members.

III New Registrations

0428
Investigator: Brian Fouty, MD
Project Title: Role of cell cycle proteins in pulmonary vascular remodeling
BSL: 2
Biohazard: Human cell lines

Action: The recommendation of the committee was approval.
Vote: For: 11 Opposed: 0 Abstain: 0

0429
Investigator: Brian Fouty, MD
Project Title: Role of cell cycle protein in pulmonary vascular remodeling
rDNA: retroviral vector

Action: The recommendation of the committee was approval pending clarification regarding the use of rDNA associated with transgenic rodents. In addition, a brief description was requested involving the use of the viruses in this project.

Vote: For: 11 Opposed: 0 Abstain: 0

IV New Business

All projects registered w/ the IBC are audited by the committee members to evaluate compliance with our COM Biosafety Manual and CDC guidelines. Ms. Layton asked that the members review the audit assignment list indicating group assignments and respective areas for auditing. Each group is assigned a team leader who is responsible for coordinating dates/time of inspections with the team members. Laboratory deficiencies from 2003 audits were included in the group leader's packet. Inspection reports should be completed no later than January 15, 2005.

V For informational purposes

a. New approvals - Vote by mail review

B0413 Dr. Stephen Ballard
Adenoviral transfection of porcine airway explants
BL2
HEK 293 cell lines, human lung epithelial (Calu-3) cell lines
Approved: April 27, 2004

b. Exemptions - Administratively approved by IBC Chair

DNA0414 Dr. Mary Townsley
Pilot protocol for delivery of siRNA to rat lung via electroporation
Approved: June 21, 2004

c. Closed Registrations

Registration#	PI	Closed Date
B0106	David Hartley	10/1/2004
B0107	David Hartley	10/1/2004
B0112	David Hartley	10/1/2004
DNA0108	David Hartley	10/1/2004
DNA0109	David Hartley	10/1/2004

The meeting adjourned at 10:15 AM.

Minutes
Institutional Biosafety Committee
July 23, 2004, 1:00PM, LMB

Present: Joseph Coggin (Chair), Elliot Carter, John Foster, Jon Garcia, Jim Gaubatz (Vice-Chair), Bill Guess, Brenda Jackson, Dusty Layton, Judy Miller, Samuel Strada and Cathy Tuck-Muller

Absent: Walt Dickerson, Jonathan Scammell, Thomasina Sharpe and David Wiik

I. New Registrations for Review:

0415
Investigator: Lalita Shevde-Samant, Ph.D.
Project Title: BRMS1 regulates osteopontin in metastatic breast cancer
BSL: 2
Recombinant DNA

Action: The recommendation of the committee was approval.
Vote: For: 10 Opposed: 0 Abstain: 0

0416
Investigator: Lalita Shevde-Samant, Ph.D.
Project Title: BRMS1 regulates osteopontin in metastatic breast cancer
BSL: 2

Action: The recommendation of the committee was approval pending additional clarifications. Human tissue and cell lines are listed as biohazards for this project. The investigator will be asked to provide a description or the nature of human tissue and cell lines for purposes of this research project. Any new cell lines that are to be used in the future should be amended to the biohazardous agent registration form.

Vote: For: 10 Opposed: 0 Abstain: 0

0417
Investigator: Rajeev Samant, Ph.D.
Project Title: Role of Nmi (N-Myc interactor) in breast cancer metastasis
BSL: 2

Action: The recommendation of the committee was approval pending clarifications. The committee requests clarification as to whether the cell lines are primary or established. In addition, the specific type of cell lines planning to be used for this project need to be identified.

Vote: For: 10 Opposed: 0 Abstain: 0

0418
Investigator: Rajeev Samant, Ph.D.
Project Title: Role of Nmi (N-Myc interactor) in breast cancer metastasis
BSL: 2
Recombinant DNA

Action: The recommendation of the committee was approval
Vote: For: 10 Opposed: 0 Abstain: 0

0419
Investigator: Mikhail Alexeyev, Ph.D.
Project Title: Selective elimination of defective mitochondrial geneomes as an approach to the reversal of NARP and MILS syndromes, heritable mitochondrial disorders
BSL: 2
Recombinant DNA

Action: The recommendation of the committee was approval.
Vote: For: 10 Opposed: 0 Abstain: 0

0420
Investigator: Valentina Grishko, Ph.D.
Project Title: Nitric oxide-induced damage to chondrocytes mitochondria
BSL: 2

