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May 5, 2006

Edward H. Hammond, Director
The Sunshine Project
P.O. Box 41987
Austin, Texas 78704

RE: Request for IBC Minutes

Dear Mr. Hammond:

Pursuant to your request, The Ohio State University submits the attached minutes from the Institutional Biosafety Committee since May 1, 2003,

The Ohio State University IBC 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).

Respectfully,

Cecil R. Smith, Dr.P.H.
Assistant Vice President

Minutes
Institutional Biosafety Committee
17 April 2003

PRESENT:

David Coplin, *Co-Chair*
Phil Pendergast
Larry Capitini
Ing-Ming Chiu
Biao Ding
Cecil Smith
Long-Sheng Chang
William Swoager
J. C. Jang

ABSENT:

Michael Oglesbee
Rev. Clarence Decker

EXCUSED:

Daral Jackwood
Robert Carey
Joseph Kowalski
Kenneth Theil
Marshall Williams

OTHER ATTENDEES:

Gregory Ellen, *Recorder*

The meeting convened at 10:00 a.m. and adjourned at 11:30 a.m.

Minutes

The minutes of the 12 December 2002 meeting were approved as corrected.

Review of Safety Plans and MUAs

2002R0084 Guidelines for working with Mycobacterium Tuberculosis in the laboratory-BSL2 practices, Larry Schlessinger, Internal Medicine

Biohazard subcommittee voted to request the following information from the PI:

- UV lights should also be changed as per manufacturers recommendation.
- The PI should indicate that less than 10 liters total volume is being used.
- The PI needs to address spill management.
- #4 add Employee Health Services and accident report

Under Section III A

- #2 Aerosol generating procedures should be performed in a biological safety cabinet
- #6 Laminar Flow hoods should be biological safety cabinet

- #10 Replace "close at hand" with "inside the BSC".
- #11 Place sharps in a sharps container prior to biohazard bag and burn box

Under Section III B

- #6 Regarding the disposal of amphyl waste containers; add "... absorb liquid and place in burn box" to the statement.

The IBC voted to request the information from the PI before approval of the protocol.

2002R0090 Macrophage Complement Receptors in Tuberculosis, Larry Schlessinger, Internal Medicine

The membership approved the MUA.
The experiments may be done at BSL2 containment.
Voting Summary: 8 affirmative votes

2002R0091 Altered M. tuberulosis Mannosylation and the Macrophage, Larry Schlessinger, Internal Medicine

The membership approved the MUA.
The experiments may be done at BSL3 containment.
Voting Summary: 8 affirmative votes

2003R0014 8 Tesla Magnetic Resonance Imaging, Donald W. Chakeres, et. al., Radiology

The IBC voted to request the information from the PI before approval of the protocol.

- Clarify if there is an ILACUC protocol associated with this protocol.
- Clarify how the animals will be packaged and transported to/from the morgue.
- Clarify what is meant by human diploid vaccine and for what agent(s) they are being vaccinated for.
- Add 1% NaOH for prions for decontamination of possible prions.

2002R0061 Zwilling

The membership approved the MUA for *F. tularensisis* LVS only at BSL2. Other strains will require a separate Safety Plan or an amendment to this plan.
Voting Summary: 8 affirmative votes

2003R0013 Characterization of plant RMase P and examination of its utility as a functional genomics tool, Venkat Gopalan, Biochemistry

The membership approved the MUA.

The experiments may be done at BSL1 and BSL1P containment.
Voting Summary: 8 affirmative votes

IBC Form

Final draft versions of the Biohazard Form, Human Gene Transfer Form, Animal Gene Transfer Form, and General rDNA form were distributed to the membership for comment. Committee members were told to send final comments to Dr. Pendergast.

IBC Procedures

Updated IBC procedures were distributed to the membership for comment.

Adjournment

The IBC was adjourned until the next scheduled meeting. Future topics include the revised forms and a flow chart of the IBC review process.

Minutes
Institutional Biosafety Committee
12 June 2003

PRESENT:
David Coplin, *RDNA Subchair*
Phil Pendergast
Larry Capitini
Ing-Ming Chiu
Biao Ding
Cecil Smith, *Biohazards Subchair*
Robert Carey
William Swoager
Rev. Clarence Decker
Kenneth Theil (via teleconference)

ABSENT:
Michael Oglesbee

EXCUSED:
Daral Jackwood
Joseph Kowalski
J. C. Jang
Long-Sheng Chang
Marshall Williams, *Gene Transfer Subchair*

OTHER ATTENDEES:
Gregory Ellen, *Recorder*
Mary Decker, *Guest*
Judith Neidig, *Guest*

The meeting convened at 10:05 a.m. and adjourned at 11:20 a.m.

Minutes
The minutes of the 17 April 2003 meeting were approved with minor corrections.

IBC Procedures/Meeting Schedules
The updated IBC procedures were distributed to the membership for comment. This document is intended to serve as an internal document. It is also meant to be consistent with the security plan that will be supplied to CDC.

The membership recommended some minor changes (such as letting the IBO determine if a protocol is exempt and adding references to the IRB).

The membership also agreed to meet every month but would only list every other month as an open meeting date. Protocols would be screened by the appropriate subcommittee chair to assess the immediacy the review. The IBC will also explore other options including teleconferencing for more members as long as a quorum of members are physically present.

Review of Safety Plans and MUAs

2003R0025 **The in planta functional analysis of candidate effector proteins of bacterial pathogen, Aster Yellows Phytoplasma AYWB,** Saskia Hogenhout, Entomology

The membership approved the MUA. The experiments may be done at BSL2P containment.
Voting Summary: 10 affirmative votes. 0 negative votes, 0 abstentions

2003R0019 **Studies of Herpes Simplex Virus Type 1 Biology and Pathogenesis,** Joanne Trgovcich, Pathology

The membership was in concurrence that the MUA met all the requirements and approved the MUA; however, the Committee requires an approved Safety Plan before the final approval letter is released. The Committee also recommends the use of masks and goggles in experiments that may have ocular exposure to the virus.
The experiments may be done at BSL2 containment.
Voting Summary: 10 affirmative votes, 0 negative vote, 0 abstentions

2003R0023 **Development of High Affinity Ligands and Methods to Detect Prions,** Srinand Sreevatsan, Veterinary Preventive Medicine

The membership voted to approve the MUA.
The experiments may be done at BSL3 containment.
Voting Summary: 8 affirmative votes, 0 negative votes, 0 abstentions

2003R0011 **A Beta-2 Microglobulin Null Non-SCID Mouse Model of Human and Murine Leukemia,** Michael A. Caligiuri, Internal Medicine

The information provided by the PI was deemed inadequate for the board to make an informed decision. The IBO and a member of the Biohazard Subcommittee will confer with the PI to help him improve the submission
Voting Summary: 0 affirmative, 8 for deferral, 0 abstentions.

2003R0012 **A Human-Mouse Chimeric Model of Epstein-Barr Virus-Associated Lymphoproliferative Disease,** Michael A. Caligiuri, Internal Medicine

The information provided by the PI was deemed inadequate for the board to make an informed decision. The IBO and a member of the Biohazard Subcommittee will confer with the PI to help him improve the submission.
Voting Summary: 0 approval, 8 for deferral, 0 abstentions

2003R0015 **Role of IL-15 in toxoplasmosis infection,** Michael A. Caligiuri, Internal Medicine

The information provided by the PI was deemed inadequate for the board to make an informed decision. The IBO and a member of the Biohazard Subcommittee will

confer with the PI to help him improve the submission.
Voting Summary: 0 approval, 8 for deferral, 0 abstention

2003R0016 **Vaccine Strategy for Epstein-Barr Virus-Associated Lymphoma: Fowlpox virus vehicle**, Michael A. Caligiuri, Internal Medicine

The information provided by the PI was deemed inadequate for the board to make an informed decision. The IBO and a member of the Biohazard Subcommittee will confer with the PI to help him improve the submission.
Voting Summary: 0 approval, 8 for deferral, 0 abstentions

2003R0017 **Vaccine strategy for Epstein-Barr Virus-Associated Lymphoma**, Michael A. Caligiuri, Internal Medicine

The information provided by the PI was deemed inadequate for the board to make an informed decision. The IBO and a member of the Biohazard Subcommittee will confer with the PI to help him improve his submission.
Voting Summary: 0 approval, 8 for deferral, 0 abstentions

IBC Form

Final draft versions of the Biohazards Form, Human Gene Transfer Form, Animal Gene Transfer Form, and General rDNA Form were distributed to the membership for comment. Committee members were told to send final comments to Dr. Pendergast. New submissions will be on the new forms.

Adjourn

The Committee was adjourned until the next meeting.

Minutes
Institutional Biosafety Committee
11 August 2003

PRESENT:
David Coplin, *RDNA Subchair*
Phil Pendergast
Larry Capitini
Michael Oglesbee
Long-Sheng Chang
Cecil Smith, *Biohazards Subchair*
Jami St. Clair, *Community Member*
William Swoager
Joseph Kowalski
Marshall Williams, *Gene Transfer Subchair*

ABSENT:
Ing-Ming Chiu
Biao Ding
Rev. Clarence Decker, *Community Member*
Kenneth Theil

EXCUSED:
Daral Jackwood
J. C. Jang

OTHER ATTENDEES:
Gregory Ellen, *Recorder*

The meeting convened at 10:05 a.m. and adjourned at 11:10 a.m.

Minutes
The minutes of the 12 June 2003 meeting were approved.

New Member
Jami St. Clair was introduced as a new community member, replacing the recently retired Bob Carey.

IBC Procedures
The updated IBC procedures were distributed to the membership. The membership voted to approve the procedures with the knowledge that this is a "living document" that will be updated as necessary.

Review of Safety Plans and MUAs

2002R0053 Opioid receptor regulation, Wolfgang Sadee, Pharmacology

The committee requests the following information before approval of the amendment to this protocol can be granted.

Voting Summary: 10 affirmative votes. 0 negative votes, 0 abstentions

Revise the form as follows and forward a copy to the IBC for review.

- Question #5—Either remove the "etc." from the sentences or list all of the genes that will be used. The use of "etc." is too open-ended for the committee.
- Question #6— Either remove the "etc." from the sentences or list all of the cell lines that will be used. As above, the use of "etc." is too open-ended for the

committee.

- Questions #17—There are occupational health issues for this research. Discuss them.
- Questions #21—Transport of biohazardous material is discussed in the *Biosafety Manual.* For transport on campus, material must be packed in two containers such that, if the package is dropped and the inner container breaks, there is sufficient absorbent material to soak up the biohazard without contaminating the outside of the container.
- Question #23—Should address Universal Precautions.
- Question #25—Provide more specific information about the training.
- Questions #27 and 28—Do you mean some dilution of household bleach instead of what is written?
- Question #32—Both spill kit and biosafety sign should be marked "Yes".

Note: You are required to have a Chemical Hygiene Plan in place for this research. The use of pertussis and cholera toxins, re-emphasizes this requirement. Please contact Tim Govenor at 292-1284.

2003R0029 Prevalence of Baylisascaris in ursine species, Teresa Morishita, Veterinary Preventive Medicine

The committee requires the following information before approval of this protocol.

Voting Summary: 9 affirmative votes, 0 negative vote, 0 abstentions (Dr. Coplin left the meeting, a quorum being maintained.)

Revise the form as follows and forward a copy to the IBC for review.

- Questions #10 and #24— The responses are inconsistent; please revise your response.
- Question #11—The refrigerator should be 37° F not C.
- Question #17—Contact Dr. Paul Kirk at Employee Health Services to discuss recommendations for medical surveillance.
- Question #18 – Specify contact times for disinfectants. Recognize that ascarid eggs are very difficult to kill.

The experiments must be done at BSL2 containment.
The IBC recommends that disposable smocks be used instead of lab coats.

2003R0031 Growth of Bacillus cereus and isolation of DNA, RNA and protein, Michael Ibba, Microbiology

The information provided by the PI was deemed inadequate for the committee to make an informed decision. The principal investigator must contact the Institutional Biosafety Officer for assistance in providing the required information.

Voting Summary: 0 affirmative, 9 for deferral, 0 abstentions. (Dr. Coplin left the meeting, a quorum being maintained.)

2003R0036 Efficacy of Oral Rabies Vaccination relative to Bait Density and Raccoon Population Density, Robert J. Gates, School of Natural Resources

The information provided by the PI was deemed inadequate for the board to make an informed decision. The principal investigator must contact the Institutional Biosafety Officer for assistance in providing the required information.

Voting Summary: 0 affirmative, 9 for deferral, 0 abstentions. (Dr. Coplin left the meeting, a quorum being maintained.)

Gene Transfer Training

Dr. Pendergast led a training session on Human Gene Transfer research and protocols. The slide presentation will be available for IBC members who were not able to attend.

Adjourn

The Committee was adjourned until the next meeting.

Minutes
Institutional Biosafety Committee
12 September 2003

PRESENT:

David Coplin, *RDNA Subchair*
Phil Pendergast
Long-Sheng Chang
Biao Ding
Marshall Williams, *Gene Transfer Subchair*
J. C. Jang
William Swoager
Michael Oglesbee

ABSENT:

Joseph Kowalski
Rev. Clarence Decker
Daral Jackwood
Kenneth Theil
Larry Capitini
Ing-Ming Chiu
Cecil Smith, *Biohazards Subchair*

Approval of 11 September 2003 Minutes

Review of Safety Plans and MUAs

2003R0032—Evaluating and mitigating possible effects of gene flow from transgenic, natural rubber-producing sunflowers, Allison Snow, EEOB

Review of revised MUA 2003R0039—Recombinant DNA and Biohazard Safe Practices for the Gunn Laboratories (BSL-2), John Gunn, MVIMG

Review of revised MUA 2003R0040—Recombinant DNA and Biohazard Safe Practices for the Gunn Laboratories (BSL-3), John Gunn, MVIMG

Review of MUA 2003R0045—Mycobacterium tuberculosis studies, Joanne Turner, Internal Medicine

Review of MUA 2003R0050—Biohazard Safe Practices for working with Mycobacteria species in the Schlesinger Laboratories (BSL-3), Larry S. Schlesinger, Internal Medicine

Review of MUA 2003R0051—Biohazard Safe Practices for working with Francisella species in the Schlesinger Laboratories (BSL-3), Larry S. Schlesinger, Internal Medicine

Review of MUA 2003R0052—Vocal behavior, habitat use, and home ranges of coyotes, Douglas A. Nelson, EEOB

Review of MUA 2003R053– Sampling Blood from wild Ohio birds for presence of West Nile Virus antibodies, Thomas C. Grubb, EEOB

Review of MUA 2003R054—Cell-associated FIV: vaginal protection and transmission, Mary Jo Burkhard, Veterinary Biosciences

Review of MUA 2003R0055—ADENO-ASSOCIATED VIRUS, SEROTYPE 2, (AAV2) GENE TRANSFER TO MICE TREATED WITH PREDNISOLONE, Jerry Mendell, Neurology

Adjourn

Minutes
Institutional Biosafety Committee
11 December 2003

PRESENT:

David Coplin, *RDNA Subchair*
Cecil Smith, *Biohazards Subchair*
Joseph Kowalski
Biao Ding
J. C. Jang
Marshall Williams, *Gene Transfer Subchair*
Phil Pendergast
Ing-Ming Chiu
Kenneth Theil

ABSENT:

William Swoager
Rev. Clarence Decker
Jami St. Clair
Larry Capitini
Michael Oglesbee
Long-Sheng Chang

Approval of 11 September 2003 Minutes

The 11 September 2003 minutes were approved as amended.

Review of Safety Plans and MUAs

2003R0032—Evaluating and mitigating possible effects of gene flow from transgenic, natural rubber-producing sunflowers, Allison Snow, EEOB

Approved at BSL1-P
Voting Summary: 9 affirmative votes, 0 negative votes, 0 abstentions

2003R0039—Recombinant DNA and Biohazard Safe Practices for the Gunn Laboratories (BSL-2), John Gunn, MVIMG

The additional information requested has been incorporated into the protocols. Please make the following revisions:

- Q. #12—Remove all franciscella spp.
- Q. #33—dust masks are inappropriate

Voting Summary: 9 affirmative votes, 0 negative votes, 0 abstentions

2003R0040—Recombinant DNA and Biohazard Safe Practices for the Gunn Laboratories (BSL-3), John Gunn, MVIMG

Approved at BSL-3
Voting Summary: 9 affirmative votes, 0 negative votes, 0 abstentions

2003R0045—Mycobacterium tuberculosis studies, Joanne Turner, Internal Medicine
Summary

Please make the following revisions:

- Q. #3—Address the specific risks associated with M. Tuberculosis to lab personnel and vivarium workers.
- Q. #10—The surgical mask should not be a N95.
- Q. #11—Delete the second sentence
- Q. #20—Verify that the last inspection date was 9/3/03
- Q. #23—Verify that all the items marked are in the lab.
- Appendix 5 was not provided.
- Appendix 7 was not provided.

2003R0050—Biohazard Safe Practices for working with Mycobacteria species in the Schlesinger Laboratories (BSL-3), Larry S. Schlesinger, Internal Medicine

Please make the following revisions:

- Q. #3—Remove references to M. tuberculosis
- Q. #17—Check for typos

2003R0051—Biohazard Safe Practices for working with Francisella species in the Schlesinger Laboratories (BSL-3), Larry S. Schlesinger, Internal Medicine

Please make the following revisions:

- Q. #3—Remove references to M. tuberculosis
- Q. #17—Check for typos

2003R0052—Vocal behavior, habitat use, and home ranges of coyotes, Douglas A. Nelson, EEOB

Please make the following revisions:

- Provide more information on what assay is used for the rabies titer.
- Approved field study with potential exposures to risk group 2 or 3 agents.

2003R0053— Sampling Blood from wild Ohio birds for presence of West Nile Virus antibodies, Thomas C. Grubb, EEOB

Please make the following revisions:

- Provide an exposure control plan.
- Q. #6 should be checked RG2 and RG3.
- Provide the disinfectant for q. #12.
- Please note the risk of salmonella exposure along with other pathogens endemic to the Ohio avian population.

2003R0054—Cell-associated FIV: vaginal protection and transmission, Mary Jo Burkhard, Veterinary Biosciences

Please make the following revisions:

- Provide more detail in regards to the animal care component.
- Q. #14 & 17—Note that people with certain health risks are at an increased risk.
- Q. #19—Add eyewash.
- Q. #25—Describe the training for the vaccinia (symptoms and potential health hazard, etc.)
- In regards to occupational health, the PI needs to be aware of the potential risks for being or not being vaccinated.

2003R0055—ADENO-ASSOCIATED VIRUS, SEROTYPE 2, (AAV2) GENE TRANSFER TO MICE TREATED WITH PREDNISOLONE, Jerry Mendell, Neurology

Approve at BSL-2.
Voting Summary: 9 affirmative votes, 0 negative votes, 0 abstentions

Minutes
Institutional Biosafety Committee
8 January 2004

PRESENT:

David Coplin, *RDNA Subchair*
Jami St. Clair, *Community Member*
Kenneth Theil
Biao Ding
Joetta McCabe, *Guest*
Phil Pendergast
Long-Sheng Chang
Larry Capitini
William Swoager
Gregory Ellen, *Recorder*

Approval of 11 December 2003 Minutes

The 11 December 2003 minutes were approved.