Action: The recommendation of the committee was approval.
Vote: For: 10 Opposed: 0 Abstain: 0

0421
Investigator: Mikhail Alexeyev, Ph.D.
Project Title: Selective elimination of defective mitochondrial geneomes as an approach to the reversal of NARP and MILS syndromes, heritable mitochondrial disorders
BSL: 2

Action: The recommendation of the committee was approval.
Vote: For: 10 Opposed: 0 Abstain: 0

0422
Investigator: Rajeev Samant, Ph.D.
Project Title: MRJ: A Molecular Switch for Cell Cycle and Cancer Metastasis
BSL: 2
Recombinant DNA

Action: The recommendation of the committee was approval
Vote: For: 10 Opposed: 0 Abstain: 0

0423
Investigator: Rajeev Samant, Ph.D.
Project Title: MRJ: A Molecular Switch for Cell Cycle and Cancer Metastasis
BSL: 2

Action: The recommendation of the committee was approval pending clarifications. The committee requests clarification as to whether the cell lines are primary or established. In addition, the specific type of cell lines planning to be used for this project need to be identified.
Vote: For: 10 Opposed: 0 Abstain: 0

0424
Investigator: Rajeev Samant, Ph.D.
Project Title: Cell signaling and cancer metastasis
BSL: 2

Action: The recommendation of the committee was approval.
Vote: For: 10 Opposed: 0 Abstain: 0

0425
Investigator: Rajeev Samant, Ph.D.
Project Title: Cell signaling and cancer metastasis
BSL: 2
Recombinant DNA

Action: The recommendation of the committee was approval.
Vote: For: 10 Opposed: 0 Abstain: 0

0426
Investigator: Lalita Shevde-Samant, Ph.D.
Project Title: Analysis of mechanisms underlying metastasis and metastasis suppression
BSL: 2

Action: The recommendation of the committee was approval.
Vote: For: 10 Opposed: 0 Abstain: 0

0427
Investigator: Lalita Shevde-Samant, Ph.D.
Project Title: Analysis of mechanisms underlying metastasis and metastasis suppression
BSL: 2
Recombinant DNA

Action: The recommendation of the committee was approval.
Vote: For: 10 Opposed: 0 Abstain: 0

II. Old Business:

Ms. Layton gave a update on the biomechnical engineering laboratory inspections. The annual routine biosafety inspection was conducted on January 12, 2004. At the IBC meeting of February 6, 2004, it was announced that several concerns were raised by the inspection team for this laboratory. As a result, a recommendation was made to revisit the lab within 90 days to ensure requirements had been met for BSL-2 operations. The follow-up inspection was scheduled and conducted on March 31, 2004. It was noted that no one was present for this inspection and the lab was still in a state of disarray. Since it did not appear that any substantive changes had been made since the previous inspection the lab was closed and work suspended. The lab was reinspected on April 26, 2004 with previous deficiencies appropriately addressed. The lab was authorized for clearance and continuation of research with biological hazards. As a result, the lab is subject to unannounced inspections for a period of up to one year. Lastly, on July 12, 2004, Dr. Sharpe and Mr. Garcia conducted a "unannounced" inspection and were pleased to report that the lab appeared to be in good condition with a few minor deficiencies. In order to ensure compliance, this lab will continue to be closely monitored.

III. New Business:

It was discussed that all human tissue, cell lines, tissue culture, etc., required review and approval by the Institutional Biosafety Committee. Despite the memorandum (dated November 2003) that was mailed to all faculty, there is still a consensus that human cells in culture like HeLa, human embryonic cells, etc., do not require registration. Therefore, policy and procedure for such registration was drafted for inclusion in the Biosafety Manual and Exposure Control Plan. A few minor changes were made at the request of the committee.

IV ***Informational Purposes:***

a. NEW APPROVALS :VOTE BY MAIL REVIEW

0413

PI:	Stephen Ballard, Ph.D.
Dept:	Physiology
Biosafety Level:	BL2
Project Title:	Adenoviral transfection of porcine airway explants
Biohazard:	HEK-293 (kidney) cell lines; human lung epithelial (Calu-3) cell lines
Approved:	April 27, 2004

b. EXEMPTIONS - ADMINISTRATIVELY APPROVED BY IBC CHAIR

0414

PI:	Mary Townsley, Ph.D.
Dept:	Physiology
Biosafety Level:	BL1
Project Title:	Pilot protocol for delivery of siRNA to rat lung via electroporation
Approved:	June 21, 2004

c. NEW/START-UP LAB REVIEWS

Registration #	PI	Date Inspected	Inspectors
B0407	Oystein Fodstad, M.D.	May 21, 2004	D. Wiik; J. Foster
B0406	Aurelio Lorico, M.D.	June 3, 2004	T. Sharpe; W. Guess
B0410	Kai-Ming Chou, Ph.D.	May 24, 2004	J. Miller; J. Scammell
B0403	David Weber, Ph.D.	May 12, 2004	J. Miller; J. Gaubatz

d. CLOSED REGISTRATIONS

Registration #	PI	Date Closed
B0216	Naomi Campbell, Ph.D.	7/15/2004

The meeting adjourned at 2:45 AM.