Review of Safety Plans and MUAs

2003R0058— MECHANISMS OF TRANSCRIPTIONAL REGULATION BY THE LEAFY FLORAL MERISTEM IDENTITY GENE, Rebecca S. Lamb, Plant Biology

Approved at BSL-1 and BSL1-P
Voting Summary: 8 affirmative votes, 0 negative votes, 0 abstentions

2003R0059— CHARACTERIZATION OF THE APETALA3/PISTILLATA TRANSCRIPTIONAL COMPLEX, Rebecca S. Lamb, Plant Biology

Approved at BSL-1 and BSL1-P
Voting Summary: 8 affirmative votes, 0 negative votes, 0 abstentions

2003R0057— RECOMBINANT DNA AND BIOHAZARDS SAFE PRACTICES FOR THE WEWERS LABORATORIES (BSL-2), Mark Wewers, Internal Medicine

Please make the following revisions:

- Provide a table that lists the recombinant work. (see Gunn protocol 2003R0040 for reference)
- q. #18—Specify what part of the lab will need to be inspected.
- q. #22—Contact EHS regarding waste disposal.
- q. #30—Specify the type of cabinets used.

The Committee felt that the SOPs were well written.

Table
Voting Summary: 8 affirmative votes, 0 negative votes, 0 abstentions

2003R0064— RETINAL STEM CELLS AND REGENERATION IN CHICKEN, Andy Fischer, Neurosciences

Please make the following revisions:

- Add "...retinal cells" to the title
- q.#2—While the PI has listed the goals of research, the Committee needs a more complete overview of what will actually be done in the lab.
- q. #14—Provide more detail on what causes the retrovirus to not be infective of SPF.
- q. #19—Add eyewear.
- q. #24a—delete quails from the sentence.
- Provide more information on RCAs virus.

The Committee will only approve the in vitro studies at this time.
Defer
Voting Summary: 8 affirmative votes, 0 negative votes, 0 abstentions

2004R0001—MEASLES VIRUS INDUCED IMMUNE SUPPRESSION, Stefan Niewiesk, Veterinary Biosciences

Please make the following revisions:

- Q. #8—Clarify if the genes will be added on at a time or all at once.
- Q. #33—Remove or clarify what is meant by "both pathogens"

Table
Voting Summary: 8 affirmative votes, 0 negative votes, 0 abstentions

2003R0060—EFFECTS OF PHOTOPERIOD ON CELLULAR AND ORGANISMAL ENERGETIC DEMANDS, Randy J. Nelson, Psychology

How will the PI determine if the deermice has hantavirus? What type of test is used? Contact the IBO for further information regarding housing and medical surveillance and what to do with suspect mice.

Table
Voting Summary: 6 affirmative votes, 0 negative votes, 0 abstentions

2003R0061—URBAN ECOLOGY OF COYOTES IN THE CHICAGO AREA, Stanley D. Gehrt, School of Natural Resources

Please make the following revisions:

- q.#2—While the PI has listed the goals of research, the Committee needs a more complete overview of what will actually be done in the lab.
- Specify how the blood and stool samples are handled.

Provide further information

Voting Summary: 6 affirmative votes, 0 negative votes, 0 abstentions

2003R0062—ESTIMATING CONTACT RATES AMONG FREE-RANGING RACCOONS FOR SPATIAL MODELING OF RABIES, Stanley D. Gehrt, School of Natural Resources

Please make the following revisions:

- Address baylis ascaris and contact with raccoons.

Provide further information
Voting Summary: 6 affirmative votes, 0 negative votes, 0 abstentions

2003R0065— STRUCTURAL AND CONFORMATIONAL ASPECTS IN PEPTIDE VACCINES (HTLV-1), Pravin T. Kaumaya, Obstetrics and Gynecology

Please make the following revisions:

- q. #1—revise the start date
- q. #6—provide more information
- q. #11—provide more information
- q. #12—provide more information
- q. #13—provide more information
- q. #15—provide more information on carcass disposal
- q. #17—ULAR lab personnel

Provide further information
Voting Summary: 6 affirmative votes, 0 negative votes, 0 abstentions

Minutes
Institutional Biosafety Committee
12 February 2004

PRESENT:
Marshall Williams, *Co-Chair*
Jami St. Clair, *Community Member*
Kenneth Theil
Joseph Kowalski
Stefan Niewiesk, *Guest*
Phil Pendergast
Cecil Smith, *IBO*
Larry Capitini
William Swoager
Gregory Ellen, *Recorder*

Approval of 8 January 2004 Minutes
The 8 January 2004 minutes were approved.

Review of Safety Plans and MUAs

2004R0001—MEASLES VIRUS INDUCED IMMUNE SUPPRESSION, Stefan Niewiesk, Veterinary Biosciences

Dr. Niewiesk gave a presentation to the committee outlining his work, training, and procedures. He was present during the discussion and was available to answer questions from the committee.

Approved at BSL-2
Voting Summary: 8 affirmative votes, 0 negative votes, 0 abstentions

2004R0006—STRESS-RELATED EFFECTS ON VIRUS-INDUCED TUMORS, Eric V. Yang, MVIMG

Approved at BSL-1
Voting Summary: 8 affirmative votes, 0 negative votes, 0 abstentions

Comments:
Question #23—Access to an autoclave should be marked "Yes".
The PI could consider using a lower concentration of sodium hypochlorite.

2004R0007—HISTONE ACETYLATION AND ENDOTHELIAL ACTIVATION, Dale G. Hoyt, Pharmacology

This protocol is considered Exempt under the *NIH Guidelines*.

2004R0008—EXAMINATION OF THE FUNCTION OF THE BARDET-BIEDL SYNDROME (BBS) PROTEINS, Kirk Mykytyn, Pharmacology

This protocol is considered Exempt under the *NIH Guidelines*.

2004R0009— ECOLOGICAL STUDIES OF TETRACYCLINE RESISTANCE, Mark Morrison, Animal Sciences

This protocol is considered Exempt under the *NIH Guidelines*.

2004R0010— PTHRP GENE EXPRESSION BY EPIDERMAL GROWTH FACTOR RECEPTORS IN MOUSE MODELS OF SQUAMOUS CELL CARCINOMA, Thomas J. Rosol, Veterinary Biosciences

This protocol is considered Exempt under the *NIH Guidelines*.
The PI needs to contact Tim Govenor at OEHS (2-1284) to see if he needs a Chemical Hygiene Plan.

Minutes
Institutional Biosafety Committee
13 May 2004

PRESENT:

Marshall Williams, *Co-Chair*
Cecil Smith, *IBO*
Kenneth Theil
Joseph Kowalski
Biao Ding
J. C. Jang
Jan Alloy, *Recorder*
David Coplin, *Co-Chair*
Phil Pendergast
Larry Capitini
William Swoager
Long-Sheng Chang
Gregory Ellen, *Recorder*
Sandra Meadows, *Guest*

Review of Safety Plans and MUAs

2004R0013— NCI NO. 5633: "A PHASE I STUDY OF SEQUENTIAL VACCINATIONS WITH FOWLPOX-CEA (6D)-TRICOM (B7.1/ICAM/LFA3) AND VACCINIA-CEA (6D)-TRICOM, IN COMBINATION WITH GM-CSF AND INTERFERON-ALFA-2B IN PATIENTS WITH CEA EXPRESSING CARCINOMAS", William E. Carson III, Surgery

Discussion: This is a Phase I clinical trial that is currently unfunded. The PI has applied for NIH funding. There are 4 cohorts to this trial; three of the cohorts will enroll 3 subjects each, the fourth cohort is scheduled to enroll 6 subjects. This protocol uses a recombinant vaccinia virus modified with TRICOM (TRICOM is the gene insert and not the vaccinia vaccine), which has been approved by the Office of Biotechnological Activities, National Institutes of Health. The proposed subject population is Stage IV colon cancer patients with a particular type of receptor on the cancer cells: carcinoembryonic antigen (CEA). The addition of TRICOM will stimulate the immune system to give increased CEA output and condition the immune system to respond to the CEA; the intention is the destruction of the cancer cells by the body's immune system. The drug regimen is the vaccinia with CEA-TRICOM, GM-CSF, and interferon followed by fowlpox with CEA-TRICOM, GM-CSF, and interferon. The recombinant vaccinia is given by intramuscular injection unlike the normal scarification process. The IM injection of the vaccinia only develops an infectious pustule about 30% of the time. Also, the pustule only appears for 14 instead of the usual 21 days in the scarification process. The PI presented a complete list of exclusion criteria for not only the subjects but also their close contacts/family. The PI also gave an extensive list of complications and possible adverse events.

The Committee proposed that the workers [staff nurses and other personnel] must be offered the chance to be vaccinated prior to the initiation of the study. The worker has the option to waive his/her right to be vaccinated and will sign a waiver. This is similar to the Workers "Right to Know" under OSHA regulations. The vote for this item is as follows:

Voting Summary: 11 affirmative votes, 0 negative votes, 0 abstentions

The Committee proposed that a dedicated room in the GCRC [General Clinical Research Center] be used as a subject treatment area. The vote for this item is as follows:

Voting Summary: 11 affirmative votes, 0 negative votes, 0 abstentions

The Committee recommended that the PI utilize an independent Human Subjects Patient Advocate to assist with the consent process and subject/close contacts education. The vote for this item is as follows:

Voting Summary: 11 affirmative votes, 0 negative votes, 0 abstentions

The Committee will require the PI to use a non-breakable container to transport the syringe from the pharmacy to the subject's treatment area. The vote for this item is as follows:

Voting Summary: 11 affirmative votes, 0 negative votes, 0 abstentions

The Committee wanted to remind the PI that he is required to inform not only the IRB but also the IBC for all adverse events and amendments to the protocol. All amendments need to be approved by both the IBC and the IBC prior to implementation.

As long as the PI agrees to the above recommendations, the protocol was approved. The vote on this item was as follows:

Voting Summary: 11 affirmative votes, 0 negative votes, 0 abstentions

2004R0014—BIG BROWN BATS (*EPTESICUS FUSCUS*) AS A MECHANISM FOR OVER-WINTERING AND REINTRODUCTION OF WEST NILE VIRUS, William J. Saville, Veterinary Preventive Medicine

The committee asked for additional information about the following:

- q. # 3—If ODH determines that bats are rabies negatives, there should be no rabies exposure
- q. # 6—RG 2+ RG 2 containment with RG 3 operational practices
- q. # 10—Must wear water-proof gown when dealing with potentially infected tissues
- Clarify why the bat carcasses are transported returned to ODH after the samples are extracted.
- q. # 16—what training does the individual have with West Nile virus?
- q. #24—water-proof gown, not lab coat
- Provide more information on the disposal of the bats and samples
- Provide more information on how the samples are treated.
- Clarify the role of Dr. Doles and his relationship to OSU (is he an employee, contractor, volunteer,?).

Requires more information from the PI at BSL-2+ containment
Voting Summary: 7 affirmative votes, 0 negative votes, 0 abstentions

2004R0016—BETA-GLOBIN MRNA DECAY IN ERYTHROID CELLS, Daniel R. Schoenberg, Molecular and Cellular Biochemistry

This protocol is considered Exempt under the *NIH Guidelines*.

2004R0017—HORMONAL REGULATION OF MRNA STABILITY, Daniel R. Schoenberg, Molecular and Cellular Biochemistry

This protocol is considered Exempt under the *NIH Guidelines*

2004R0018— STUDIES OF HERPES SIMPLEX TYPE 1 AND HUMAN CYTOMEGALOVIRUS BIOLOGY AND PATHOGENESIS, Joanne Trgovcich, Pathology

The review of this protocol was tabled.

2004R0019— BEHAVIORAL STUDIES OF ECHO-PROCESSING AND COMMUNICATION BY BATS, William M. Masters, EEOB

The committee asked for additional information about the following:

- Provide a completed EHS Occupation Health Registry forms for q. #17.

Approved at BSL-2 containment
Voting Summary: 7 affirmative votes, 0 negative votes, 0 abstentions

2004R0020—FUNCTIONAL ANALYSIS OF SOYBEAN DEFENSE GENES, Terrence L. Graham, Plant Pathology

Approved at BSL-1 and BSL-1P containment
Voting Summary: 10 affirmative votes, 0 negative votes, 0 abstentions

2004R0021—MEASUREMENT OF RETROVIRAL-SPECIFIC CTL RESPONSES IN ANIMAL MODELS OF HUMAN RETROVIRUSES, Michael D. Lairmore, Veterinary Biosciences

The committee asked for additional information about the following:

- q. #21—Provide more detail on transportation between the labs.
- q. #22 and #27 need to be consistent—109° C at 15 psi for 60 minutes.
- q. #24b—Provide a response.
- q. #26—The occupational medicine registry needs to be completed and sent to EHS.
- q. #28—Add spill management information.
- q. #30a—Provide a response.
- q. #33—Provide more information about an exposure control plan.
- q. #34—Delete the reference to *Francisella tularensis* from the text.

Requires more information at BSL-2 containment
Voting Summary: 10 affirmative votes, 0 negative votes, 0 abstentions

2004R0022—TEST SYSTEMS FOR Michael D. Lairmore, Veterinary Biosciences

Comment: The IBC is requiring all personnel to be vaccinated prior to working on this project.

Approved at BSL-3 containment as long as PI agrees to vaccination condition
Voting Summary: 8 affirmative votes, 0 negative votes, 0 abstentions

MINUTES

INSTITUTIONAL BIOSAFETY COMMITTEE
THE OHIO STATE UNIVERSITY

August 12, 2004

Attendance	Members Present	Affiliation	Non-Scientist
X	Brian Ahmer	Biological Sciences	
X	David Coplin (co-chair)	Plant Patholgy	
X	Lawrence A. Capitini	ULAR	
	Long-Sheng Chang	Peds, Children's	
X	Ing-Ming Chiu	Internal Med	
X	Biao Ding	Plant Biology/Biotec	
X	Jyan-Chyun Jang	Hort/Crop Sci	
	Joseph J. Kowalski	Vet Clin Sci	
X	Stefan Niewiesk		
X	Phil Pendergast	EHS	
	Cecil Smith (IBO)	EHS	
X	Jami St. Clair		Community
X	William Swoager	Microbiology	
X	Kenneth Theil		
X	Marshall Williams (co-chair)	MVIMG	
	Non-Voting Members Present (none)		
	Office of Responsible Research Practices Staff		
X	Jan Leibovitz Alloy, Coordinator		
X	Greg Ellen, Administrator		
	Sandra Meadows, Human Subjects Manager		
	Judith Neidig, Director		

The Meeting was called to order at 10:05 am in Room 422 Research Foundation Building. The Meeting was adjourned at 11: 35 am. The meeting was open to the public, and a quorum was maintained at all times. The minutes of the 13 May 2004 meeting were approved.

Drs. Coplin, Ding, and Jang left at 11:25

NEW DRAFT CHARTER

Substantive changes include:

IBC must review select agent protocols before work can start. A PI who in the past has continually violated biosafety requirements can be denied approval of additional protocols.

Article 6 of the charter is changed to indicate that the Biohazard Subcommittee is the only subcommittee permitted to meet by email. Others must meet face to face or by teleconference. Electronic meetings don't meet open-meeting requirements as specified in the *NIH Guidelines*. It was suggested that this article specify that all rDNA protocols must be open to the public.

There is no national standard regarding whether animal-use protocols can be approved before IBC approval. University policy is that the ILACUC cannot approve such protocols until the IBC does. The issue is crucial in that it involves timely purchase of animals.

There was a suggestion to define "majority" in article 7 as the majority of committee members present.

Dr. Pendergast will make changes to the draft and present it again at the next meeting.

NEW PROTOCOL SUBMISSIONS

2004R0024 INTERNATIONAL, RANDOMIZED, MULTICENTER, PHASE III STUDY IN PATIENTS WITH RELAPSING-REMITTING MULTIPLE SCLEROSIS COMPARING OVER A TREATMENT PERIOD OF 104 WEEKS:

1. DOUBLE-BLINDED THE SAFETY, TOLERABILITY, AND EFFICACY OF BETASERON/BETAFERON 250 G (8 MIU) AND BETASERON/BETAFERON 500 G (16 MIU), BOTH GIVEN SUBCUTANEOUSLY EVERY OTHER DAY,
2. RATER-BLINDED THE SAFETY, TOLERABILITY, AND EFFICACY OF BETASERON/BETAFERON S.C. EVERY OTHER DAY WITH COPAXONE 20 MG S.C. ONCE DAILY, Kottil W. Rammohan, Neurology

Discussion: Concern that researchers comply with university policies regarding blood-borne pathogens and disinfection. Needs more information about adverse reactions to interferon. Requires exposure control plan.

Biosafety level: BSL-2
Total: 12; vote for: 12; opposed 0; abstained 0

Protocol was unanimously **DEFERRED FOR FURTHER INFORMATION.**

2004R0026 MOLECULAR MECHANISMS OF VASCULAR α2C-ADRENOCEPTOR EXPRESSION AND TRAFFICKING, Maqsood A. Chotani, Internal Medicine/Davis Heart & Lung Research Institute

Discussion: Protocol involves standard viruses that are replication deficient, all easily obtainable, with no blood involved. Application needs more information about where the research leads. Potential risks, though minimal, need to be acknowledged, then the protocol can be administratively approved.

Biosafety level: BSL-2
Total: 12; vote for: 12; opposed 0; abstained 0

Protocol was unanimously **DEFERRED FOR FURTHER INFORMATION.**

2004R0029 MOLECULAR AND CELLULAR BIOLOGY OF TRYPANOSOMATID PROTOZOA, Bradford S. McGwire, Infectious Diseases/CMIB

Discussion: There was concern regarding how researcher will handle waste. He needs more specifics on containment.

Biosafety level: BSL-2
Total: 12; vote for: 12; opposed 0; abstained 0

Protocol was unanimously **DEFERRED FOR FURTHER INFORMATION.**

2004R0031 DNA PROBES FOR ACANTHAMOEBA GENOMES AND EPIDEMIOLOGY, Paul A. Fuerst, Evolution, Ecology and Organismal Biology

Discussion: Concerns were expressed regarding how researcher will store vectors and control insects. Investigator exposure needs to be discussed; double-gloving was recommended. More detail is needed regarding who is trained to package the biologicals, SOPs for training, infection control, and recommendations for Employee Health. Packing details are needed if infected material goes to autoclave. It was also suggested that Legal Affairs review material transfer agreements.

Biosafety level: BSL-2
Total: 12; vote for: 12; opposed 0; abstained 0

Protocol was unanimously **DEFERRED FOR FURTHER INFORMATION.**

2004R0034 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, Yiqing Xu, Hematology and Oncology

Discussion: Needs dedicated room. No mention is made of adverse reactions in patients with stroke or myocardial infarction. Product should be transported encapsulated in absorbent material in secondary container. Protocol issues are similar to those in Dr. Carson's protocol; committee will review that one before next month's meeting and respond to this one in a similar fashion.

Biosafety level: BSL-2
Total: 12; vote for: 12; opposed 0; abstained 0

Protocol was unanimously **DEFERRED FOR FURTHER INFORMATION.**

2004R0035 SWOG 0011: 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, David E. Schuller, Otolaryngology

Discussion: Dr. Schuller was asked to attend meeting and provide additional information. As he was not available, discussion was deferred.

Biosafety level: BSL-2
Total: 12; vote for: 12; opposed 0; abstained 0

Protocol was unanimously **DEFERRED FOR FURTHER INFORMATION.**

2004R0038 (2004R00xx) INTRACELLULAR CALCIUM SIGNALING IN HEART, Sandor Gyorke, Physiology and Cell Biology

Discussion: Researcher needs to spell out generation of adenovector, whether it is human or animal, whether it is in vitro *or* in vivo, *and how it will be transported.*

Needs to provide more information on occupational health issues. Needs to clarify specific procedures and mechanisms to document who is trained to do them. Typos in protocol should be corrected.

Biosafety level: BSL-2
Total: 12; vote for: 12; opposed 0; abstained 0

Protocol was unanimously **DEFERRED FOR FURTHER INFORMATION.**

EXEMPT PROTOCOLS

2004R0023 NO SYNTHASE SIGNALING IN CARDIAC MYOCYTES AND ITS EFFECTS ON EC COUPLING, Mark T. Ziolo, Physiology and Cell Biology

Date of determination: August 4, 2004

2004R0030 BUILDING BLOCKS OF A BIOCHEMICAL CPU BASED ON DNA TRANSCRIPTION LOGIC, Mario Lauro, Computer and Information Science

Date of determination: July 15, 2004

2004R0032 HEAT-ACTIVATED CHANNELS: CHEMICAL SIGNALS AND REGULATION, Michael X. Zhu, Neuroscience and Center for Molecular Neurobiology

Date of determination: July 6, 2004

2004R0033 FINE-TUNING OF PURKINJE NEURON SIGNAL WITH L7/PCP2 PROTEINS, Michael X. Zhu, Neuroscience and Center for Molecular Neurobiology

Date of determination: July 6, 2004

CONTINUING REVIEWS APPROVED BY ADMINISTRATIVE REVIEW

2000R0017 ROLE OF CHROMATIN REMODELERS IN B AND T CELL DEVELOPMENT, Said Sif, Molecular & Cellular Biochemistry

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

2001R0004 AN INTEGRATIVE APPROACH TO STUDY VIROID MOVEMENT, Biao Ding, Plant Biology Administration

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

2002R0050 RESEARCH PROGRAM ON EHRLICHIA CANIS ANTIGENS, Yasuko Rikihisa, Veterinary Biosciences

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

2002R0051 INVESTIGATION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES, Jiyan Ma, Molecular & Cellular Biology

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

2002R0054 TRANSIENT KINETIC AND DYNAMICAL STUDIES OF A LESION BYPASS DNA POLYMERASE, Zucai Suo, Biochemistry

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

2002R0055 URACIL-DNA GLYCOSYLASE: A NOVEL TARGET FOR HIV-1 THERAPY, Marshall V. Williams, Molecular Virology, Immunology and Medical Genetics

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

2002R0089 BIOCHEMISTRY OF TRNA EDITING, Juan D. Alfonzo, Microbiology

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

2003R0036 EFFICACY OF ORAL RABIES VACCINATION RELATIVE TO BAIT DENSITY AND RACCOON POPULATION DENSITY. Robert J. Gates, School of Natural Resources

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

2000R0002 REGULATION OF GENE EXPRESSION DURING ORGANOGENESIS, Helen M. Chamberlin, Molecular Genetics

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

1987R0003 MOLECULAR AND FUNCTIONAL ANALYSIS OF HUMAN CLASS 1 – HBGF, Ing-Ming Chiu, Internal Medicine

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

1992R0066 MOLECULAR STUDIES ON INFECTIOUS BURSAL DISEASE VIRUSES, Daral J. Jackwood, Food Animal Health

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

1999R0057 IBDV INFECTIOUS CLONE, Daral J. Jackwood, Food Animal Health

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

1999R0074 PEPTIDE DEFORMYLASE: MECHANISM AND INHIBITOR DESIGN, Dehua Pei, Chemistry

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

2001R0027 ABERRANT DNA METHYLATION IN ACUTE MYELOID LEUKEMIA, Christoph Plass, Molecular Genetics

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

2002R0053 OPIOID RECEPTOR REGULATION, Wolfgang Sadee, Pharmacy

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

2002R0059 HUMAN BLOOD, TISSUE, AND RANDOM SOURCE MATERIALS, Christoph Plass, Molecular Genetics

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

2002R0086 REGULATION OF APOPTOSIS IN BREAST CANCER CELLS, Andrea I. Doseff, Internal Medicine,

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

2002R0087 REGULATION OF THE APOPTOTIC PATHWAY BY TH1/TH2 CYTOKINES, Andrea I. Doseff, Internal Medicine,

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

2002R0083 GENETIC, MOLECULAR, AND DEVELOPMENTAL ANALYSIS OF VARIATION IN TOMATO FRUIT MORPHOLOGY, Esther K. Vanderknaap, Horticulture & Crop Science

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

2001R0002 PLANT TRANSCRIPTIONAL ACTIVATION MECHANISMS AND THE GENES CONTROLLED IN RESPONSE TO ENVIRONMENTAL STIMULI, Eric J. Stockinger, Horticulture & Crop Science

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

1999R0048 TRANSLATIONAL CONTROL OF RETROVIRAL UNSPLICED RNA, Kathleen A. Boris-Lawrie, Veterinary Biosciences

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

1999R0073 SAFE RETROVIRAL VECTORS FOR STUDY OF GENE EXPRESSION, Kathleen A. Boris-Lawrie, Veterinary Biosciences

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

2002R0047 THE CELLULAR STRESS RESPONSE IN VIRAL ENCEPHALITIS, Michael J. Oglesbee, Veterinary Biosciences

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

2002R0057 ADVANCED SURGICAL TECHNIQUES AND DEVICE TRAINING, Robert E. Michler, College of Medicine and Public Health

Continuing Review was **APPROVED BY ADMINISTRATIVE REVIEW.**

MINUTES

INSTITUTIONAL BIOSAFETY COMMITTEE
THE OHIO STATE UNIVERSITY

September 9, 2004

Attendance	Members Present	Affiliation	Non-Scientist
x	Brian Ahmer	Biological Sciences	
x	David Coplin (co-chair)	Plant Patholgy	
x	Lawrence A. Capitini	ULAR	
no	Long-Sheng Chang	Peds, Children's	
x	Ing-Ming Chiu	Internal Med	
no	Biao Ding	Plant Biology/Biotec	
no	Jyan-Chyun Jang	Hort/Crop Sci	
no	Joseph J. Kowalski	Vet Clin Sci	
no	Stefan Niewiesk		
no	Phil Pendergast	EHS	
x	Cecil Smith (IBO)	EHS	
x	Jami St. Clair		Community
x	William Swoager	Microbiology	
x	Kenneth Theil		
x	Marshall Williams (co-chair)	MVIMG	
	Non-Voting Members Present (none)		
	Office of Responsible Research Practices Staff		
X	Jan Leibovitz Alloy, Coordinator		
X	Greg Ellen, Administrator		
X	Sandra Meadows, Human Subjects Manager		

The Meeting was called to order at 10:04 am in Room 422 Research Foundation Building. The Meeting was adjourned at 10.50 am. The minutes of the August 2004 meeting were approved.

NEW PROTOCOL SUBMISSIONS

2004R0039 A NEW PARADIGM FOR FIBROSIS: MONOCYTE ACTIVATION OF TGF AND INTRACELLULAR PATHWAYS REGULATING MONOCYTE SURVIVAL, Clay Marsh, Internal Medicine

Discussion: The PI is investigating the role of macrophages in the development or repair of fibrosis in the lung. He plans to examine the role of specific genes responsible for cell survival and vessel development in these processes. He proposes to use the pLenti6/V5 Direction Viral Expression System from Invitrogen to introduce specific genes into primary culture cells and use mouse models to express genes in a tissue-specific manner.

Todd Guttman was consulted about the legality of Human Embryonic Kidney (HEK) cell lines. Aborted fetal cells cannot be used in Ohio.

The Committee **DEFERRED** the protocol for the following reasons:

1. General
   - What are the primary cells to be used in the experiments?
   - What is derivation of HEK cells?
   - Describe the mouse models.

2. Potential risks (rDNA, section 3). Explain "liquid virus."

3. Laboratory containment (Biohazard, section 9)
   - How would cells survive in "sealed" flasks?
   - Change "viral system does not replicate" to "viral system does not propagate the viral particles from an infected cell to another cell."

4. Medical surveillance (rDNA, section 11). Each employee must complete the Occupational Health Registry formand participate in ongoing medical surveillance.

5. Animal procedures (Biohazard, section 15). Provide more information about animal carcass and bedding disposal.

6. Spill management (Biohazard, section 19; rDNA, section 13). 70% ethanol may not be adequate for decontamination. If bleach cannot be used as described, 1% SDS should be used.

7. Training (Biohazard, section 25). Is there an active protocol for Lentivirus transduction studies in the lab he plans to use?

Type of research: rDNA, Biohazard
Biosafety level: RG2

2004R0041 HTLV-I TRANSFORMED T CELL LINES, Stefan Niewiesk, Molecular Virology, Immunology & Medical Genetics

Discussion: Relatively straightforward biohazards proposal. The principal risk to laboratory workers involved in the proposed work is through accidental inoculation of in vitro or in vivo cultivated human adult T cell leukemia cells.

The Committee **REQUIRES MODIFICATIONS** to the protocol.

1. Agent acquisition (section 7). Check "no" in applicable boxes.

2. Transport (section 12). Specify that the screw top tube in an unbreakable sealed container.

3. Waste (section 13).
   - It is unclear precisely what waste is involved here (laboratory, laboratory animal, etc.). Clarify.
   - After waste is autoclaved, place in a burn box for pickup by Office of

Environmental Health and Safety (2-1284) for disposal.
- Must complete bloodborne pathogen training.

4. Animal use (sections 15c/d). Carcasses must be treated as infectious waste (see comments for section 13).

5. Training (section 16). Reference is made to an "already submitted biosafety plan." Be more specific.

6. Medical surveillance (section 17).
- It is stated that employees will submit blood samples. How frequently will this be done? Any special procedures to be done following a known laboratory exposure (needle stick, etc.)?
- Each employee must complete the Occupational Health Registry form and participate in ongoing medical surveillance.

7. Spill management (section 19). It is stated that in case of a large spill the PI will notify the spill response personnel. Who are they, and what will they do? What will the PI do after notification?

Type of research: Biohazard
Biosafety level 2: RG2; if culture the virus, RG3

2004R0029 MOLECULAR AND CELLULAR BIOLOGY OF TRYPANOSOMATID PROTOZOA, Bradford S. McGwire, Infectious Diseases/CMIB

PI's response was reviewed and approved.

Biosafety level: BSL2
Total: 9; vote for 9; opposed 0; abstained 0

Protocol was unanimously **APPROVED.**

2004R0031 DNA PROBES FOR ACANTHAMOEBA GENOMES AND EPIDEMIOLOGY, Paul A. Fuerst, Evolution, Ecology and Organismal Biology

PI's response was reviewed and approved

Biosafety level: BSL2
Total: 9; vote for 9; opposed 0; abstained 0

Protocol was unanimously **APPROVED.**

NOTE: Committee asks PI to check "no" in section 4 and, in section 13, add that used pipettes be placed in a sharps container.

2004R0034 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, Yiqing Xu, Hematology and Oncology

The Committee **REQUIRES MODIFICATIONS** to the protocol.

1. Staff nurses and other personnel must be offered the chance to be vaccinated prior to initiation of the study. Workers will be able to opt out of vaccination but must sign a waiver.

2. A dedicated room in the GCRC (General Clinical Research Center) should be used as a subject treatment area.

3. The PI must utilize a human subjects patient advocate to assist with the consent process and subject/close contacts education.

4. An unbreakable container must be used to transport the syringe from the pharmacy to the subject treatment area.

5. The PI must inform the IBC, in addition to the IRB, of all adverse events and amendments to the protocol. Amendments must be approved by both the IBC and the IRB before implementation.

Biosafety level: BSL2

2004R0035 SWOG 0011: 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, David E. Schuller, Otolaryngology

The Committee **DEFERRED** the protocol for the following reasons:

PI is required to make a presentation to the IBC. ORRP will draft a letter to inform him that the protocol is on hold until he does so.

Biosafety level: BSL2

2004R0038 INTRACELLULAR CALCIUM SIGNALING IN HEART, Sandor Gyorke, Physiology and Cell Biology

The Committee **DEFERRED** the protocol for the following reasons:

PI has not responded to request for more information.

Biosafety level: BSL2

EXEMPT PROTOCOLS

None

CONTINUING REVIEW ADMINISTRATIVE APPROVALS

None

AMENDMENTS

None

MINUTES

INSTITUTIONAL BIOSAFETY COMMITTEE
THE OHIO STATE UNIVERSITY

October 14, 2004

Attendance	Members Present	Affiliation	Non-Scientist
x	Brian Ahmer	Biological Sciences	
x	Angel Arroyo-Rodriguez	Community	
x	David Coplin (co-chair)	Plant Patholgy	
x	Lawrence A. Capitini	ULAR	
x	Long-Sheng Chang	Peds, Children's	
	Ing-Ming Chiu	Internal Med	
	Biao Ding	Plant Biology/Biotec	
x	Jyan-Chyun Jang	Hort/Crop Sci	
x	Joseph J. Kowalski	Vet Clin Sci	
x	Stefan Niewiesk	Vet Bio Sci	
x	Phil Pendergast	EHS	
	Cecil Smith (IBO)	EHS	
x	Jami St. Clair	Community	
	William Swoager	Microbiology	
x	Kenneth Theil	FAHRP	
x	Marshall Williams (co-chair)	MVIMG	
	***Ad hoc* Members Present (none)**		
	Office of Responsible Research Practices Staff		
x	Greg Ellen, Administrator		
x	Sandra Meadows, Human Subjects Manager		

The Meeting was called to order at 10:03 am in Room 422 Research Foundation Building. The Meeting was adjourned at 10.50 am. The minutes of the September 2004 meeting were approved.

1. Approval of September 2004 minutes-approved unanimously

2. New Biohazard Form-Phil Pendergast presented a draft of the new biohazard form. The changes will be discussed at the next meeting. After attending the

September 2004 Recombinant DNA Advisory Committee meeting, Dr. Pendergast believes that the current biohazard form isn't asking the appropriate questions for the committee to make risk assessments. The Preliminary Review Form was also changed slightly. Dr. Pendergast has been reviewing PA-005s but again believed there is insufficient information on the PA-005 to determine whether the new grant proposal is covered under the previous exemption. This necessitates phone calls to the PIs to discover whether the new research is covered or not. The PRF will now elicit more information about the proposed research and hopefully provide adequate information to make determinations about proposed research.

3. Discussion of 1918 flu virus article- A Reuters report that University of Wisconsin researchers had mimicked the pathogenesis of the 1918 flu virus in mice was presented to the committee. They reengineered the hemaglutinin lipoprotein of the 1918 flu virus and inserted it into an H1N1 backbone to produce pulmonary hemorrhage in mice. The issue is discussed in the Safety Considerations document that was sent to the membership. The issue will be discussed at the IBCC and IBC meetings next month.

Administratively reviewed protocol was approved by Dr. Smith. (2004R0041): The information was sufficient to approve the protocol.

Announcements: Tom Wilcox will be the new ORRP Biosafety coordinator. His first day will be Monday October 18, 2004.

The committee membership welcomed Angel Arroyo-Rodriguez, the new community representative, from the Ohio EPA to the committee.

NEW PROTOCOL SUBMISSIONS

2004R0037

[rDNA]—*IN VIVO* IMMUNOMODULATIONOF CYTOKINES USING A NOVEL NANOPARTICLE DELIVERY SYSTEM, Charles G. Orosz, Surgery

Discussion: The investigator proposed to produce plasmid DNA in *E coli.* Three plasmid DNAs will be used that comprise the pDNA3.1 vector backbone. Human hepatocyte growth factor, murine CTGF, and murine Decorin are the cytokine cDNAs to be inserted. The *E. coli* strain that is to be used is Invitrogen DH5α cells.

Total: 12; vote for 12; opposed 0; abstained 0

The Committee **DEFERRED** the protocol for the following reasons:

1. General (question 2):

- Describe the proposed research so that the committee may make an adequate risk analysis. The committee needs to know the nature and purpose of the research, the genes and hosts involved, and the manipulations to be performed. It was not clear to the committee why this research should be performed at BSL-2. If all recombinant molecules are to be propagated in *E. coli* K-12 and the nanonparticles are coated with naked DNA, then the research could be exempt from the NIH Guidelines. Are any mammalian cells being used? Will any gene therapy experiments involving humans or animals be done?

- Provide information regarding possible risks to experimental animals or human laboratory workers from exposure to the transformed nanoparticles or *E. coli*. Are any biohazardous agents involved?

- Provide information about the use of the vectors after they are coupled to the nanoparticles.

2. Potential risks (question3):

- Provide information regarding possible risks to experimental animals or human laboratory workers from exposure to the transformed nanoparticles or *E. coli*.

3. Host systems (question 6):

- Describe the host cells in more detail.

4. Training (question 12):

- What manipulations will be performed?

- Where will the manipulations be performed?

- Describe specific training for the performance of the described manipulations.

5. Medical surveillance (question 13):

- Provide information related to applicable occupational medical surveillance as this is a Safety Level 2 protocol.

6. Spill Management (question 15):

- What good laboratory practices will be used in the spill cleanup?

- Describe the spill cleanup. Distinguish between large and small spills.

7. Laboratory (question 17):

- Clarify whether a biosafety cabinet is present as Question. 18 indicates one is located in 943N Doan.

Type of research: Recombinant DNA and Biohazard

2004R0040

[rDNA, Biohazards]—3D TISSUE ENGINEERING MODEL FOR ADIPOGENESIS, Douglas A. Kniss, Obstetrics & Gynecology

Discussion: Most current tissue culture methods use conventional 2-dimentional methods to study fat cell behavior. The investigator proposes to construct a 3-dimentional (3-D) culture model to simulate the in vivo microenvironment that exists in adipose tissue. The 3-D model will be fabricated from slow-degrading polycaprolactone using an electerospinning technique. 3T3-L1 preadipocytes will be used for the initial studies. All experiments will be conducted with primary cells isolated from human and mouse white adipose tissue. Mouse embryonic stem cells will be used in the tissue model.

Total: 12; vote for 12; opposed 0; abstained 0

The Committee **DEFERRED** the protocol.

1.General (question 2):

- Provide additional information regarding the human cells and primary tissue including the source of the human cells i.e. certification for HIV and HSV status.

2.Vectors (question 9):

- Provide additional information regarding the vectors to be used.

2. Personal Protective Equipment (question 19)

- Include eyewear as required equipment whenever working with biohazardous material

3.Bloodborne pathogen compliance (question 23):

- Please justify why no BBP training is given with the use of human cells.

4.Training (question 25):

- Provide information related to laboratory technique training.

5.Disinfection

- Provide complete disinfection information related to contact time, etc.

6.Spill management (question 28):

- Provide additional information related to varying sizes of spills and PPE worn.

Type of research: Recombinant DNA, Biohazard

2004R0046

[HGT]— A PHASE I STUDY OF ADV-TK + VALACYCLOVIR GENE THERAPY IN COMBINATION WITH STANDARD RADIATION THERAPY FOR MALIGNANT GLIOMAS, E. Antonio Chiocca, Neurosurgery

The investigator has proposed a phase I trial to study the safety of a proprietary adenovirus vector (AdV-tk) and valacyclovir when combined with standard therapy for malignant gliomas. The vector will deliver the RSV promoter-driven thymidine kinase gene from a herpes virus to eligible subjects. After the tumor cells begin producing thymidine kinase, the subject is treated with valacyclovir for fourteen days, which activates the thymidine kinase to kill the cell. Radiation therapy will begin 3-7 days after the injection. Standard treatment for this cancer consists of surgery and/or radiation.