Minutes
Institutional Biosafety Committee
March 26, 2004, 9:00 AM, LMB

Present: Joseph Coggin (Chair), John Foster, Jon Garcia, Jim Gaubatz (Vice-Chair), Bill Guess, Dusty Layton, Judy Miller, Samuel Strada, Cathy Tuck-Muller, and David Wiik

Absent: Brenda Jackson, Elliot Carter, Walt Dickerson, Jonathan Scammell and Thomasina Sharpe

Item I. ***Registrations for Review***:

B0405

Investigator: John Kovaleski, Ph.D.
Project Title: The stabilizing effect of ankle taping and bracing on the three-dimensional passive support characteristics of the ankle-subtalar joint complex
BSL: 2

This biohazardous research project is contingent upon funding by the Southeast Athletic Trainers Association Research and Education Commission. This project involves collaboration with Drs. Hollis and Pearsall to be carried out in the Biomechanical Engineering Lab, ELGB 124. Significant problems have been identified in this laboratory in the past during audit inspections. After the most recent on-site audit held on January 12, 2004, a recommendation was made to reinspect the lab due to a number of deficiencies. This lab is scheduled for re-inspection on March 31, 2004 to ensure that the requirements for work within a BSL-2 laboratory have been satisfied.

Action: The recommendation of the committee was conditional approval pending satisfactory re-inspection of the work location.
Vote: For: 9 Opposed: 0 Abstain: 0

B0406

Investigator: Aurelio Lorico, M.D.
Project Title: New technology for neural stem cell-based gene therapy of primary and metastatic brain tumors
BSL: 2

This lab will be scheduled for a new lab review inspection.

Action: The recommendation of the committee was approval
Vote: For: 9 Opposed: 0 Abstain: 0

B0407

Investigator: Oystein Fodstad, M.D., Ph.D.
Project Title: Characterization of cancer cell lines
BSL: 2

The committee requested that each cell line listed on page 3 of the registration be individually identified. Each cell line should be specifically matched to the biohazardous material used. This lab will be scheduled for a new lab review inspection.

Action: The recommendation of the committee was approval pending clarifications.

Vote: For: 9 Opposed: 0 Abstain: 0

DNA0408
Investigator: Kai-ming Chou, Ph.D.
Project Title: Mutational studies of human polymerase and anticancer drug design.

Recombinant DNA - research exempt, NIH Guidelines Section III-F-2 and F-3. Submission of this project is associated with the medical student summer research program.

Action: The recommendation of the committee was approval as exempt classification.
Vote: For: 9 Opposed: 0 Abstain: 0

B0409
Investigator: Lewis Pannell, Ph.D.
Project Title: Binding of chemotherapy drugs to plasma proteins
BSL: 2

The investigator will be informed that the appropriate containment level for using human serum and plasma is BSL-2. Infectious agents indicated on the registration form included viruses, but the appropriate selection is human cell lines. Therefore, the investigator will be informed that the Hepatitis B vaccine will be offered to all employees involved in the project. An inquiry was made with the investigator regarding disinfectant procedures. Alcohol is initially used for sterilization in addition to bleach. This is the standard laboratory practice for disposal of contaminated materials. Submission of this project is associated with the medical student summer research program. This lab will be scheduled for a new lab review inspection.

Action: The recommendation of the committee was to approval pending clarifications.

Vote: For: 9 Opposed: 0 Abstain: 0

B0410
Investigator: Kai-ming Chou, Ph.D.
Project Title: Lesion bypass polymerases and therapeutic anticancer compounds
BSL: 2

The committee requested that if more than one human cancer cell line is to be used in this project that all biohazardous materials and associated cell lines be identified on page 3 of the registration form. A blanket approval to work with cancer cell lines is not permissible. The investigator will be reminded that if additional cell lines are to be used in this research project, the biohazardous agent registration form may be amended to include such cell lines and their sources. This lab will be scheduled for a new lab review inspection.