Over 250 patient doses of AdV-tk have been administered in previous clinical trials. Previous studies with brain tumors and prostate cancer have shown the proposed dose was well tolerated alone.

The trial includes two arms based on the underlying disease characteristics: 1) unresectable disease which involve intratumoral injections or 2) resectable disease with injections into the tumor bed after resection. Dose escalations from $3x10^{10}$ to $3x10^{11}$ viral particles will be performed independently for each arm. Three to six subjects enrolled per dose in each arm for an accrual goal of 24 – 36 subjects. Dr. Chiocca will come in November to present this protocol to the board.

Total: 12; vote for 12; opposed 0; abstained 0

Protocol was unanimously **DEFFERED.**

1. The PI must appear before the committee and present the research.
2. Summary (question 2): Please provide the valacyclovir regimen as compared to the gancyclovir.
3. Training/Disinfection (question 14 {#3}, 26, 27): Specify which organic decontaminants will be used.
4. The subject rooms need to be labeled with a biohazard sign.
5. Training (question 14): Please provide actual document detailing training provided to physicians and staff that specifically addresses the procedures conducted. Specify who will conduct the training.
6. Transport (question 16): Provide more details regarding the method of transport, materials used to transport, location of room, biosafety hood, etc.
7. A new protocol must be submitted for a future phase II study.

Type of research: Human Gene Transfer

2004R0043 [Biohazards]—LESIONAL CHEMOTHERAPEUTIC MANAGEMENT FOR ORAL AIDS-KS, Susan R. Mallery, Dentistry

Discussion: This protocol will examine chemotherapeutic management for Kaposi's sarcoma found in AIDS patients. The investigator proposes to grow subcutaneously inoculated human Kaposi Sarcoma cells in the flanks of nude mice with the sometime co-inoculation of laboratory cultivated human lymphocytes infected with Human Herpes Virus 8. Lesions induced at the inoculation site will be treated with slow-continuous nearby injections of drugs in an attempt to half cancer growth. Subsequently tissue specimens will be taken from the affected region at necropsy for evaluation of effect.

Biosafety level: BSL1
Total: 10; vote for 10; opposed 0; abstained 0

The Board **REQUIRES MODIFICATIONS** to the protocol.

1. Risks (question 3): Provide the source of the KS cells and if derived from different AIDS patients, the investigator should take into account the prospect that these biopsies may harbor other potential human pathogens.

2. Maintenance of Agent (question 8): Correct spelling of "cyrovials".
3. Laboratory containment (question 9): Is the tissue culture ware disinfected prior to disposal in biohazard bags? What is the ultimate disposition of these biohazard bags?
4. Personal Protective Equipment (question 10): Include the use of eyewear for all operations.
5. Transport (question 12): Address the transport of tissue specimens collected at necropsy back to the lab and risks posed by subsequent processing of these specimens to the workers i.e. preparation of cryostat sections or other exposure to unfixed cells. Is there sufficient absorbent material in the container to absorb leaks?
6. Waste disposal (question 13): Provide additional details including whether there is treatment with bleach or other disinfectant prior to disposal.
7. Bloodborne pathogen compliance (question 14): Address sharps management including subcutaneous inoculation of the mice with human cells, the insertion of the drug delivery device into the region adjacent to the inoculation site, and the specimen collection at necropsy.
8. Animals (question 15b): Can the human lymphocytes bearing this virus systematically permeate the mouse tissue? What about other human infectious agents possibly available in the human KS biopsy cells?
9. Animals (question 15e): Provide a description of bedding disposal.
10. Animals (question 15f): Provide information regarding the length of persistence by HHV 8 human lymphocytes in nude mice. Address dissemination throughout the nude mouse.
11. Training (question 16): Discuss the Bloodborne Pathogen training and documentation.
12. Medical Surveillance (question 17): Provide the plan for medical surveillance in the event of an accidental needle stick. Has Employee Health Services been contacted for consultation?
13. Disinfection (question 18): Address what disinfectants are to be used, when they are to be used, the contact time for each disinfectant, and how the biosafety cabinets are cleaned including frequency.
14. Spill Management (question 19): Delineate the spill management plan in the event of aerosols generated by mechanical procedures.
15. Procedures for protection from exposure (question 24): Describe training completed by the investigator.

Biosafety level: BSL2
Type of research: Biohazard

2004R0044 [Biohazards]—INITIATION OF CELL MEDIATED IMMUNITY TO MYCOBACTERIUM TUBERCULOSIS, Paula Bryant, Microbiology

The investigator proposes to define the components of the MHC class II-restricted antigen presentation pathway required to elicit Mycobacterium

specific CD4+ T cells. Mice will be infected with *M. tuberculosis* using an aerosol-generating device that delivers a low dose infection into the lungs. Bacterial load will be determined at specific time points post-infection by harvesting lungs and spleens. The antigen specificity of the CD4+ T cells will be measured using *ex vivo* tissue cultures from the harvested organs. Additionally, cultured macrophages will be infected with M. tuberculosis to determine the cellular components required to process and present Mycobacterial derived antigens to T cells.

Total: 9; vote for 9, opposed 0; abstained 0

The Committee **REQUIRES MODIFICATIONS** to the protocol.

1. Summary (question 2): Provide more information regarding the procedures to be used in the handling of *Mycobacterium tuberculosis* in order for the committee to complete a risk analysis of the project.
2. Risks (question 3): Specify that the mice are maintained in HEPA filtered isolator cages within an isolation rack. Are glove boxes available in the labs?
3. Biosafety level (question 9): Add "...which have been approved by the BSL3 Advisory Group, the Institutional Biosafety Office and the IBC." to the end of the second sentence.
4. Personal Protective Equipment (question 10): Include the use of eyewear and respiratory protection (either N-95 or powered air purifying respirators) for all operations.
5. Animals (question 15e): Describe disposal of water bottles and cage parts.
6. Medical Surveillance (question 17): Include plan for individuals involved in an incident to report the incident and then present to Employee Health Services or the Hospital Emergency Department. All lab workers must complete the Occupational Health Questionnaire.
7. Disinfection (question 18): Provide contact time and contraindications for Amphyll. Provide autoclave requirements (122°C, 15 psi [1 bar] for one hour).
8. Laboratory Space (question 20): Last inspection date for LAC 6 is 2/18/04.
9. Procedures for protection from exposure (question 24): Please clarify that the N95 respirator is in the form of a surgical mask and that a surgical mask (*per se*) is not an N-95 respirator.

Biosafety Level: BSL3/ABSL3
Type of Research: Biohazard

DEFFERED PROTOCOLS

2003R0044 [Biohazards]— INDUCED INNATE IMMUNE RESPONSES, Michael Lairmore, Veterinary Biosciences

The investigator has proposed research designed to study key events that occur following phagocytosis of *Bacillus anthracis* spores by macrophages, leading up to lysis of infected macrophages and release of vegetative cells. *B anthracis* Sterne strain (genotype pX01+, pX02-) is 10^5-10^7 fold less virulent than isogenic strains with both plasmids.

Total: 9; vote for 9, opposed 0; abstained 0

The Committee decided that **MODIFICATIONS ARE REQUIRED** for the protocol because of the following reasons:

1. Date for research (question1): Revise the start date to be consistent with initiation of research. Completion date may also need revision.
2. Summary (question 2): Provide additional information regarding the research including a short history of *Bacillus anthracis* in a macrophage. Explain what happens when *B. anthracis* enters the body. Specify what work will be done with the bacterium in the study in order to assess risks of the proposal.
3. Risks (question 3): Revise risks to include the manipulations requested in Question #2.
4. Risk Group (question 6): Assign a risk group higher than RG1.
5. Personal Protective Equipment (question 10): Include the use of eyewear for all operations.
6. Storage requirements (question 11): Describe labeling of the frozen stocks.
7. Waste Disposal (question 13): Describe disposal of treated liquid waste. Include that all decontaminated waste must be placed in a burn box and picked up by Environmental Health and Safety.
8. Animals (question 15b): Include animal bites as a risk as personnel are handling rodents.
9. Medical Surveillance (question 17): All lab workers must complete the Occupational Health Questionnaire.
10. Disinfection (question 18): Provide the required autoclave exposure necessary to kill spores.
11. Spill Management (question 19): Include EHS Emergency Response contact as part of large spill containment. The Institutional Biosafety Officer must receive report of all large spills within 24 hours. Personnel should vacate the area after the spill so that aerosol exposure is limited. Provide the appropriate PPE for cleanup.

12. Laboratory Space (question 20): Labs in Goss (107 and 108) must be inspected annually.
13. Training of personnel (question 25): Include a note about Dr. Phipps' experience in working with as his qualification to serve as the trainer.

Biosafety level: BSL2
Type of Research: Biohazard

2004R0038 —INTRACELLULAR CALCIUM SIGNALING IN HEART, Sandor Gyorke, Physiology and Cell Biology

This investigator is exploring the molecular basis of intracellular calcium signaling in normal and diseased hearts. An adenoviral-mediated gene transfer strategy will be employed to manipulate expression of proteins comprising the multimolecular calcium signaling complex in isolated rat ventricular myocytes. The individual roles of these proteins and how their genetic defects lead to altered calcium handling, arrhythmia and sudden death will be determined.

The investigator responded as required

Total: 9; vote for 9, opposed 0; abstained 0

The Committee **APPROVED** the protocol.

Biosafety Level: BSL2

2004R0039 A NEW PARADIGM FOR FIBROSIS: MONOCYTE ACTIVATION OF TGF AND INTRACELLULAR PATHWAYS REGULATING MONOCYTE SURVIVAL, Clay Marsh, Internal Medicine

The investigator responded to the board's request for additional information related to the type of primary cells and mouse models to be used, potential risks, laboratory containment, medical surveillance, animal procedures, spill management and training. The investigator responded as required

Total: 9; vote for 9, opposed 0; abstained 0

The Committee **APPROVED** the protocol.

CONTINUING REVIEW ADMINISTRATIVE APPROVALS

None

AMENDMENTS

2004R0027 [Biohazards]—IMMUNE CORRELATES OF REACTIVATION TUBERCULOSIS, Joanne Turner, Internal Medicine

The amendment involves only minor changes to the research.

Total: 9; vote for 9, opposed 0; abstained 0

The Committee **APPROVED** the amendment.

Minutes
Institutional Biosafety Committee
18 November 2004

PRESENT:

Marshall Williams, *Co-Chair*
Cecil Smith, *IBO*
Kenneth Theil
Long-Sheng Chang
Ing-Ming Chiu
Tom Wilcox, *Recorder*
Elizabeth Wiley, *Guest*
E. Antonio Chiocca, *Guest*
David Coplin, *Co-Chair*
Brian Ahmer
Larry Capitini
Joseph Kowalski
Phil Pendergast
Gregory Ellen, *Recorder*
Sandra Meadows, *Guest*
Sue Bell, *Guest*

The meeting was called to order at 10:03 am in the Research Foundation Building, room 422. The meeting was adjourned at 10:48 am.

Review of Minutes

The minutes of the 14 October meeting were approved.

Revision of Forms

Due to information from the most recent RAC meeting, Dr. Pendergast has revised the Biohazard form to provide further information about highly pathogenic agents. The new form would require the PI to take a greater look at the risks associated with the biohazard. The Biohazard and rDNA form will be updated shortly. Dr. Pendergast will forward the revised copy to the committee and asks that comments be directed to him or Dr. Smith. Dr. Smith requests that IBC members examine the form closely and make suggestions between now and the December meeting, at which time the board will vote on amending the form.

Review of Safety Plans and MUAs

2004R0046— A PHASE I STUDY OF ADV-TK + VALACYCLOVIR GENE THERAPY IN COMBINATION WITH STANDARD RADIATION THERAPY FOR MALIGNANT GLIOMAS, E. Antonio Chiocca, Neurosurgery

This is a phase I study with 2 arms (unresectable tumors and resectable tumors) looking at three dosage levels with 3 to 6 patients per dose level per cohort. Potential subjects have brain gliomas and are given normal standard of care treatment along with the gene transfer component. Day 0 starts with surgery in which the glioma is resected or biopsied (if the tumor is inoperable)

along with the AdV-TK injection. This is followed by valacyclovir and standard radiation therapy. As this is still a phase I trial, the PI is looking at subject safety and tumor response.

AdV-TK is a replication defective adenoviral vector that has E1 and E3 deleted and HSV-thymidine kinase inserted into the E1 region. It also uses RSV-LTR as a promoter. The vector is not infectious and will be administered directly into the tumor or tumor bed during surgery. Aerosols will not be created and all fluids will be handled with universal precautions. Shedding studies have shown the vector in urine and CSF.

The vector is sensitive to pH and general disinfectants including 70% alcohol and 10% bleach. Training will be conducted by the sponsor (Advantagene). The PI has SOPs for transportation of the vector and spill management.

A Data Safety Monitoring Board (DSMB) will be created consisting of the PI, a representative of the sponsor, and two *ad hoc* experts. The PI will be responsible for reporting Adverse Events to the IRB and the IBC.

Voting Summary: 10 affirmative votes, 0 negative votes, 0 abstentions.
The Board **REQUIRES MODIFICATIONS** to the protocol.

The PI will need to provide further information for q. #20 regarding close contact protection, and barrier contraception needs to be part of the discussion. The letter sent to Dr. Chiocca will indicate that this is part of the standard recommendation.

Biosafety level: BSL2
Type of research: Human Gene Transfer

2004R0037 IN-VIVO IMMUNODULATION OF CYTOKINES USING A NOVEL NANOPARTICLE DELIVERY SYSTEM, Charles Orosz, Surgery

This protocol was originally deferred pending additional information from the PI. No new information has been received yet. The PI will be sent a reminder letter.

2004R0040— 3D TISSUE ENGINEERING MODEL FOR ADIPOGENESIS, Douglas A. Kniss, Obstetrics & Gynecology

This protocol was originally deferred pending additional information from the PI. No new information has been received yet. The PI will be sent a reminder letter.

2004R0045— EVOLUTION OF SNAKE VENOM, H. Lisle Gibbs, Evolution, Ecology, and Organismal Biology

The Biohazard Subcommittee reviewed this protocol electronically, and a letter has been sent to Dr. Gibbs requesting additional information.

2004R0049— DEVELOPMENT OF A MODEL OF CARPAL TUNNEL SYNDROME-R24 SUPPORT, John Buford, School of Allied Medical Professions—Division of Physical Therapy

Dr. Smith stated that the application will be reviewed electronically by the biohazard subcommittee, and a letter with the results of the review will be sent to Dr. Buford.

2004R0050—RETICULOSPINAL CONTROL OF REACHING, John Buford, School of Allied Medical Professions—Division of Physical Therapy

Dr. Smith stated that the application will be reviewed electronically by the biohazard subcommittee, and a letter with the results of the review will be sent to Dr. Buford.

The meeting was adjourned until 9 December 2004.

Minutes
Institutional Biosafety Committee
9 December 2004

Attendance	IBC Members Present	Affiliation
no	Brian Ahmer	Biological Sciences
X	Angel Arroyo-Rodriguez	Community
X	David Coplin (co-chair)	Plant Patholgy
no	Lawrence A. Capitini	ULAR
no	Long-Sheng Chang	Peds, Children's
no	Ing-Ming Chiu	Internal Med
no	Biao Ding	Plant Biology/Biotec
no	Jyan-Chyun Jang	Hort/Crop Sci
no	Joseph J. Kowalski	Vet Clin Sci
no	Stefan Niewiesk	Vet Bio Sci
X	Phil Pendergast	EHS
X	Cecil Smith (IBO)	EHS
no	Jami St. Clair	Community
X	William Swoager	Microbiology
no	Kenneth Theil	FAHRP
X	Marshall Williams (co-chair)	MVIMG
	Office of Responsible Research Practices Staff	
X	Sandra Meadows, Human Subjects Manager	ORRP
X	Greg Ellen, IRB Administrator	ORRP
X	Tom Wilcox, Biosafety Coordinator	ORRP
	Invited Speaker	
X	Amit Agrawal	Otolaryngology

The meeting was called to order at 10:05 am in the Research Foundation Building, room 422.
The meeting was adjourned at 11:18 am.

Review of Minutes

The minutes of the 18 November 2004 meeting were discussed. Voting will be tabled until the 13 January 2005 meeting, due to a lack of quorum.

Old Business

Dr. Pendergast asked for comments on the revised biohazard form, and indicated that he is still in the process of receiving them. Consequently, the form was tabled, pending additional comments. Dr. Pendergast requested comments be returned to him before the IBC convenes again in January. The revised biohazard form will be voted on at the January IBC meeting.

Dr. Bryant has fully met the committee's request for modifications to her protocol, 2004R0044 [Biohazards]—INITIATION OF CELL MEDIATED IMMUNITY TO *MYCOBACTERIUM TUBERCULOSIS*; she will be sent a letter, informing her that approval has been granted.

The committee administratively approved Dr. Gibbs' protocol, 2004R0045 [Biohazards]—EVOLUTION OF SNAKE VENOM.

Review of Safety Plans and MUAs

2004R0035 [HGT]— SWOG 011: 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, Amit Agrawal, David Schuller, John Grecula, Chris Rhoades, Otolaryngology

Summary of proposal:
Patients with advanced squamous cell carcinoma of the head and neck (SCCHN) have a 5-year survival rate of less than 40%, and current treatment options are toxic as well as functionally and cosmetically debilitating. After surgery removes gross disease, microscopic cancer cells remaining in the margins of resection are killed via adjuvant radiotherapy and/or chemotherapy. However, a 35 – 50% recurrence rate exists, and patients with advanced SCCHN have a high rate of local-regional recurrence and low survival rate with the existing treatment modalities. Therefore, novel biological therapies, such as gene therapy, have to be developed and tested.

Gene therapy may provide an alternative mechanism for controlling the microscopic residual disease with limited or no added toxicity. Tumor growth suppression in head and neck cancer cells has been demonstrated to occur within in-vitro and in-vivo models, using both mutated or non-mutated p53 human SCCHN cell lines, by inducing over-expression of p53. After

adenovirus-p53 INGN 201 was injected into surgically resected tumor beds of mice, tumor control and survival rates were improved. The mechanism of growth suppression was found to primarily be apoptosis. Additional mechanisms of actions for INGN 201 have been evoked, including Fas-mediated apoptosis and anti-angiogenesis effects.

In the proposed trial, the investigators are planning to transduce p53 in tumor and preneoplastic foci within the surgical microenvironment to induce apoptosis. Replication defective adenovirus serotype 5 will be utilized as a vector; this vector will contain the human p53 gene, a CMV promoter, and a SV40 polyadenylation signal. The safety and antitumor activity demonstrated in Phase I and II trials have led the investigators to develop this perioperative Phase II trial. The three objectives of the study under consideration are to assess the feasibility of treating high risk, selected Stage III and IV squamous cell carcinoma of the oral cavity and oropharynx with perioperative INGN 201 gene transfer along with surgery and chemoradiation in a multi-institutional setting; to assess progression-free survival, overall survival, and local control; and to assess toxicity of perioperative INGN 201 and chemoradiation.

The Committee discussed the proposal, and made the following comments:

1. General:
   - The IBC requests a copy of the pharmacy's standard operating procedures, in order that the committee may consider transport details of the materials.
   - The proposal will be reviewed by the full committee at the January meeting, and considered for approval at that time.
2. Subjects:
   - The IBC recommends that subjects be provided with emergency ID cards, to place in their purses or wallets.
   - The IBC recommends that patient advocates be provided to all subjects.
   - The IBC recommends that all subjects be provided with information regarding close contact issues, and the usage of barrier contraception methods.

2004R0051 [Biohazards]— GENERATION OF TRANSGENIC MICE USING LENTIVIRAL VECTORS, Anthony Young, Center for Molecular Neurobiology

Summary of proposal:

- The investigator proposes to generate transgenic mice, using replication-incompetent HIV-based lentivirus to deliver the transgene. To accomplish this, the lentivirus that carries a transgene will be injected into the perivitelline space of a single-cell mouse embryo. The injected

embryos will be cultured overnight in a 5% CO_2 incubator at 37^0C. Embryos that advance to the two-cell stage will be surgically transferred into pseudo pregnant females and carried to term. Offspring bearing the integrated transgene will be identified by PCR.

The Committee discussed the proposal, and made the following comments:

1. General:
   - The PI indicates 3 microliters will be drawn up, but then indicates that 4 microliters will be delivered. The PI should resolve this discrepancy.
   - What type of DNA is being transferred into the animals?
   - Question #7: is the DNA injected, or conveyed via a virus?
2. Vector details:
   - Specify which lentiviruses will be used.
   - Question #12 does not describe the virus with deletions and insertions.
   - The PI needs to describe the viral particles, and the number of viral particles that will be inserted.
3. Potential risks (question 3)
   - It is not clear where the vector is produced.
   - There is no vector description or description of genes which will be inserted.
   - The procedure is not conducted as a BSL2 procedure.
4. Risk group assessment (question 6):
   - The risk group cannot be assessed until the specific lentivirus that will be used is indicated.
5. Disinfection:
   - The PI should discuss the volumes of 5% and 10% bleach that will be used.
   - Liquid should be autoclaved.
   - Bleach concentration needs to be clearly stated. E.g. does 10% bleach mean a 1-10 of store purchased (about 5% sodium hypochlorite) material?
   - The PI should autoclave some of the discarded supplies.
6. Personal Protection Equipment (question 10):
   - Eyewear should always be used when handling microbes.
7. Medical surveillance (question 17):
   - Medical surveillance is not addressed.
8. Animal exposure risk (question 15b)
   - The PI did not answer this question.
9. Spill management (question 19):
   1. What volumes and concentrations of virus will be in use?
   2. The spill management does not seem realistic, given the small volumes used. Is aerosol formation during microinjection a

problem?

10. Transport:
    - The PI should specify where the transport is occurring (i.e. from whence to where).
    - The secondary container should have absorbent material.

2004R0052 [Biohazards]— OSUCCC AND CALGB LEUKEMIA TISSUE BANKS AND CALIGIURI RESEARCH LABORATORY, Michael Caligiuri, Internal Medicine

Summary of proposal:
The investigator's research studying the development of Natural Killer Cells (NKCell) in humans requires the use of white blood cells (WBCs) obtained from the American Red Cross and normal tissues from commercial suppliers or the NIH-Cooperative Human Tissue Network—Tissue procurement service. The WBCs are a by-product of the processing blood donated by the Red Cross; these WBCs are usually discarded after the blood is processed. The supplier screens the normal tissues prior to shipping. The Red Cross also screens white blood cells prior to distribution.

The investigator's research uses cell lines that may be grown in culture indefinitely. Although none of these cell lines contain organisms that cause disease in humans, they are treated as potentially biohazardous and handled and discarded as such.

Bacteria are used to cultivate plasmids containing genes related to human leukemias, which will be isolated and used to study the genes related to leukemia. There is no recombinant DNA that is used in this research. The bacteria strains are similar to those found in the human intestinal tract.

The Committee discussed the proposal, and made the following comments:

1. General:
    - The PI needs to expand on the nature of the work with mice and any associated potential hazards associated (e.g. sharps management). How will specimens be collected from the mice, for example? In section (5), E. coli should be spelled out. In section (20), there is no mention of animal facilities to cover the work with mice.
    - Question #1: the proposed start date is in the past; the proposed anticipation date is not specified.
2. Proposal summary (question 2):
    - Describe the nature of the bacterial plasmids (i.e., characterize the plasmid and DNA inserts).
    - Describe the manipulations to be performed in the plasmid work.
3. Potential risks (question 3):

- Cite potential exposure to all bloodborne pathogens. Screening tests do not cover entire spectrum of infectious agents.

4. Transport (question 12):
   - How is the contaminated material moved to the autoclave? Is the repository in just one lab or multiple labs?
   - How are blood and blood products transported to the laboratories and between the laboratories?
5. Bloodborne pathogen compliance (question 14):
   - All staff must also complete an annual refresher course for Bloodborne Pathogen training.
6. Personnel training (question 16):
   - Personnel training for the plasmid work should be specified.
7. Medical Surveillance (question 17):
   - Please complete Occupational Medicine Registry forms for all affected staff.
8. Disinfection (question 18):
   - Why use isopropyl for routine disinfection as opposed to a substituted phenolic?
   - Explain use of 10% bleach solution for disinfection.
   - 10% bleach at concentration of 5,000-7,500 ppm sodium hypochlorite should be made up fresh with each use. The required contact time is a minimum of 10 minutes.
9. Spill management (question 19):
   - Notify EHS and the Institutional Biosafety Officer of all spills greater than one liter or three square feet.
10. Locations (question 22):
    - Polaris labs should also be cited, or an amendment should be submitted at a later date.

2004R0054 [rDNA, Biohazards]—RESPIRATORY SYNCYTIAL VIRUS, Stefan Niewiesk, Veterinary Biosciences

Summary of proposal:
Infants are protected against measles virus by maternal antibodies. These antibodies, however, inhibit vaccination even when levels of antibodies are too low to be protective, thus opening a window of opportunity for the wild-type virus to infect the host. The investigators have previously shown that intranasal application with a recombinant vesicular stomatitis virus (RSV) expressing the measles virus hemagglutinin is one way to overcome these maternal antibodies. The investigators conjecture that a respiratory syncytial virus expressing the measles virus hemagglutinin may protect against measles and RSV in the presence of maternal antibodies in the cotton rat model.

Provided addendum:
The RSV vector will be produced in Dr. Mark Peeples laboratory in the

Children's Hospital. Further, the measles virus hemagglutinin will be cloned in the RSV vector and expressed as an additional open reading frame. The viruses will then be used to infect the animals.

The virus vector contains 100% of the viral genome, and is categorized as RG1. The PI proposes to carry out the described work in BSL2.

The Committee discussed the proposal, and made the following comments:

1. General:
   - The PI mentions that RSV infections in adults lead to symptoms from common cold to bronchitis. However, RSV infections in the very young can have lethal consequences, and this should also be mentioned.
   - Which Children's Hospital is being referred to in section 6? Where is it located?
2. Potential risks (question 3):
   - This work proposes to use a recombinant RSV bearing the gene sequence for the measles virus hemagglutinin protein. RSV causes primarily a superficial infection of the respiratory tract, whereas measles virus causes a systemic infection involving immunosuppression and widespread organ involvement. One of the immunosuppressive components in the measles virus infection is the hemagglutinin protein, working in concert with other factors. The PI should discuss each of these agents. Suggested details follow.
   - The potential risk of introducing the hemagglutinin gene into the RSV genome should be discussed. Is there any previous, known published documentation that this does not enhance the virulence of RSV, or change this virus's tissue tropism? This should be provided in the application if it is available. Does this hemagglutinin get incorporated into the RSV envelope so that all progeny virions carry this surface antigen, or is it just expressed during virus replication? Surface antigens clearly can have a role in determining how the virus reacts immediately in the host environment, and profoundly affect the sequence of events during the course of infection.
   - Describe how the recombinant RSV will be introduced into the respiratory tract of cotton rats.
   - With the measles virus/cotton rat infection model one mechanism protecting the laboratory workers is that all are vaccinated against measles virus, and therefore are believed to be protected against the more severe consequences of the systemic infection. With RSV, the protective immunologic barrier will necessarily be mostly limited to mucosal immunity induced by natural exposure, a type of immunity known to wane quickly. At one time it was believed that high of levels of IgG to RSV in the bloodstream resulted in increased pulmonary lesions in infected vaccinated children; is there any risk

that should a laboratory worker become infected with this RSV recombinant that the anti-measles virus hemagglutinin IgG antibodies from their vaccination could enhance the clinical signs that they experience?

- While it is indicated in section 19 that face masks will be worn, will these be sufficient to protect against virus aerosol generated during intranasal inoculation of cotton rats? A little more description here is necessary.

3. Transport:
   - Please provide details of the transport of the RSV from Children's Hospital.

2004R0055 [Biohazards]— CANINE DISTEMPER VIRUS INFECTION IN VIVO AND IN VITRO, Stefan Niewiesk, Veterinary Biosciences

Summary of proposal:
Canine distemper virus is closely related to measles virus. As for measles virus infection the main problems with CDV infection are the inefficiency of vaccine virus in the presence of maternal antibodies and the strong immunosuppressive effect of wild-type virus. The investigators have established an infection model for measles virus in cotton rats and want to establish a model for CDV infection for comparative research.

The Committee discussed the proposal, and made the following comments:

1. General:
   - Wild canine distemper virus poses no threat to humans, but if it is a very virulent strain, there could be a potential problem associated with canines that visit the veterinary hospital should this agent escape containment. For this reason, more detail on how the necropsy will be conducted, and how the tissues will be transported back to the laboratory for assay, etc. should be given so that an assessment of the safety of these procedures may be made.
2. Proposal summary (question 2):
   - The PI needs to discuss how the measles virus infection model fits into the research proposal. E.g. what are the similarities and differences between the established measles virus infection model in the cotton rat, and the proposed infection model for CDV? The PI needs to detail the experimental methods that will be used, in order that a risk assessment of the project may be made.
   - Describe the likely target model system, and provide additional details. For example, what virus strain will be used? Will this be a wild type-strain, or a vaccine strain? Will recombinant virus be used? What will be the route of inoculation of the virus into the cotton rat? Will necropsies of virus exposed cotton rats be performed? If so, describe this process and instrument clean-up, disinfection, etc. A brief overview of the in vivo work to be conducted should be provided.
3. Personal Protective Equipment (question 10):
   - Protective eyewear is required for this proposal.
4. Transportation (question 12):
   - Agents need to have sufficient absorbent material inside inner container to absorb material. That container needs to be inside a barrier meant to absorb shock. Transport to/from Sisson should be conducted correctly.
   - Could non-exploding cryotubes in liquid nitrogen be used?
5. Animal exposure risks (question 15):
   - If material is shed in mucus, it can be transferred to handlers via

bites, and the material may be present in the feces of animals. What type of handling of bedding material does the PI recommend?

6. Medical surveillance (question 17):
   - The PI suggests that skin and injection sites will be disinfected, but only soap and water are specified as disinfectants.
7. Disinfection (question 18):
   - The PI indicates chlorine will be used for disinfection, but the form of chlorine is not clearly specified; sodium hypochlorite is assumed. If so, is 1% bleach necessary? 1-10 (0.5%) should be enough for low organic material decontamination.
8. Spill management (question 19):
   - Will sufficient volumes be used so as to constitute a "major" spill?
   - See the comments for question 18, regarding chlorine.
   - Specify how contaminated clothing will be decontaminated.

2004R0056 [rDNA, Biohazards]— CHARACTERIZATION OF COTTON RAT RECEPTORS FOR MEASLES VIRUS, Stefan Niewiesk, Veterinary Biosciences

Summary of proposal:
Cotton rats are the only small animals susceptible to measles virus infection via the intranasal route. The investigator will attempt to define in vitro the cotton rat receptor molecules of measles virus by using a cDNA library. The cDNA library will be inserted into a retroviral vector, murine leukemia virus (MLV), and will be used to express the various cotton rat molecules in hamster CHO cells. The receptor usage will be analyzed by a replication-deficient vesicular stomatitis virus (VSV) pseudotyped with measles virus glycoproteins expressing green fluorescent protein (GFP).

Both the MLV and VSV vector systems are replication defective. The MLV vector contains 50% of the viral genome, while the VSV vector includes 90% of the viral genome. Packaging of recombinant viruses using the two vector systems will be performed using helper plasmid cotransfection in human 293T cells. The risk group classification for the host/vector is RG1. The proposed experiments will be performed under the BSL2 condition, due to the use of pathogens.

The Committee discussed the proposal, and made the following comments:

1. General:
   - The IBC requests that the acronym "GMOs" be clearly defined in items 19 and 34.
2. Transport:
   - Transport of BLV should take place via a container with absorbent material that is capable of containing the fluid of any broken tubes.

3. Animal exposure risks (question 24b):
   - The PI does not list any exposure risks.
4. Medical Surveillance (question 26):
   - The PI suggests that skin and injection sites will be disinfected, but only soap and water are specified as disinfectants.
5. Disinfection (question 27):
   - For disinfection, 10% bleach instead of "chlorine (500 pp, (1% bleach)) as indicated in item 27 is recommended. The PI needs to state when "higher concentration of chlorine" will be used.
   - The PI indicates chlorine will be used for disinfection, but the form of chlorine is not clearly specified; sodium hypochlorite is assumed. If so, is 1% bleach necessary? 1-10 (0.5%) should be enough for low organic material decontamination.
6. Spill management (question 28):
   - Please change "Spilled area will be rinsed" to "Spilled area will be decontaminated with bleach."
   - Specify how contaminated clothing will be decontaminated.
7. Laboratory space (questions 24, 33 and 34):
   - Although the experiments described will be performed using cultured cells in the lab, the PI indicates in item 33, "...Transport of the agents into and organs out of the animal facility..." On the other hand, the PI indicates in item 24, no animal will be used.
   - If the PI is not going to use animals for the study, the statement regarding transport of the agents and animal organs in/out of the animal facility should be deleted from items 33 and 34.

2004R0057 [rDNA, Biohazards]—BOVINE LEUKEMIA VIRUS VECTOR, Stefan Niewiesk, Veterinary Biosciences

Summary of proposal:
Infants are protected against measles virus by maternal antibodies. These antibodies, however, inhibit vaccination even when levels of antibodies are too low to be protective, thus opening a window of opportunity for the wild-type virus to infect the host. The investigators have previously shown that intranasal application with a recombinant vesicular stomatitis virus (RSV) expressing the measles virus hemagglutinin is one way to overcome these maternal antibodies. The investigators conjecture that a respiratory syncytial virus expressing the measles virus hemagglutinin may protect against measles and RSV in the presence of maternal antibodies in the cotton rat model. The investigators propose to test an alternative method, where the protective antigen (measles virus hemagglutinin) is constantly expressed by a persisting attenuated bovine leukemia virus vector.

Provided addendum:
The Bovine Leukemia virus vector is a hybrid virus containing the LTR of spleen necrosis virus with the encapsulation signal, primer binding site, polypurine tract and at site of BLV as well as the gag-pol and envelop genes. 80% of the genome is contained. The measles virus hemagglutinin gene is expressed through an IRES element. The vector will be produced in Dr. Boris-Lawrie's laboratory. The modified vector (assuming that it lacks measles hemagglutinin) is pathogenic in the rabbit model of BLV infection; one assumes that the vector is pathogenic in cattle. No human infection has been reported with BLV. Once the vector is constructed, it will be used in cotton rats to quantify hemagglutinin efficacy as a vaccination vector.

The Committee discussed the proposal, and made the following comments:

1. Proposal summary (question 2):
   - The IBC requests that the provided proposal be discussed in more detail.
2. Transport
   - Transport of BLV should take place via a container with absorbent material that is capable of containing the fluid of any broken tubes.
   - The IBC requires that the material be transported in a sealed, non-breakable container.
   - Transport of BLV should be discussed in further detail.
3. Animal exposure risk (question 24b):
   - The question has not been answered.
4. Medical Surveillance (question 26):
   - The PI suggests that skin and injection sites will be disinfected, but only soap and water are specified as disinfectants.
5. Disinfection (question 27):

- The PI indicates chlorine will be used for disinfection, but the form of chlorine is not clearly specified; sodium hypochlorite is assumed. If so, is 1% bleach necessary? 1-10 (0.5%) should be enough for low organic material decontamination.

MINUTES

INSTITUTIONAL BIOSAFETY COMMITTEE
THE OHIO STATE UNIVERSITY

January 13, 2005

Attendance	Members Present	Affiliation	Non-Scientist
x	Brian Ahmer	Biological Sciences	
x	Angel Arroyos-Rodriguez	Ohio EPA	Community
x	David Coplin (co-chair)	Plant Pathology	
x	Lawrence A. Capitini	ULAR	
x	Long-Sheng Chang	Peds, Children's	
x	Ing-Ming Chiu	Internal Med	
no	Biao Ding	Plant Biology/Biotec	
x	Jyan-Chyun Jang	Hort/Crop Sci	
x	Joseph J. Kowalski	Vet Clin Sci	
no	Stefan Niewiesk	Vet Biol Sci	
x	Phil Pendergast	EHS	
no	Cecil Smith (IBO)	EHS	
x	Jami St. Clair	Columbus PD	Community
x	William Swoager	Microbiology	
x	Kenneth Theil	OARDC	
x	Marshall Williams (co-chair)	MVIMG	

Non-Voting Members Present (none)

	Office of Responsible Research Practices Staff
X	Tom Wilcox, Biosafety Coordinator
X	Sandra Meadows, Human Subjects Manager

The Meeting was called to order at 10:07 am in Room 422 Research Foundation Building. The Meeting was adjourned at 10:55 am.

Review of Minutes
Approval of December 2004 minutes-approved unanimously

Old Business

1. New Biohazard Form-The revised Biohazard Form has been distributed to the membership for discussion. Comments from individuals will be incorporated into the document and revised copies of the form will be forwarded to the committee for discussion at the February meeting. The biological biosafety cabinet certification date will be included on the next version of all of the forms.
2. The Human Gene Transfer form will be revised to indicate to the Principal Investigator and/or sponsor of the committee's requirement that a human subjects advocate be utilized during the consent process.

NEW PROTOCOL SUBMISSIONS

2004R0054 RESPIRATORY SYNCYTIAL VIRUS, Stefan Niewiesk, Veterinary Biosciences

Summary of proposal:

Infants are protected against measles virus by maternal antibodies. These antibodies, however, inhibit vaccination even when levels of antibodies are too low to be protective, thus opening a window of opportunity for the wild-type virus to infect the host. The investigators have previously shown that intranasal application with a recombinant vesicular stomatitis virus (RSV) expressing the measles virus hemagglutinin is one way to overcome these maternal antibodies. The investigators conjecture that a respiratory syncytial virus expressing the measles virus hemagglutinin may protect against measles and RSV in the presence of maternal antibodies in the cotton rat model.

Provided addendum:

The RSV vector will be produced in Dr. Mark Peeples' laboratory in the Children's Hospital. Further, the measles virus hemagglutinin will be cloned in the RSV vector and expressed as an additional open reading frame. The modified virus will then be used to infect the animals.

The virus vector contains 100% of the viral genome, and is categorized as RG2. The PI proposes to carry out the described work in BSL2.