Action: The recommendation of the committee approval pending clarifications.

Vote: For: 9 Opposed: 0 Abstain: 0

DNA0411
Investigator: Kai-ming Chou, Ph.D.
Project Title: Lesion bypass polymerases and therapeutic anticancer compounds

Recombinant DNA - research exempt, NIH Guidelines Section III-F-3

Action: The recommendation of the committee was approval as exempt classification.

Vote: For: 9 Opposed: 0 Abstain: 0

DNA0412
Investigator: Stephen Ballard, Ph.D.
Project Title: Adenoviral transfection of porcine airway explants

Recombinant DNA use, NIH Guidelines, Category E. Clarification is requested for the vector source of HAV5. The growth of virus particles will occur in HEK-293 kidney cells, the host strain for propagation of the recombinant. The committee request the submission of a biohazard registration form for the use of this cell line.

Action: The recommendation of the committee was approval of the recombinant DNA registration pending receipt of a biohazard agent registration for the use of HEK-293 kidney cell lines.

Vote: For: 9 Opposed: 0 Abstain: 0

Item II. ***Old Business:***

The committee was informed that Jon Garcia and David Wiik are scheduled to re-inspect the laboratory of Drs. Marcus Hollis and Sudhakar Madanagopal located in the Biomechanical Engineering lab, ELGB 124. In addition, the Office of Research Compliance and Assurance recommended that this laboratory receive unannounced inspections on a quarterly basis considering the evolving problems associated with this location. The committee unanimously agreed.

Item III. ***New Business - Security of Shipments:***

Mr. Guess briefly spoke about homeland security, with emphasis on security plans for shipping. Dr. Strada stated that we have a process in place for oversight of select agents. However, we can provide additional educational awareness on these types of agents and requirements for possession. Mr. Guess suggested that we look at our shipping processes and if there are specific biohazards that the committee should be aware. This could be accomplished by requesting an inventory list from the investigators. The Office of Environmental Safety and Compliance provides guidance for shipping hazardous materials and the Radiation Safety Office handles the shipment of all radioactive materials. However, there is no guidance or document available for the shipment of biological materials or dry ice. The University of New Hampshire's manual for shipment of biological materials was referred to as a model for information on how to properly classify, package, mark and label for shipment. Federal rules require those who ship biological materials and/or dry ice have shipping training. Ms. Layton stated that agencies who regulate this rule include the International Air Transport Association (IATA), US Department of Transportation (DOT), and the Occupational Health and Safety Administration (OSHA). The University of New Hampshire requires those that package biological materials/dry ice for shipment or who fill out a Shipper's Declaration for Dangerous Goods that certain training certification requirements are carried out. Training is required every two years. It was recommended that a reference chart be developed outlining a summary of shipping information.

Item IV. ***Training/Information:***

The committee was informed that Denise Nims, Safety and Environmental Compliance and Dusty Layton, Office of Research Compliance and Assurance will be offering combined training sessions on biomedical and chemical waste. Three sessions have been scheduled for the second and third week of April. A flyer will be distributed to all research personnel in advance.

The meeting adjourned at 10:15 AM.

Minutes
Institutional Biosafety Committee
February 6, 2004, 1:00pm, CSAB 170

Present: John Foster, Jim Gaubatz (Vice-Chair), Bill Guess, Dusty Layton, Brenda Jackson, Jonathan Scammell, Thomasina Sharpe, Samuel Strada, Cathy Tuck-Muller, and David Wiik

Absent: Joseph Coggin (Chair), Barbara Burckhartt, Elliot Carter, Walt Dickerson, Judy Miller and Jon Garcia

Registrations for Review:

DNA0401
Investigator: Judy King, M.D., Ph.D.
Project Title: ALCAM and Lung Metastasis
BSL: 2
Recombinant DNA use

Action: The recommendation of the committee was approval
Vote: For: 9 Opposed: 0 Abstain: 0

B0402
Investigator: Judy King, M.D., Ph.D.
Project Title: ALCAM and Lung Metastasis
BSL: 2

Action: The recommendation of the committee was approval
Vote: For: 9 Opposed: 0 Abstain: 0

DNA0403
Investigator: David Weber, Ph.D.
Project Title: Reactive oxygen species regulation of vascular smooth muscle cell migration
BSL: 2
Recombinant DNA use

The committee requested additional information on pAdtract CMV and pAdeasy-1 as listed in the application on page 2, section entitled "Vector" item 2b. The investigator will be asked to furnish specific, detailed information about these vectors/sequences.