The motion to require modifications was defeated by the following vote:
Total: 13; vote for 3; opposed 10; abstained 0

The Committee expressed concern about the risks related to this vector and moved to defer so that the full board could discuss the investigator responses.

Total: 13; vote for 13; opposed 0; abstained 0

The Committee **DEFERRED** the biosafety plan for the following reasons:

1. General:
   - The PI mentions that RSV infections in adults lead to symptoms from common cold to bronchitis. However, RSV infections in the very young can have lethal consequences, and this should also be

mentioned.

- Which Children's Hospital is being referred to in section 6? Where is it located?

2. Potential risks (question 3):
   - This work proposes to use a recombinant RSV bearing the gene sequence for the measles virus hemagglutinin protein. RSV causes primarily a superficial infection of the respiratory tract, whereas measles virus causes a systemic infection involving immunosuppression and widespread organ involvement. One of the immunosuppressive components in the measles virus infection is the hemagglutinin protein, working in concert with other factors. The PI should discuss each of these agents. Suggested details follow.
   - The potential risk of introducing the hemagglutinin gene into the RSV genome should be discussed. Is there any previous, known published documentation that this does not enhance the virulence of RSV, or change this virus's tissue tropism? This should be provided in the application if it is available. Does this hemagglutinin get incorporated into the RSV envelope so that all progeny virions carry this surface antigen, or is it just expressed during virus replication? Surface antigens clearly can have a role in determining how the virus reacts immediately in the host environment, and profoundly affect the sequence of events during the course of infection.
   - Describe how the recombinant RSV will be introduced into the respiratory tract of cotton rats.
   - With the measles virus/cotton rat infection model, one mechanism protecting the laboratory workers is that all are vaccinated against measles virus, and therefore are believed to be protected against the more severe consequences of the systemic infection. With RSV, the protective immunologic barrier will necessarily be mostly limited to mucosal immunity induced by natural exposure, a type of immunity known to wane quickly. At one time it was believed that high levels of IgG to RSV in the bloodstream resulted in increased pulmonary lesions in infected vaccinated children. Is there any risk should a laboratory worker become infected with this RSV recombinant, that the anti-measles virus hemagglutinin IgG antibodies from their vaccination could enhance the clinical signs that they experience?
   - While it is indicated in section 19 that face masks will be worn, will these be sufficient to protect against virus aerosol generated during intranasal inoculation of cotton rats? Please provide additional information.
3. Recombinant DNA (question 9)
   - The question was not answered. Provide a description of the modified virus (a map of the virus would be helpful).
4. Transport (question 21):
   - Please provide details of the transport of the RSV from Children's Hospital to OSU.

Biosafety Level: BSL 2
Type of research: Recombinant DNA, Biohazard

2004R0056 CHARACTERIZATION OF COTTON RAT RECEPTORS FOR MEASLES VIRUS, Stefan Niewiesk, Veterinary Biosciences

Summary of proposal:
Cotton rats are the only small animals susceptible to measles virus infection via the intranasal route. The investigator will attempt to define the cotton rat receptor molecules of measles virus in vitro by using a cDNA library. The cDNA library will be inserted into a retroviral vector, murine leukemia virus (MLV), and will be used to express the various cotton rat molecules in hamster CHO cells. The receptor usage will be analyzed by a replication-deficient vesicular stomatitis virus (VSV) pseudotyped with measles virus glycoproteins expressing green fluorescent protein (GFP).

Both the MLV and VSV vector systems are replication defective. The MLV vector contains 50% of the viral genome, while the VSV vector includes 90% of the viral genome. Packaging of recombinant viruses using the two vector systems will be performed using helper plasmid cotransfection in human 293T cells. The risk group classification for the host/vector is RG1. The proposed experiments will be performed under the BSL2 condition, due to the use of pathogens.

Total: 13; vote for 13; opposed 0; abstained 0

The Board **REQUIRES MODIFICATIONS** to the biosafety plan.

1. General:
   - The IBC requests that the acronym "GMOs" be clearly defined in items 19 and 34.
2. Transport (question 21):
   - Transport of the modified virus should take place via a container with absorbent material that is capable of containing the fluid of any broken tubes. This should be inside an outer container that will contain any spill from the broken tubes.
3. Animal exposure risks (question 24b):
   - The PI does not list any exposure risks.
4. Medical Surveillance (question 26):
   - The PI suggests that skin and injection sites will be disinfected, but only soap and water are specified as disinfectants.
5. Disinfection (question 27):
   - For disinfection, 10% bleach (5000 ppm) instead of "chlorine (500

ppm, (1% bleach)) as indicated in item 27 is recommended. The PI needs to state when the "higher concentration of chlorine" will be used.

- The PI indicates chlorine will be used for disinfection, but the form of chlorine is not clearly specified; sodium hypochlorite is assumed. If so, is 1% bleach necessary? 1-10 (0.5%) should be enough for low organic material decontamination.

6. Spill management (question 28):
   - Please change "Spilled area will be rinsed" to "Spilled area will be decontaminated with bleach."
   - Specify how contaminated clothing will be decontaminated.
7. Laboratory space (questions 24, 33 and 34):
   - Although the experiments described will be performed using cultured cells in the lab, the PI indicates in item 33, "...Transport of the agents into and organs out of the animal facility..." If the PI is not going to use animals for the study, the statement regarding transport of the agents and animal organs in/out of the animal facility should be deleted from items 33 and 34.

Biosafety Level: BSL 2

Type of Research: Recombinant DNA, Biohazard

2004R0057 BOVINE LEUKEMIA VIRUS VECTOR, Stefan Niewiesk, Veterinary Biosciences

Summary of proposal:
Infants are protected against measles virus by maternal antibodies. These antibodies, however, inhibit vaccination even when levels of antibodies are too low to be protective, thus opening a window of opportunity for the wild-type virus to infect the host. The investigators have previously shown that intranasal application with a recombinant vesicular stomatitis virus (RSV) expressing the measles virus hemagglutinin is one way to overcome these maternal antibodies. The investigators conjecture that a respiratory syncytial virus expressing the measles virus hemagglutinin may protect against measles and RSV in the presence of maternal antibodies in the cotton rat model. The investigators propose to test an alternative method, where the protective antigen (measles virus hemagglutinin) is constantly expressed by a persisting attenuated bovine leukemia virus vector.

Provided addendum:
The Bovine Leukemia virus vector is a hybrid virus containing the LTR of spleen necrosis virus with the encapsulation signal, primer binding site, polypurine tract and att site of BLV as well as the gag-pol and envelop genes. 80% of the genome is retained. The measles virus hemagglutinin gene is expressed through an IRES element. The vector will be produced in Dr. Boris-Lawrie's laboratory. The modified vector (assuming that it lacks measles hemagglutinin) is pathogenic in the rabbit model of BLV infection; one assumes that the vector is pathogenic in cattle. No human infection has been reported with BLV. Once the vector is constructed, it will be used in cotton rats to quantify hemagglutinin efficacy as a vaccination vector.

Total: 13; vote for 13; opposed 0; abstained 0

The Board **REQUIRES MODIFICATIONS** to the biosafety plan.

1. Proposal summary (question 2):
   - Provide more detail about the research and how it will be conducted.
2. Transport (question 21) Check Chapter XII of the *Institutional Laboratory Biosafety Manual* for instructions regarding transport of material on campus.
   - Transport of BLV should take place accordingly.
3. Animal exposure risk (question 24b):
   - The question has not been answered.
4. Medical Surveillance (question 26):
   - The PI suggests that skin and injection sites will be disinfected, but only soap and water are specified as disinfectants.
5. Disinfection (question 27):
   - The PI indicates chlorine will be used for disinfection, but the form

of chlorine is not clearly specified; sodium hypochlorite is assumed. If so, is 1% NaOCl necessary? 1-10 (0.5% NaOCl) should be sufficient for decontamination in cases of limited organic material load.

Biosafety Level: BSL 2
Type of Research: Recombinant DNA, Biohazard

2004R0051 GENERATION OF TRANSGENIC MICE USING LENTIVIRAL VECTORS, Anthony Young, Center for Molecular Neurobiology

Summary of proposal:

- The investigator proposes to generate transgenic mice, using replication-incompetent HIV-based lentiviruses to deliver the transgene. To accomplish this, the lentiviruses that carry transgenes will be injected into the perivitelline space of a single-cell mouse embryo. The injected embryos will be cultured overnight in a 5% CO_2 incubator at 37^0C. Embryos that advance to the two-cell stage will be surgically transferred into pseudo pregnant females and carried to term. Offspring bearing the integrated transgene will be identified by PCR.

Total: 13; vote for 13; opposed 0; abstained 0

The Board **REQUIRES MODIFICATIONS** to the biosafety plan.

Please revise the Animal Gene Transfer application as follows:

1. Potential risks (question 3)
   - The PI indicates 3 microliters will be drawn up, but then indicates that 4 microliters will be delivered. The PI should resolve this discrepancy.
   - Please describe the viral particles and number of particles to be inserted.
   - The PI should discuss the volumes of 5% and 10% bleach that will be used.
   - Bleach concentration needs to be clearly stated. E.g. does 10% bleach mean a 1-10 of store purchased (about 5% sodium hypochlorite) material?
   - Liquid should be autoclaved.
   - The procedure is not conducted as a BSL2 procedure.
2. Risk group assessment (question 14):
   - The risk group cannot be assessed until the specific lentivirus that will be used is indicated.
3. DNA acquisition (question 16)
   - Clarify whether the DNA is injected or conveyed via a virus
4. Personal Protection Equipment (question 20):
   - Eyewear should always be used when handling microbes.

5. Transport (question 22):
   - The PI should specify where the transport is occurring (i.e. from whence to where). Check Chapter XII of the *Institutional Laboratory Biosafety Manual* for instructions regarding transport of material on campus.
   - The secondary container should have absorbent material.
6. Animal exposure risk (question 25b)
   - The PI did not answer this question.
7. Training (question 26):
   - Please address why some of the discarded supplies are not autoclaved.
8. Medical surveillance (question 27):
   - Medical surveillance is not addressed. Contact Dr. Paul Kirk of Employee Health Services for information.
9. Spill management (question 29):
   - What volumes and concentrations of virus will be in use?
   - The spill management does not seem realistic, given the small volumes used. Is aerosol formation during microinjection a problem?

Biosafety Level: BSL 1
Type of Research: Biohazards

2004R0058 TUMOR SUPPRESSOR GENE RECOMBINANT EXPERIMENTS, Kay Huebner, Molecular Virology, Immunology and Medical Genetics

The investigator proposes to use recombinant adenovirus and Adenoassociated virus (AAV) to deliver FHIT, WWOX, LacZ and GFP genes as well as mutants of FHIT and WWOX to mice by various routes. The recombinant adenoviruses are replication defective. The AAV will not replicate unless helper virus is used and the mice will not be infected with the helper.

Total: 13; vote for 13; opposed 0; abstained 0

The Committee **DEFERRED** the biosafety plan for the following reasons:

1. Vectors (question 12):
   - Please clarify the term "homologous recombination".
   - Please provide additional details related to the process of construct
2. Agent Maintenance (question 17):
   - Please respond to each question.
3. Biohazard Transport (question 22):
   - Specify non-breakable containers to be used for transport. Check Chapter XII of the *Institutional Laboratory Biosafety Manual* for instructions regarding transport of material on

campus.

4. Disinfection compounds (question 28): Please specify the concentration of chlorox solution.

Biosafety Level: BSL 1
Type of Research: Recombinant DNA, Animal Gene Transfer

2004R0052 OSUCCC AND CALGB LEUKEMIA TISSUE BANKS AND CALIGIURI RESEARCH LABORATORY, Michael Caligiuri, Internal Medicine

Summary of proposal:
The investigator's research studying the development of Natural Killer Cells (NKCell) in humans requires the use of white blood cells (WBCs) obtained from the American Red Cross and normal tissues from commercial suppliers or the NIH-Cooperative Human Tissue Network—Tissue procurement service. The WBCs are a by-product of the processing blood donated by the Red Cross; these WBCs are usually discarded after the blood is processed. The supplier screens the normal tissues prior to shipping. The Red Cross also screens white blood cells prior to distribution.

The investigator's research uses cell lines that may be grown in culture indefinitely. Although none of these cell lines contain organisms that cause disease in humans, they are treated as potentially biohazardous and handled and discarded as such.

Bacteria are used to cultivate plasmids containing genes related to human leukemias, which will be isolated and used to study the genes related to leukemia. There is no recombinant DNA that is used in this research. The bacteria strains are similar to those found in the human intestinal tract.

Total: 13; vote for 13; opposed 0; abstained 0

The Board **REQUIRES MODIFICATIONS** to the biosafety plan.

1. General:
   - Please expand on the nature of the work with mice and any associated potential hazards associated (e.g. sharps management). How will specimens be collected from the mice, for example?
2. Research initiation: (question 1):
   - The proposed start date is in the past; the anticipated completion date is not specified.
3. Proposal summary (question 2):
   - Describe the nature of the bacterial plasmids (i.e., characterize the plasmid and DNA inserts).
   - Describe the laboratory manipulations to be performed in the plasmid work.

4. Potential risks (question 3):
   - Cite potential exposure to all bloodborne pathogens. Screening tests do not cover the entire spectrum of infectious agents.
5. Biohazards (question 5):
   - Please spell out "*E. coli*"
6. Transport (question 12):
   - How is the contaminated material moved to the autoclave? Is the repository in just one lab or multiple labs? Check Chapter XII of the *Institutional Laboratory Biosafety Manual* for instructions regarding transport of material on campus.
   - How are blood and blood products transported to the laboratories and between the laboratories?
7. Bloodborne pathogen compliance (question 14):
   - All staff must also complete an annual refresher course for Bloodborne Pathogen training.
8. Personnel training (question 16):
   - Personnel training for the plasmid work should be specified.
9. Medical Surveillance (question 17):
   - Please complete Occupational Health Registry forms for all affected staff.
10. Disinfection (question 18):
    - Why use isopropyl for routine disinfection as opposed to a substituted phenolic?
    - Explain use of 10% bleach solution for disinfection.
    - 10% bleach at concentration of 5,000-7,500 ppm sodium hypochlorite should be made up fresh with each use. The required contact time is a minimum of 10 minutes.
11. Spill management (question 19):
    - Notify EHS and the Institutional Biosafety Officer of all spills greater than one liter or three square feet.
12. Laboratories (question 20):
    - There is no mention of animal facilities to cover the work with mice.
13. Locations (question 22):
    - Polaris labs should also be cited, or an amendment should be submitted at a later date.

Biosafety Level: BSL 2
Type of Research: Biohazard

2004R0055 CANINE DISTEMPER VIRUS INFECTION IN VIVO AND IN VITRO, Stefan Niewiesk, Veterinary Biosciences

PI's response was reviewed and approved.

Total: 13; vote for 13; opposed 0; abstained 0

Biosafety plan was unanimously **APPROVED.**

Biosafety level: BSL 2
Type of Research: Biohazard

Administrative Note: This protocol was incorrectly approved prior to receipt of revised investigator materials. **The revised materials will be reviewed when submitted by the investigator. The following information was requested by the Committee after review at the December 9, 2004 meeting:**

1. General:
   - Wild canine distemper virus poses no threat to humans, but if it is a very virulent strain, there could be a potential problem associated with canines that visit the veterinary hospital should this agent escape containment. For this reason, more detail on how the necropsy will be conducted, and how the tissues will be transported back to the laboratory for assay, etc. should be given so that an assessment of the safety of these procedures may be made.
2. Proposal summary (question 2):
   - The PI needs to discuss how the measles virus infection model fits into the research proposal. E.g. what are the similarities and differences between the established measles virus infection model in the cotton rat, and the proposed infection model for CDV? The PI needs to detail the experimental methods that will be used, in order that a risk assessment of the project may be made.
   - Describe the likely target model system, and provide additional details. For example, what virus strain will be used? Will this be a wild type-strain, or a vaccine strain? Will recombinant virus be used? What will be the route of inoculation of the virus into the cotton rat? Will necropsies of virus exposed cotton rats be performed? If so, describe this process and instrument clean-up, disinfection, etc. A brief overview of the in vivo work to be conducted should be provided.
3. Personal Protective Equipment (question 10):
   - Protective eyewear is required for this proposal.
4. Transportation (question 12):
   - Agents need to have sufficient absorbent material inside inner container to absorb material. That container needs to be inside a barrier meant to absorb shock. Transport to/from Sisson should be conducted correctly.
   - Could non-exploding cryotubes in liquid nitrogen be used?
5. Animal exposure risks (question 15):

- If material is shed in mucus, it can be transferred to handlers via bites, and the material may be present in the feces of animals. What type of handling of bedding material does the PI recommend?

6. Medical surveillance (question 17):
   - The PI suggests that skin and injection sites will be disinfected, but only soap and water are specified as disinfectants.
7. Disinfection (question 18):
   - The PI indicates chlorine will be used for disinfection, but the form of chlorine is not clearly specified; sodium hypochlorite is assumed. If so, is 1% bleach necessary? 1-10 (0.5%) should be enough for low organic material decontamination.
8. Spill management (question 19):
   - Will sufficient volumes be used so as to constitute a "major" spill?
   - See the comments for question 18, regarding chlorine.
   - Specify how contaminated clothing will be decontaminated.

DEFFERED PROTOCOLS

2004R0049 DEVELOPMENT OF A MODEL OF CARPAL TUNNEL SYNDROME-R24 SUPPORT, John Buford, School of Allied Medical Professions-Division of Physical Therapy

PI's response to the committee's comment was reviewed and approved.

Total: 9; vote for 9; opposed 0; abstained 0

Biosafety plan was unanimously **APPROVED.**

Biosafety level: BSL 2
Type of Research: Biohazard

2004R0050 RETICULOSPINAL CONTROL OF REACHING, John Buford, School of Allied Medical Professions-Division of Physical Therapy

PI's response to the committee's comments was reviewed and approved.

Total: 9; vote for 9; opposed 0; abstained 0

Biosafety plan was unanimously **APPROVED.**

Biosafety level: BSL 2
Type of Research: Biohazard

2004R0040 3D TISSUE ENGINEERING MODEL FOR ADIPOGENESIS, Douglas A. Kniss, Obstetrics & Gynecology

The investigator has been contacted and will submit a response.

MINUTES

INSTITUTIONAL BIOSAFETY COMMITTEE
THE OHIO STATE UNIVERSITY

January 27, 2005

Attendance	Members Present	Affiliation	Non-Scientist
x	Brian Ahmer	Biological Sciences	
x	Angel Arroyos-Rodriguez	Ohio EPA	Community
x	David Coplin (co-chair)	Plant Patholgy	
no	Lawrence A. Capitini	ULAR	
x	Long-Sheng Chang	Peds, Children's	
no	Ing-Ming Chiu	Internal Med	
no	Biao Ding	Plant Biology/Biotec	
x	Jyan-Chyun Jang	Hort/Crop Sci	
no	Joseph J. Kowalski	Vet Clin Sci	
no	Stefan Niewiesk	Vet Biol Sci	
x	Phil Pendergast	EHS	
x	Cecil Smith (IBO)	EHS	
x	Jami St. Clair	Columbus PD	Community
no	William Swoager	Microbiology	
no	Kenneth Theil	OARDC	
x	Marshall Williams (co-chair)	MVIMG	

Non-Voting Members Present (none)

	Office of Responsible Research Practices Staff	
X	Sandra Meadows, Human Subjects Manager	

The Meeting was called to order at 12:18 pm via conference call. The meeting was announced on the Office of Responsible Research Practices web site prior to the designated time. The Meeting was adjourned at 12:31 pm.

Review of Minutes
Approval of November 2004 minutes-approved unanimously

Old Business

NEW PROTOCOL SUBMISSIONS

2004R0035 SWOG 011: 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, Amit Agrawal, David Schuller, John Grecula, Chris Rhoades, Otolaryngology

Summary of proposal:
Patients with advanced squamous cell carcinoma of the head and neck (SCCHN) have a 5-year survival rate of less than 40%, and current treatment options are toxic as well as functionally and cosmetically debilitating. After surgery removes gross disease, microscopic cancer cells remaining in the margins of resection are killed via adjuvant radiotherapy and/or chemotherapy. However, a 35 – 50% recurrence rate exists, and patients with advanced SCCHN have a high rate of local-regional recurrence and low survival rate with the existing treatment modalities. Therefore, novel biological therapies, such as gene therapy, have to be developed and tested.

Gene therapy may provide an alternative mechanism for controlling the microscopic residual disease with limited or no added toxicity. Tumor growth suppression in head and neck cancer cells has been demonstrated to occur within in-vitro and in-vivo models, using both mutated or non-mutated p53 human SCCHN cell lines, by inducing over-expression of p53. After adenovirus-p53 INGN 201 was injected into surgically resected tumor beds of mice, tumor control and survival rates were improved. The mechanism of growth suppression was found to primarily be apoptosis. Additional mechanisms of actions for INGN 201 have been evoked, including Fas-mediated apoptosis and anti-angiogenesis effects.

In the proposed trial, the investigators are planning to transduce p53 in tumor and preneoplastic foci within the surgical microenvironment to induce apoptosis. Replication defective adenovirus serotype 5 will be utilized as a vector; this vector will contain the human p53 gene, a CMV promoter, and a SV40 polyadenylation signal. The safety and antitumor activity demonstrated in Phase I and II trials have led the investigators to develop this perioperative Phase II trial. The three objectives of the study under consideration are to assess the feasibility of treating high risk, selected Stage III and IV squamous cell carcinoma of the oral cavity and oropharynx with perioperative INGN 201 gene transfer along with surgery and chemoradiation in a multi-institutional setting; to assess progression-free survival, overall survival, and local control; and to assess toxicity of perioperative INGN 201 and chemoradiation.

Total: 9; vote for 9; opposed 0; abstained 0

The Committee **required modifications** to the protocol.

1. General:
   - Please provide correspondence requesting a change in Principal Investigator.
   - Please revise the protocol and consent form to reflect that Dr. Agrawal is the principal investigator.
   - The IBC requests a copy of the pharmacy's standard operating procedures, in order that the committee may consider transport details of the materials.
2. Protocol:
   - Revise the protocol to include emergency ID cards for subjects to place in their purses or wallets.
   - Revise the protocol to provide a subject advocate to all potential subjects.
   - Revise the protocol to include counseling for all subjects related to close contact issues and the usage of barrier contraception methods.

Biosafety Level 2
Type of research: Human Gene Transfer

MINUTES

INSTITUTIONAL BIOSAFETY COMMITTEE
THE OHIO STATE UNIVERSITY

February 10, 2005

Attendance	Members Present	Affiliation	Non-Scientist
no	Brian Ahmer	Biological Sciences	
x	Angel Arroyos-Rodriguez	Ohio EPA	Community
x	David Coplin (co-chair)	Plant Patholgy	
x	Lawrence A. Capitini	ULAR	
no	Long-Sheng Chang	Peds, Children's	
no	Ing-Ming Chiu	Internal Med	
x	Biao Ding	Plant Biology/Biotec	
no	Jyan-Chyun Jang	Hort/Crop Sci	
no	Joseph J. Kowalski	Vet Clin Sci	
x	Stefan Niewiesk	Vet Biol Sci	
x	Phil Pendergast	EHS	
x	Cecil Smith (IBO)	EHS	
no	Jami St. Clair	Columbus PD	Community
x	William Swoager	Microbiology	
x	Kenneth Theil	OARDC	
x	Marshall Williams (co-chair)	MVIMG	
	Office of Responsible Research Practices Staff		
x	Sandra Meadows, Human Subjects Manager		

The Meeting was called to order at 10:03 am via conference call. The Meeting was adjourned at 10:18 am.

Review of Minutes
Approval of January 27, 2005 minutes-approved unanimously.

Old Business

DEFERRED PROTOCOLS

2004R0058 TUMOR SUPPRESSOR GENE RECOMBINANT EXPERIMENTS, Kay Huebner, Molecular Virology, Immunology & Medical Genetics

PI's response to the committee's comment was reviewed. In response to questions raised during discussion, the Committee determined that a mask is not required for the research; 70% alcohol is adequate for disinfection as the removal of viral genes that make the virus replication defective interferes with the integrity of the envelope; and the vials used for cryopreservation have adequate breakage resistence.

Total:10; vote for 10; opposed 0; abstained 0

The Board **REQUIRES MODIFICATIONS** to the biosafety plan.

1. Laboratory Biosafety Cabinet (# 31a)
    - Complete the Class information (and please indicate when the cabinet was last certified)
2. Laboratory Safety Practices (#33)
    - Respond to spill kit question

Biosafety Level: BSL 1
Type of research: Recombinant DNA, Animal Gene Transfer

2004R0026 MOLECULAR MECHANISMS OF VASCULAR ALPHA2C-ADRENOCEPTOR EXPRESSION AND TRAFFICKING, Maqsood Chotani, Internal Medicine, Heart and Lung Institute

Administratively approved February 2, 2005.

Biosafety Level: BSL 2
Type of research: Recombinant DNA, Biohazards

2004R0031 DNA PROBES FOR ACANTHAMOEBA GENOMES AND EPIDEMIOLOGY, Paul A. Fuerst, Evolution, Ecology and Organismal Biology

A reminder notice will be sent to the investigator requesting submission of revised materials.

Type of research: Biohazards

2004R0040 3D TISSUE ENGINEERING MODEL FOR ADIPOGENESIS, Douglas A. Kniss, Obstetrics and Gynecology

A reminder notice will be sent to the investigator requesting submission of revised materials.

Type of research: Recombinant DNA, Biohazards

2004R0043 LESIONAL CHEMOTHERAPEUTIC MANAGEMENT FOR ORAL AIDS-KS, Susan R. Mallery, Dentistry

A reminder notice will be sent to the investigator requesting submission of revised materials.

Type of research: Biohazards

MINUTES
Institutional Biosafety Committee
10 March 2005

Attendance	Members Present	Affiliation
	Brian Ahmer	Biological Sciences
	Angel Arroyo- Rodriguez	Ohio EPA
X	David Coplin, Co-Chair	Plant Pathology
	Lawrence A. Capitini	ULAR
	Long-Sheng Chang	Pediatrics
	Ing-Ming Chiu	Internal Medicine
	Biao Ding	Plant Biology/ Biotechnology
X	Jyan-Chyun Jang	Horticulture and Crop Sciences
X	Joseph J. Kowalski	Veterinary Clinical Sciences
	Stefan Niewiesk	Veterinary Biological Sciences
	Phil Pendergast	EHS
X	Cecil Smith, IBO	EHS
	Jami St. Clair	Columbus PD
X	William Swoager	Microbiology
X	Kenneth Theil	OARDC
X	Marshall Williams, Co-Chair	MVIMG
	Office of Responsible Research Practices	
X	Adam McClintock, Biosafety Coordinator	
X	Sandra Meadows, Human Subjects Manager	

The meeting began at 10:05 am in Room 422 Research Foundation Building. The meeting ended at 10:50 am. The requirement for quorum was not met.

OTHER BUSINESS

Office of Biotechnology Activities (OBA) Letter

The OBA has distributed a letter to all institutions receiving NIH Funding, which was distributed to, and reviewed by the present members. Dr. Smith highlighted the following points:

1. Biosafety laboratories need to be inspected on a regular schedule.
2. All protocols require a paper trail documenting Committee decisions.
3. Exempt protocols need to be monitored for adherence to exempt requirements.
4. All protocols need to be monitored for adherence to protocols.

The NIH has the ability to freeze NIH funding if it suspects regulatory non-compliance.

Procedural Updates

The agenda will provide current status on all protocols pending Committee approval. Notices will be issued to investigators who have not responded so that IBC approval will be obtained in a timely manner.

Investigators would prefer to submit applications after funding is approved. The rationale for submitting prior to funding approval is so that no delay in research will result from the time needed to obtain IBC approval. Another potential problem with delayed IBC submission is the perception of increased pressure to approve research once it is funded. The Institutional Risk Committee will review protocols such as human gene therapy after approval by the IBC and IRB to make a final risk determination.

Biosafety Level 3 Facility Update

Dr. Smith updated the Committee on the status of the West Campus Biocontainment facility. The facility is awaiting life safety code inspections and ILACUC inspections. Testing for the autoclave odors and proper ventilation are underway. A request has been made for greater velocity building outtake to better prevent surface odors.

Equipment will be moving into the facility by the end of next week. Committee members and researchers will soon be able to schedule private tours of the facility prior to the public open house scheduled in approximately four weeks. It is anticipated that the facility will go "hot" in approximately six weeks.

***Franciscella tularensis* at Boston University**

Boston University has received a grant to build a BSL 4 facility located across the street from the Boston University Hospital, which has led to strong public outcry. This community dissent was exacerbated by accidental exposure of three university researchers to live strains of *Franciscella tularensis*, over the past summer. Two researchers were exposed in early summer to what was believed to be the live vaccine strain. A third researcher was exposed in September and subsequently hospitalized.

Upon investigation, it was found that BSL 3 work was being conducted in a BSL 2 facility. The CDC discovered that the strain used in Boston originated from the University of Nebraska, and was either contaminated or altered upon receipt. All strains at the University of Nebraska were found to be pure strains. Boston University failed to report the incidents to the State Health Commission until three weeks after the fact; while regulation stipulates that notification must be made within 24 hours. There has been a long history of successful work with *Francisella tularensis* LVS. Consequently, it probably does not have a high enough conversion rate back to wild type to pose an unexpected risk.

While the University of Nebraska was not found to be at fault, Dr. Smith emphasized the importance of verifying the purity of strains obtained from other institutions. The NIH has received letters requesting a decrease in funding for bioterrorism organisms and an increase in clinically relevant applications.

RECOMBINANT DNA NEW PROTOCOL SUBMISSIONS

2005R0009	MICROBIOLOGICAL SAFETY OF FOODS OF ANIMAL ORIGIN, Jeffrey T. LeJeune, Food Animal Health Research Program The investigator intends to undertake experiments that further the understanding of (1) the control of regulation of toxin and virulence factor expression in foodborne pathogens and (2) the mechanisms by which antibiotic resistance genes persist in foodborne pathogens. To accomplish this, the investigator will exchange naturally occurring DNA sequences that can interrupt the reputed gene regulatory regions responsible for toxin production and then observe the effect on toxin production by *E. coli*. A second study will be conducted to interrupt the plasmid encoded virulence genes or cure or transform *Salmonella* and *E. coli*

with plasmids to determine the effects of these interruptions on plasmid persistence. Although the *E. coli* will produce shigatoxin, this will be in small amounts and exempt from regulation.

The Board reviewed the protocol and requested additional information regarding the biosafety plan.

1. **General**
- Provide specific information regarding animal experiment including method of exposure, *and location of animal housing.*
- Clarify whether the animals will be sacrificed after exposure.

2. **Section 4 (Select Agents)**
- Document the quantity of shigatoxins present in the lab.

3. **Section 5 (Nature/Source rDNA)**
- Clarify genus and species of the "foodborne" pathogens, the nature and sources of DNA, and the commercial DNA (plasmids) that might be used.
- Clarify whether animals will receive laboratory modified bacterial strains or both bacteria and phages.

4. **Section 6 (Host Systems)**
- Clarify if "other laboratory strains of *E. coli* field-isolates" contain virulence factors other than shigatoxins.

5. **Section 8 (Vectors/Inserts)**
- List specific vectors that are to be used, including commercially available laboratory strains.

6. **Section 13 (Risk Group)**
- Change answer to "Risk Group 2".

7. **Section 14 (Consequences of Exposure)**
- Correct the spelling of "gastroenteritis".
- Provide additional consequences of *Salmonella* infection.
- Address additional risks to contacts or family members, particularly young children, exposed to an infected investigator.

8. **Section 16 (Agent Maintenance)**
- Provide a response for each storage method.

9. **Section 18 (Laboratory Containment Requirements)**
- Change from "recommended" to "required".
- Clarify what biocontainment procedures will be in place.

10. **Section 19 (Personal Protective Equipment)**
- Clarify how animal handlers will be protected from exposure to pathogens.

11. **Section 21 (Biohazards Transport)**
- Specify what "organisms" are to be transported and the related containment procedures.
- Address precautions used to prevent accidental removal of infectious agents from the animal areas.

12. **Section 24 (Animal Usage)**
- Clarify whether the manure will be incinerated.

13. **Section 27 (Disinfection)**
- Specify procedure for disinfection.

14. **Section 29 (Laboratories)**
- Based on the response in Section 24c, that "indirect contamination from fecal material in the housing environment," is a risk, clarify whether the animal work

	will be done in the gnotobiotic facility. Type of Research: Recombinant DNA, Biohazards

RECOMBINANT DNA DEFERRED PROTOCOLS

2004R0054	RESPIRATORY SYNCYTIAL VIRUS, Stefan Niewiesk, Veterinary Biosciences This protocol was tabled due to lack of quorum Type of Research: Recombinant DNA, Biohazards

BIOHAZARDS NEW PROTOCOLS

None

BIOHAZARDS DEFERRED

2003R0044	BACILLUS ANTHRACIS-INDUCED INNATE IMMUNE RESPONSES, Andrew Phipps, Veterinary Biosciences This protocol was tabled due to lack of quorum Type of Research: Biohazards

PENDING PROTOCOLS

2004R0031	DNA PROBES FOR ACANTHAMOEBA GENOMES AND EPIDEMIOLOGY, Paul A. Fuerst, Evolution, Ecology and Organismal Biology The investigator has been contacted and will provide requested revisions. Biosafety Level: BSL 2 Type of research: Biohazards
2004R0051	GENERATION OF TRANSGENIC MICE USING LENTIVIRAL VECTORS, Anthony Young, Center for Molecular Neurobiology The investigator has been contacted and will provide requested revisions. Biosafety Level: BSL 1 Type of research: Animal Gene Transfer
2004R0055	CANINE DISTEMPER VIRUS INFECTION IN VIVO AND IN VITRO, Stefan Niewiesk, Veterinary Biosciences Investigator correspondence issued 2/28/05. Investigator response is pending. Biosafety Level: BSL 2 Type of research: Biohazards

2005R0002	EFFICACY STUDIES OF SARCOCYSTIS NEURONA VACCINE, William J. Saville, Veterinary Preventative Medicine Investigator correspondence issued 3/2/05. Investigator response is pending. Biosafety Level: BSL 1 Type of research: Biohazards

PROTOCOLS APPROVED ADMINISTRATIVELY

2004R0035	SWOG 0011: 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, Amit Agrawal, David E. Schuller, John Grecula, Chris Rhoades, Otolaryngology Administratively approved February 21, 2005. Biosafety Level: BSL 2 Type of Research: Human Gene Transfer
2004R0043	LESIONAL CHEMOTHERAPEUTIC MANAGEMENT FOR ORAL AIDS-KS, Susan R. Mallery, Dentistry Administratively approved February 21, 2005. Biosafety Level: BSL 1 Type of Research: Biohazards
2004R0046	A PHASE I STUDY OF ADV-TK + VALACYCLOVIR GENE THERAPY IN COMBINATION WITH STANDARD RADIATION THERAPY FOR MALIGNANT GLIOMAS, E. Antonio Chiocca, Neurological Surgery Administratively approved February 10, 2005. Biosafety Level: BSL 2 Type of Research: Human Gene Transfer
2004R0056	CHARACTERIZATION OF COTTON RAT RECEPTORS FOR MEASLES VIRUS, Stefan Niewiesk, Veterinary Biosciences Administratively approved February 23, 2005. Biosafety Level: BSL 2 Type of Research: Recombinant DNA, Biohazards
2004R0057	BOVINE LEUKEMIA VIRUS VECTOR, Stefan Niewiesk, Veterinary Biosciences Administratively approved February 23, 2005.

	Biosafety Level: BSL 2 Type of Research: Recombinant DNA, Biohazards
2004R0058	TUMOR SUPPRESSOR GENE RECOMBINANT EXPERIMENTS, Kay Huebner, Molecular Virology, Immunology & Medical Genetics Administratively approved March 1, 2005. Biosafety Level: BSL 1 Type of research: Recombinant DNA, Animal Gene Transfer
2004R0026	MOLECULAR MECHANISMS OF VASCULAR ALPHA2 -ADRENOCEPTOR EXPRESSION AND TRAFFICKING, Maqsood Chotani, Internal Medicine, Heart and Lung Institute Administratively approved February 2, 2005. Biosafety Level: BSL 2 Type of research: Recombinant DNA, Biohazards

EXEMPT PROTOCOLS

2005R0001	ROLES OF NOTCH SIGNALING IN THE SEGMENTATION CLOCK, DEVELOPMENT AND DISEASE, Susan Cole, Molecular Genetics Date of determination: January 4, 2005
2005R0006	THE ROLE OF MUSCLE PROTEINS IN SYNAPTIC STRUCTURE, NEUROMUSCULAR DISEASE, AND CARDIOMYOPATHY, Jill Rafael-Fortner, Molecular and Cellular Biochemistry Date of determination: February 10, 2005
2005R0010	DEVELOPMENT OF INHIBITORY METHODS FOR PRION PROTEIN CAUSED NEURODEGENERATION, Jiyan Ma, Molecular and Cellular Biochemistry Date of determination: February 28, 2005
2005R0014	MYOFIBRILLAR DETERMINANTS OF CARDIAC MUSCLE RELAXATION, Jonathan P. Davis, Physiology and Cell Biology Date of determination: February 28, 2005

CONTINUING REVIEWS APPROVED BY ADMINISTRATIVE REVIEW

None

MINUTES
Institutional Biosafety Committee
14 April 2005

Revised November 29, 2005

Attendance	Members Present	Affiliation
NO	Brian Ahmer	Biological Sciences
X	Angel Arroyo- Rodriguez	Ohio EPA
X	David Coplin (co-chair)	Plant Pathology
X	Lawrence A. Capitini	ULAR
NO	Long-Sheng Chang	Pediatrics
X	Ing-Ming Chiu	Internal Medicine
X	Biao Ding	Plant Biology/ Biotechnology
X	Jyan-Chyun Jang	Horticulture and Crop Sciences
X	Joseph J. Kowalski	Veterinary Clinical Sciences
X	Stefan Niewiesk	Veterinary Biological Sciences
NO	Phil Pendergast	EHS
X	Cecil Smith (IBO)	EHS
X	Jami St. Clair	Columbus Police Department
X	William Swoager	Microbiology
X	Kenneth Theil	OARDC
X	Marshall Williams (co-chair)	MVIMG
	Non-Voting Members Present (none)	
	Office of Responsible Research Practices	
X	Adam McClintock—Biosafety Coordinator	
X	Sandra Meadows—Human Subjects Manager	

The meeting was called to order at 10:05 am in Room 422 Research Foundation Building. The meeting was adjourned at 1:05 pm. Dr. Larry Capitini left at 10:45 am. Ing-Ming Chiu, J.C. Jang, and Dave Coplin left at 12:15 pm. Marshall Williams left at 12:20 pm. The meeting was adjourned at 1:15 pm.