Action: The recommendation of the committee was to approve the registration with these clarifications. The investigators response will be circulated to a selected panel of members for review before final approval is granted.

Vote: For: 9 Opposed: 0 Abstain: 0

B0404
Investigator: Jingfang Ju, Ph.D.
Project Title: High throughput transcriptional activation assay via laser induced capillary array .....
BSL: 2

Action: The recommendation of the committee was approval
Vote: For: 9 Opposed: 0 Abstain: 0

ew Business:

Dr. Foster asked if the Institutional Biosafety Committee had ever conducted initial laboratory inspections for new investigators in the establishment of their research operations pertaining to USA's guidelines in biological safety. In some cases new labs are set-up at the beginning of the year, however they are not inspected until the fall of every year. Therefore, biological safety issues may go uncovered for many months before corrective action is accomplished. The purpose of these inspections is not to create a restrictive environment but rather to assist in educating and informing investigators of biological safety practices and policies at the University of South Alabama. The committee unanimously agreed that new laboratories should be inspected prior to initiating biohazardous or recombinant DNA work. New investigators will have their laboratory inspected approximately two weeks after biosafety approval. The committee recommended that two members will be sufficient in conducting the new labs.

Biosafety Audits:

The 2003 biosafety audit report was distributed to members of the committee. Thirty-nine labs were inspected. A list of deficiencies, including total number observed for each deficiency was compiled. The biomechanical laboratory in the College of Engineering where work is being conducted by Drs. Marcus Hollis and Sudhakar Madanagopal, Department of Orthopaedics, raised several concerns by the inspection team. A recommendation was made by the inspection team to revisit the laboratory within 90 days to ensure that the requirements have been met for operating with a biosafety level 2 laboratory. After discussion of these deficiencies, the committee unanimously agreed to reschedule a follow-up inspection. If the deficiencies have not been resolved, biosafety approval will be temporarily suspended until corrective action is followed. The Office of Research Compliance and Assurance will coordinate the follow-up visit with the inspectors.

It was suggested that the biosafety inspection checklist used in conducting laboratory inspections be made available for investigators in preparing for compliance with biological safety. The committee agreed with this suggestion. The checklist ill be incorporated in the Biosafety Manual and Exposure Control Plan and distributed to investigators in advance of 2004 inspections. The intent is that the checklist will be used by investigators in carrying out a documented self-inspection using the same criteria as the biosafety committee uses.

Closed registrations - For informational purposes:

Registration #	PI	Date Closed
B9805	Dr. Susan Gibson	10/22/03
B0110	Dr. David Hartley	11/18/03
B0005	Dr. Danna Zimmer	10/22/03
B9001	Dr. Danna Zimmer	11/24/03
DNA9020	Dr. Danna Zimmer	11/24/03
B9029	Dr. Warren Zimmer	11/17/03
B9031	Dr. Warren Zimmer	11/17/03
B0306	Dr. James Downey	12/9/03

The meeting adjourned at 2:00 PM.

Minutes

Institutional Biosafety Committee

October 31, 2003, 9:00 AM, Dean's Conference Room, CSAB 170

Present: Joseph Coggin (Chair), Elliot Carter, John Foster, Jim Gaubatz, Bill Guess, Dusty Layton, Judy Miller, Brenda Jackson (community representative), Jonathan Scammell , Thomasina Sharpe, Samuel Strada, Cathy Tuck-Muller, and David Wiik

Absent: Barbara Burckhartt, Walt Dickerson (community representative), Jon Garcia and Velma Scantlebury

Item 1. *2003-04 Committee Roster*

The committee membership listing for 2003-04 was distributed. Four new members have joined the committee including Drs. Barbara Burckhartt, Elliot Carter, Velma Scantlebury and Ms. Brenda Jackson, a new community representative. Mr. Walt Dickerson, Planning and Operations Officer at the Mobile County Emergency Management Association will continue to serve on the committee as the second community representative. In the past the committee typically met 1-2 times per year. A quarterly meeting schedule has been established to discuss related biosafety issues in a more timely fashion. However, meetings will be canceled if there are no items for discussion. Dr. Coggin passed out a informational sheet outlining various terms used in biosafety and recombinant DNA technology review process that may be especially helpful to the new members.

Item 2. *IBC Registration Data:*

Ms. Layton presented a brief overview of current registration data. There are currently 88 active registrations; 66 (or 75%) involve biohazard agents and 22 (or 25%) are recombinant DNA registrations. Risk group classifications by biosafety levels are as follows: BSL-1/ 10; BSL-2/ 69 and BSL-3/ 9. A total of 40 investigators are conducting biological approved protocols with many having multiple registrations. To-date, fifteen registrations have been submitted for review and approval. The majority of the registrations are in biochemistry, microbiology and pharmacology.

The institution is required to file an annual report with National Institutes of Health, Office of Biotechnology Activities, and provide a roster of all members to ensure compliancy with committee membership requirements. The IBC is required to have certain areas of expertise represented, plus 2 community members. This report was approved in June for the year 2003.

Item 3. *Review of committee responsibilities and regulatory requirements:*

Ms. Layton presented information on biosafety regulatory requirements which are placed upon our institution by the NIH (rDNA guidelines), the Occupational Health and Safety Administration (OSHA) which regulates the "BBP Standard of 1991", The Centers for Disease Control and Prevention (CDC), and the Department of Transportation who regulates biomedical waste. It was noted that Alabama is a member of the "Safe State" alliance in complying with OSHA Standards. This basically means that the State of Alabama has agreed to comply with OSHA standards or exceed them and, in return, will be responsible for self-monitoring it's institutions for compliance. The committee's existence is required as part of compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules and is the cornerstone of institutional oversight of rDNA research. However, like most institutions, the University of South Alabama College of Medicine has a broader purview of oversight to include review and approval of infectious agents. In summary, the committee is responsible for:

- review and approval of biological hazards/rDNA research, safety practices and containment levels
- inspections of facilities and operations
- annual review of the Exposure Control Plan
- oversee responsibility for biosafety training practices
- report any significant research related accidents or illnesses to NIH, Office of Biotechnology Activities within less than 30 days.

Furthermore, no member may be involved in the review or approval of a project if they are engaged in or has a financial interest in the project.

Item 4. *Revision of Registration Forms:*

Ms. Layton informed the committee that the registration forms were revised in August, 2003 to include administrative changes. These involved including training information and requirements in the section involving key personnel and adding a new section containing information on Select Agents as required by the Public Health and Bioterriorism Preparedness Act of 2002. A list of restricted agents/toxins are attached to the registration form so that the investigator can verify whether the material they are registering is a regulated material. The Responsible Facility Official, Dr. Samuel Strada, is responsible for the management of this program and will determine if official registration with the CDC is required.

Item 5. *Select Agent Update:*

Ms. Layton gave a brief update on the new Select Agent Regulation that became effective on February 7, 2003. In order to prepare for compliance with the new rule, an internal survey was conducted in September, 2002 per the Department of Health and Human Services, requesting that investigators report any of the materials located on the select agent/ toxins list. It was noted that select agents are being used on campus which have been formally registered with the CDC. Other toxins discovered during the internal survey included materials such as ricin, tetrodotoxin, and conotoxins but these are excluded from the Select Agent regulation as the amount being used does not exceed the amount specified in the exclusion criteria.

On February 11, 2003 the LMB facility was inspected by the CDC for compliance with the select agent regulation followed by a report indicating no deficiencies and the facility was found to be in compliance with the CDC/NIH Biosafety and Microbiological and Biomedical Laboratories. However after the inspection we were informed that all sinks in the BSL-3 suite needed to be hands-free. This process has now been completed. Ms. Layton explained that there is a compliance timeline for implementation of the new rule which consists of appointment of a Responsible Facility Official, formal registration of institution possessing/using select agents/toxins, government approval of individuals having access to select agents via the Department of Justice, implementation of security and safety plans, emergency response procedures, training and detailed record keeping procedures. A new section was incorporated in the Biosafety Manual on select agents outlining new safety, security and compliance procedures. Full compliance is scheduled for November 12, 2003. Major efforts have involved upgrading security, government approvals of institution and staff, and processing paperwork and records management.

Item 6. *Review and affirm new registrations:*

The subcommittee had previously reviewed and initially approved twelve new registrations. The full board was provided with the new registrations prior to the meeting for their review. New registrations that were reviewed and affirmed by the committee are as follows:

Registration # B0301
Investigator: Judy King, M.D., Ph.D. BSL: 2
Project Title: Three Dimensional Analysis of Lung Vasculature in Sickle Cell Patients

Action: The recommendation of the committee was approval

Vote: For: 12 Opposed: 0 Abstain: 0

Registration # B0302
Investigator: Joseph Coggin, Ph.D. BSL: 2
Project Title: Immunization and Challenge of Mice with Murine Lymphoma and Sarcoma Cell Lines

Action: The recommendation of the committee was approval

Vote: For: 11 Opposed: 0 Abstain: 1

Registration # B0303
Investigator: Troy Stevens, Ph.D. BSL: 2
Project Title: Pseudomonas aeruginosa Adenylyl Cyclase, Exoy, Induces Microvascular Permeability in Lung Endothelial Cells

Action: The recommendation of the committee was approval

Vote: For: 12 Opposed: 0 Abstain: 0

Registration # DNA0304
Investigator: Herbert Winkler, Ph.D. BSL: 3
Project Title: Biology of the Obligate Intracytoplasmic Rickettsia

Action: The recommendation of the committee was approval

Vote: For: 11 Opposed: 0 Abstain: 1

Registration # B0305
Investigator: J. Marcus Hollis, Ph.D. BSL: 2
Project Title: Determination of Cervical Spine Substructure Mechanism Properties

Action: The recommendation of the committee was approval

Vote: For: 12 Opposed: 0 Abstain: 0

Registration # B0306
Investigator: James Downey, Ph.D. BSL: 2
Project Title: Role of Akt in Receptor-Mediated Preconditioning

Action: The recommendation of the committee was approval

Vote: For: 12 Opposed: 0 Abstain: 0

Registration # B0307
Investigator: Joseph Coggin, Ph.D. BSL: 2
Project Title: Propagation of Fibrosarcoma 1315 and 5T Lymphoma in Syngeneic Mice

Action: The recommendation of the committee was approval

Vote: For: 11 Opposed: 0 Abstain: 1

Registration # B0308
Investigator: Judy King, M.D., Ph.D. BSL: 2
Project Title: Analysis of Foreign Material in Lungs

Action: The recommendation of the committee was approval

Vote: For: 12 Opposed: 0 Abstain: 0

Registration # B0309
Investigator: David McGee, Ph.D. BSL: 2
Project Title: Bacillus anthracis arginase

Action: The committee requested additional information from the investigator regarding the concern for potential manipulation of the organism that might result in the virulence being restored. Dr. McGee was asked to join the meeting for clarification on whether Bacillus anthracis Sterne 7702 can be restored to full virulence. Dr. McGee informed the committee that this strain is severely attenuated because it lacks the pXO2 virulence plasmid which is not in his collection. The Bacillus anthracis Sterne 7702 was obtained from Dr. Richard Rest's laboratory at Drexel University. Dr. McGee will use the strain to isolate the arginase gene, disrupt the gene and send the construct back to Dr. Rest for additional studies. Dr. McGee reiterated that there is no intention of introducing the pXO2 plasmid. Furthermore, this select agent has been excluded from the Select Agent Program including registration, transfer and shipment of the material. The committee requested that Dr. McGee respond in writing to the IBC regarding these concerns, specifically addressing the virulence of the organism.

Vote: For: 11 Opposed: 0 Abstain: 1

Registration # B0310
Investigator: Solomon Ofori-Acquah, Ph.D. BSL: 2
Project Title: Cellular, Molecular and Migration Properties of Activated Leukocyte Adhesion Molecule

Action: The recommendation of the committee was approval

Vote: For: 12 Opposed: 0 Abstain: 0

Registration # B0311
Investigator: Sudhakar Madanagopal, M.D. BSL: 2
Project Title: Determination of Viscoelastic Properties of the Human Supraspinatus Tendon

Action: The recommendation of the committee was approval

Vote: For: 12 Opposed: 0 Abstain: 0

Registration # B0312
Investigator: Cathy Tuck-Muller, M.D. BSL: 2
Project Title: DNA Hypomethylation and Cancer

Action: The recommendation of the committee was approval

Vote: For: 11 Opposed: 0 Abstain: 1

Item 7. *Committee review and approval process:*

Dr. Coggin informed the committee of Ms. Layton's inquiry to Mr. Allan Shipp, Director of Outreach, NIH, Office of Biotechnology Activities concerning methods of review and approval for recombinant DNA registrations that is regulated by the NIH Guidelines for Research Involving Recombinant DNA Molecules . The current method of review includes a three member subcommittee to review and grant preliminary approval and then reaffirmed/approved by the full committee at the next scheduled meeting. This initial screening process of IBC registrations by a select panel is not adequate, registrations are to be approved at a convened meeting with a majority vote. Also, a meeting must have a quorum (half + 1 of membership) in order to conduct business. In addition to having convened meetings, teleconferences are permissible as long as each registration was reviewed and voted on by the full committee. A inquiry was made about posting registration forms on the Biosafety website accessible for committee members to use for review and approval. Mr. Shipp indicated that this was an acceptable method, however the preferred method is that the committee convene and vote on registrations during an interactive session. Dr. Coggin proposed a change in the review and approval process for both biohazardous agents and rDNA registrations. Although the NIH only regulates the review of rDNA research, for continuity purposes we plan to use the same method for all registrations. Ms. Layton will notify each member of the need to review a proposal via email. Each member will vote on the registration(s) and a passing majority of votes established. The members will return their review sheet to Ms. Layton. The request for approval will either be granted, approved with specified changes as indicated by the committee or denied. In addition, Ms. Layton circulated a visual aid/flow chart outlining the proposed review and approval procedures that Dr. Coggin discussed. The flow chart appends the minutes.

Item 8. *New Business:*

Biosafety Audits:

All projects registered w/ the IBC are audited by the committee members. Ms. Layton asked that the members review the audit assignment list indicating team members and respective areas for auditing. Each group is assigned a team leader who is responsible for coordinating dates/time of inspections with the team members. Each group has been assigned approximately 10 or 11 labs for inspection and provided with a copy of the appropriate checklist (BSL 1,2, 3) for assigned

investigators and a protocol detail report for each registration indicating pertinent information such as biosafety level, name of project, agents used, key personnel, etc. In addition, if the lab was inspected last year, a copy of deficiencies will be provided to the inspectors. The team leader will be responsible for assembling the checklists from team members and compiling a summary report of deficiencies. Inspection reports are due no later than December 15, 2003. The committee requested that a current Biosafety Manual and Exposure Control Plan be provided for the investigators' laboratory in advance of the scheduled inspections. Dr. Strada second the request and asked Ms. Layton to prepare and distribute copies to all registered investigators.

Bloodborne pathogen training:

Ms. Layton reviewed the method of training used for compliance with the OSHA Standard for those investigators and key personnel involved with potential exposure to bloodborne pathogens such as non-human primate or human blood, body fluids, tissues or cell lines. Complynow® is a computer-based training program used to comply with these requirements. Training is initiated at the time of initial hire and annual retraining is mandated by OSHA. Ms. Layton informed the committee that significant changes have been implemented with the program and therefore those that are now due for annual retraining will complete the amended initial training and then in subsequent years complete the annual re-training/refresher course which require about 20 minutes to complete. Separate training modules are directed to supervisors and employees. Ms. Layton expects that early next year a "Biosafety Bulletin Board" will be implemented which will be completely customized for our institution. Biosafety alerts, regulatory updates, and a notices/announcements will be posted at this site as an additional resource. Furthermore, a notice will being mailed to all investigators with registrations informing them of biosafety training requirements and that all key personnel involved in biosafety work to proceed with training updates.

Biomedical waste training:

Ms. Layton informed the committee that the biomedical waste policy was revised in July, 2002 . As a result, training sessions were initiated in August 2002 for biomedical waste handling to include policies/procedures, proper packaging/ segregation and handling/disposal of the waste. Ms. Layton explained that several concerns were raised regarding liquid waste disposal .or discussion at the training sessions. Input was sought from the CDC and other institutions regarding acceptable methods of disposal for liquids. The proposed method for disposal of liquid waste is autoclaving, this policy was revised to allow inactivation by using commercial bleach and disposed of down the sanitary sewer provided that the guidelines are strictly followed. The committee was encouraged to review this policy located in the Biosafety Manual. In addition, a flowchart was developed, listed as attachment 9 in Biosafety Manual outlining disposal for sharps, medical/laboratory waste, solids and liquids. Additional training sessions are planned for December, 2003.

Exposure Control Plan:

Dr. Coggin informed the committee that the Expsoure Control Plan described in Section IV of the Biosafety Manual must be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure (29 CFR 1910.1030(c)(1)(iv)) Laboratories using BSL-3 microbes must file additional biosafety related Exposure Control Plans (ie, Standard Operating Procedures) to be used in the labs handling those microbes. Dr. Strada asked that the committee members review the Exposure Control Plan and provide feedback to their group's inspection leader. All comments and/or recommendations for changes regarding this document should be submitted to Ms. Layton along with the annual inspection reports.

The meeting adjourned at 10:30 AM.