1. **Dr. Susan Koletar—2005R0023 HGT Presentation**

2. **Approval of Minutes**
   a. The committee approved the revised 13 January 2005 minutes unanimously.
   b. The committee approved the 10 February 2005 minutes unanimously.

3. **Marshall Cancer Update**
   Three human gene transfer protocols have been approved by the IRB and IBC. They will undergo institutional risk assessment. One human gene transfer protocol has received IBC approval and is undergoing review by the IRB.

4. **Procedures for reviewer sheet completion**

Study and reviewer specific reviewer sheets have been implemented for Committee use. Primary and secondary reviewers will be assigned to all new protocols. Reviewers should make specific recommendations citing the question needing revision or clarification. If concerns are addressed during Committee discussion, the reviewer may line out comments that are no longer applicable. Reviewers may also change their recommended action for a protocol (i.e. approve, defer, etc.), after discussion. The reviewer sheets will be distributed with meeting materials one week prior to IBC meeting dates. A hard copy of the reviewer sheet should be submitted by the meeting date.

5. **Continuing Review**

   Continuing review forms will be distributed prior to the May meeting. The Committee will discuss the review process at that time.

6. **New amendment forms**

   Amendment forms have been drafted for changes made to approved IBC protocols. An HGT amendment request form will be used only for research involving gene transfier with human subjects. Aspects unique. An amendment form should initiate all changes made to protocols. Dr. Coplin raised the question of whether a separate amendment form may be necessary for concerns more specific to biohazards protocols. Dr. Theil raised concern about discrepancies between some of the language used on forms and the review processes. For example, the heading "CHANGES MUST NOT BE INITIATED PRIOR TO IBC APPROVAL," while NIH Guidelines allow simultaneous notification to the IBC and initiation of research for certain types of recombinant DNA protocols.

HUMAN GENE TRANSFER NEW PROTOCOLS

2005R0023 A5197, VERSION 2.0, 01/05/2005: A PHASE II DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED STUDY TO EVALUATE THE ANTIRETROVIRAL EFFECT OF IMMUNIZATION WITH THE MRK AD5 HIV-1 GAG VACCINE IN HIV-1 INFECTED INDIVIDUALS WHO INTERRUPT ANTIRETROVIRAL DRUG THERAPY, Susan L. Koletar, Infectious Diseases

Summary:

This is an NIH funded proposal that is part of a multicenter placebo-controlled study designed to determine whether the immune responses elicited by a therapeutic vaccine are capable of maintaining human immunodeficiency virus (HIV) suppression following interruption of anti-HIV therapy. Participants will be HIV infected adults with CD4 counts > 500 cells/mL, viral suppression for at least two years and have HIV RNA (viral loads) <50 copies/mL at screening. Subjects will receive a series of immunizations and then interrupt all anti-retroviral therapy (ART). Immune responses to HIV will be measured at pre-entry, following immunization and after interruption of ART to determine whether there are immune marker surrogates associated with better control of viral rebound. The primary endpoint will be virological response (viral replication) after interruption of ART. Phases: Step 1: Immunization Phase, Step 2: A 16 week ART interruption, Step 3: Follow up phase where patients will either continue interruption of ART or move on to Step 4: resume ART, Step 5: Long term follow up.

- The vector is a Merk adenovirus MRK AD5 HIV-gag that is replication defective. It has been studied in volunteers and HIV-infected patients and considered safe and tolerated.
- This vector has been reviewed by the Recombinant DNA Advisory Committee, Office of Biotechnology Assessment, NIH. The investigator included Schedule M.

Biosafety concerns are related to occupational health as HIV replication due to vaccine failure may result in increased levels of HIV being present in subjects' body fluids. Personnel use universal precautions. Viral testing will be done off site.
The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Human Subjects Advocate** (Question #20)—Use an external subject advocate during the consent process instead of a designee of the investigator.

Total: 12; vote for 12; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Human Gene Transfer

RECOMBINANT DNA DEFERRED PROTOCOLS

2003R0044 BACILLUS ANTHRACIS-INDUCED INNATE IMMUNE RESPONSES, Andrew J. Phipps, Veterinary Biosciences

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Waste Disposal** (Question #13)
   - Delete second sentence "Treated liquid waste will be discharged into sanitary sewer."
   - Designate contact time.
2. **Personal Protective Equipment (PPE)** (Question #24)—Change PPE to "safety goggles," instead of "safety glasses."

Total: 12; vote for 12; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Recombinant DNA, Biohazards

2004R0021 MEASUREMENT OF RETROVIRAL-SPECIFIC CTL RESPONSES IN ANIMAL MODELS OF HUMAN RETROVIRUSES, Michael Lairmore, Veterinary Biosciences

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Consequences of Exposure** (Question #14)—Add myocardial as an eighth item in the third paragraph.

Total: 12; vote for 12; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Recombinant DNA, Biohazards

2004R0054 RESPIRATORY SYNCYTIAL VIRUS, Stefan Niewiesk, Veterinary Biosciences

The committee reviewed the modifications and determined that the PI addressed all concerns. Dr. Niewiesk left the room during the vote

The Committee **APPROVED** the biosafety plan unanimously

> **Note:** Please forward a revised copy of the application with original signatures of the investigators and chair.

Total: 11; vote for 11 opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Recombinant DNA, Biohazards

RECOMBINANT DNA NEW PROTOCOL SUBMISSIONS

2005R0007 ROLE OF AMPK IN CHOLESTEROL HOMEOSTASIS, Kamal D. Mehta, Molecular and Cellular Biochemistry

The protocol was tabled as no reviewers were assigned.

Type of Research: Recombinant DNA, Biohazards

2005R0008 FUNCTIONAL ANALYSIS OF RICE DEFENSE GENES, Guo-Liang Wang, Plant Pathology

Summary:
This is a review of the protocol that Dr. Wang's lab has been using for the last five years. He will be making cDNA libraries of maize and rice genes in E. coli, which is exempt from IBC review. Cloned, candidate rice disease resistance genes will be introduced back into rice by Agrobacterium tumefaciens-mediated transformation. The plants themselves will be exempt under self-cloning. However, research involving the Agrobacterium strains requires IBC review. Standard vectors will be used. The Agrobacterium treated plants will be contained in the laboratory. Regenerated plants, which should be Agrobacterium-free, will be maintained in the laboratory, indoor growth chambers and the greenhouse. The investigator's facilities have been inspected by the Animal Plant Health Inspection Service (APHIS).

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Summary** (Question #2)—List specific bacterial strains involved in the work.
2. **Recombinant DNA Source Genes** (Question#5)—List the specific organisms for the source genes.
3. **IBC Review** (Question #11)—Check the appropriate boxes.

Total: 12; vote for 12; opposed 0; abstained 0

Biosafety Level: BSL-1, BL1-P
Type of Research: Recombinant DNA

2005R0009 MICROBIOLOGICAL SAFETY OF FOODS OF ANIMAL ORIGIN, Jeffrey T. LeJeune, Food Animal Health Research Program

Summary:
The PI proposes to undertake studies to better understand the regulation of toxin and

virulence factor expression in foodborne pathogens, mainly shigatoxin producing *Escherichia coli* and Salmonella. Also to be studied is how bacteriophages destroy shigatoxin producing E. coli in live animals and the mechanisms of antibiotic gene persistence in the absence of antibiotic selective pressures. To do this, swine and cattle will be orally inoculated with bacteria or bacteriophage containing naturally occurring or recombinant DNA, or both.

The experiments involve abrogating the toxin production of the bacteria by exchanging the shigatoxin gene with an antibiotic resistance gene (chloramphenicol). Other experiments involve interrupting or exchanging the bacterial genes in reputed regions responsible for toxin regulation in *Escherichia coli* O157. In other experiments, cattle will be exposed to unmodified shigatoxin *Escherichia coli* as well as those in which the toxin gene has been replaced. Cattle exposed to this mixture then will be given lytic bacteriophage isolated from environmental sources and/or antibiotics.

Thirdly, the PI plans to interrupt plasmid encoded virulence genes, cure (or transform) *Salmonella* and *Escherichia coli* with plasmids to observe the effects of these genes on the persistence on the plasmid in the bacterium within the animal host.

The Committee **DEFERRED** the biosafety plan

1. **Summary** (Question #2)
   - Specify genes that might be transferred from bacteriophages isolated from natural sources.
   - Indicate how naturally occurring plasmids that have been genetically modified will be screened for genes that might contain other virulence factors.
   - Indicate the concentration of chloramphenicol acetyltransferase to be used.
2. **Select Agents** (Question #4)—Uncheck the box for shigatoxin in the USDA-HHS OVERLAP AGENTS list.
3. **Bacterial Vectors** (Question #8b)—Indicate how the naturally occurring bacteriophages will be characterized as lambdoid.
4. **Biohazard** (Question #12)—Specify the serotype of *Salmonella* for each indication of *Salmonella.*
5. **Agent Acquisition** (Question #15)—Spell out the institution referred to by the acronym "MSU."
6. **Biohazard Transport** (Question #21)—Describe how animals will be transported from quarantine to the site of sacrifice.
7. **Disinfection** (Question #27)—Describe how the rooms will be disinfected.
8. **Laboratory Space** (Question #29)—Clarify where the cattle and swine will be kept (i.e. cattle in once location and swine in another).

Total: 12; vote for 12; opposed 0; abstained 0

Type of Research: Recombinant DNA, Biohazards

2005R0011 ECOLOGY OF FOODBOURNE PATHOGENS ON VEGETABLES, Jeffrey LeJeune, Food Animal Health Research Program

Summary:
The PI proposes to infect tomato and lettuce plants with several bacterial plant pathogens, which cause leaf spots and rots. He proposes to determine potential internalization sites by

spraying them with a suspension of *Escherichia coli* O157 and an unspecified *Salmonella* strain, both of which are human pathogens. The plasmid pAsRed2 will be added to bacterial plant pathogens. Such modified bacteria will fluoresce red and can be monitored by confocal microscopy to determine if they are entering wound sites, which is differentiated from the unmodified *Escherichia coli*, which does not fluoresce red. He will determine if prior infection of the plant with a plant pathogen predisposes them to vascular colonization. He will also add various unspecified virulence genes, e.g. pectolytic enzymes, to the *E. coli* and *Salmonella* strains to see if they increase their ability to colonize plants.

He will use wild type and mutant strains of *Xanthomonas campestris, Pseudomonas syringae*, and *Erwinia carotovora.* The subspecies and pathovars are not designated. If these are all indigenous to Ohio, there is no APHIS oversight here. If he constructs mutants by standard means or simply labels with the dsRed plasmid, the work should be exempt from the NIH Guidelines. However, it would be very easy to obtain these from other labs, and there is no indication of why he needs to make them. The protocol is very vague on what intergenic constructs will be made and this part could be substantially improved. Cloning genes from *Erwinia* into wild type *E. coli* and *Salmonella* would be exempt, but those cloned from *Xanthomonas* or *Pseudomonas syringae* would not.

Laboratory containment appears to be adequate. However, it is uncertain that he can provide BSL-2 containment for a human pathogen in the Natural Resources greenhouse. The greenhouse is probably adequate to prevent escape of plant pathogens, but it appears that no precautions will be taken to prevent exposure of workers to plants that have been treated with O157 and *Salmonella*. He says the *E. coli* O157 strain is non-pathogenic, but still proposes to treat it as RG-2. The pathogenicity of the *Salmonella* strain is not stated. It is uncertain that he can offer BL-2 containment in the greenhouse for a human pathogen, unless he keeps the plants in a biological safety cabinet. (BL-2-P is designed for transgenic or exotic plants and plant pathogens.) Plants can shed bacteria and aerosols. An alternative approach could employ wild-type *E. coli* or *Salmonella* strains that are not classified as biohazards.

The Committee **DISAPPROVED** the biosafety plan

Comments:
The committee suggests that the PI rewrite and resubmit the protocol taking the following considerations into account:

1. **Potential Risks** (Question #3)—Indicate the species of *Salmonella* to be used and its pathogenicity.
2. **Gene Clones** (Question #6)—Indicate the specific genes to be inserted in *E. coli* and *Salmonella*, and their sources.
3. **Hosts** (Question #7)
   - Specify the pathovar and subspecies of the hosts *P. syringae* pv. *Tomato* and *Pectobacterium (Erwinia) carotovorum.*
   - Indicate whether knockouts will be obtained from another lab or made. If made indicate how they will be made.
   - Specify how the genes will be cloned or mutated and recombined back into the same pathovar or subspecies.
4. **Risk Group** (Question #8)—Verify that RG-2 applies to both the *E. coli* and *Salmonella* strains.
5. **Vectors** (Question #9)

- Give more detail on the plasmids.
- Indicate the replicon for the dsRed plasmid.
- Indicate if pGP704 is being used as the suicide plasmid for making knockout mutants.
- Clarify pGP701.
- Indicate any other vectors used for general cloning.

6. **Consequences of Exposure** (Question #14)—Expand on the consequences of exposure.
7. **Containment Requirements** (Question #18)—Expand on the containment requirements (the greenhouse is BL-2-P, however BSL-2 is required to protect humans).
8. **Biohazard Transport** (Question #21)
   - Indicate how the bacterial cultures will be transported from the laboratory to the greenhouse.
   - Indicate how the sprayed plants will be transported to the laboratory for confocal microscopy.
   - Indicate the preparation location of the spray mixture.
   - Indicate what happens to the sprayed plants after confocal microscopic examination.
9. **Risks to Investigator** (Question #24b)—Indicate the risk to the PI from *E. coli* and *Salmonella.*
10. **Laboratory Space** (Question #29)—Indicate the role that the animals, listed as being in the NIH barn, will serve in the research.
11. **Personnel Protection** (Question #33)
    - Clarify the location of the fumehood (the greenhouse is BL-2-P, however BSL-2 is required to protect humans).
    - Indicate whether or not the fumehood will vent to the outside environment or if it is a biosafety cabinet.
    - Indicate the risks of human and plant pathogens escaping into the outside environment.
    - Indicate the size of the droplets and how they are generated.
    - It would be advisable that a particle filter respirator be worn during spraying.
12. **Signatures** (Question #36 and Question #38)—Obtain investigator signatures and chair signatures.

Total: 12; vote for 12; opposed 0; abstained 0

2005R0012 FUNCTIONAL INTERPLAY BETWEEN SARCOLIPIN AND PHOSPHOLAMBAN IN SR CALCIUM HOMEOSTASIS, Gopal J. Babu, Physiology and Cell Biology

The protocol was tabled due to an earlier version of the application being distributed to the Committee. The revised application will be provided prior to the May meeting.

Type of Research: Recombinant DNA, Biohazards

BIOHAZARDS DEFERRED PROTOCOLS

2004R0055 CANINE DISTEMPER VIRUS INFECTION IN VIVO AND IN VITRO, Stefan Niewiesk, Veterinary Biosciences

The committee reviewed the modifications and determined that the PI addressed all concerns.

The Committee **APPROVED** the biosafety plan unanimously

Dr. Niewiesk left the room during the vote
Total: 7; vote for 7; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Biohazards

2005R0002 EFFICACY STUDIES OF SARCOCYSTIS NEURONA VACCINE, William J. Saville, Veterinary Preventative Medicine

The committee reviewed the modifications and determined that the PI has not addressed all the concerns.

The Committee **DEFERRED** the biosafety plan

1. **General**—The PI will incorporate the revisions into a revised application and submit to the Office of Responsible Research Practices.
2. **Biohazard Transport** (Question #12)—Expand on the procedures for transportation.
3. **Background of Personal** (Question #26)—Provide the medical surveillance forms as requested in the application.

Total: 7; vote for 7; opposed 0; abstained 0

Type of Research: Biohazards

BIOHAZARDS NEW PROTOCOLS

2004R0012 TREATMENT OF CHRONIC WOODCHUCK HEPATITIS VIRAL INFECTIONS, Daral Jackwood, Food Animal Health Research Program

Summary:
The PI proposes to conduct research with the intent of developing an animal model for evaluating the mechanisms of Birnavirus therapy for chronic hepadnavirus infection. The aim is to better understand how Birnavirus therapy works therapeutically in chronic human Hepatitis B virus infections. The research will use Infectious Bursal Disease Virus (IBDV) a birnavirus that causes an immunosuppressive disease in young chickens, as a potential therapeutic agent against Woodchuck Hepatitis Virus chronic infections. Neither Woodchuck Hepatitis Virus nor IBDV infect humans, and both viruses have extremely narrow host ranges. They are RG-1 agents. The woodchucks are derived from a purpose-bred colony and should pose reduced potential for zoonotic infections to laboratory workers.

Proposed biosafety procedures attain the level of BSL-2, which is more than adequate to provide appropriate protection to the laboratory personnel exposed to these agents. As

Woodchuck Hepatitis Virus is endemic in the woodchuck populations of the Northeastern United States, this research poses little potential risk to natural woodchuck populations.

The Committee **APPROVED** the biosafety plan unanimously

NOTE: All university personnel involved with this project must complete the Occupational Health Registry Questionnaire and participate in a medical surveillance program.

NOTE: A contact time must be designated for disinfection.

Total: 7; vote for 7; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Biohazards

2005R0019 INFECTIOUS BURSAL DISEASE VIRUS INFECTION STUDIES, Daral J. Jackwood, Food Animal Health Research Program

Summary:
The PI intends to administer vaccines designed to protect chickens from Infectious Bursal Disease Virus (IBDV) to chickens housed in isolators. After an appropriate interval, birds will be challenged with virulent strains of IBDV. The vaccines to be used are inactivated virus or subunit proteins and are designed to vaccinate in the face of maternal antibodies to IBDV.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Summary** (Question #2)—Clarify whether or not tissue will be removed for examination post-mortem.
2. **Potential Risks** (Question #3)—Indicate potential exposures to human pathogens endemic to chickens.
3. **List of Biohazards** (Question #5)—Omit "or animals" from statement.
4. **Agent Acquisition** (Question #7)—Mark a response in each box.
5. **Agent Maintenance** (Question #8)—Mark a response in each box.
6. **Potential Risks to Investigator** (Question #15b)—Mark "animal bite or scratch" and delete "other remark."
7. **Animal Waste Handling and Disposal** (Question #15f)—Designate contact time for disinfection.
8. **Personnel Training** (Question #16)—Training to include basic animal husbandry technique.
9. **Medical Surveillance** (Question #17)—Complete the Occupation Health Registry Questionnaire for all research personnel. Enroll all lab personnel in the appropriate medical surveillance program for animal handlers.
10. **Disinfection** (Question #18)— Designate contact time for disinfection.
11. **Spill Management** (Question #19)—Designate contact time for disinfection.

Total: 7; vote for 7; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Biohazards

2005R0020 MOSQUITO BITING, Woodbridge A. Foster, Entomology

Summary:
The PI hypothesizes that plant sugars greatly affect the lives of all male and female human-feeding mosquitoes, including biting behavior. If this hypothesis proves correct, then it may be possible to use sugar-related plant attractants to catch mosquitoes and monitor their populations. Mosquitoes are important vectors of microbial pathogens, including protozoa and arboviruses. To test the hypotheses, the PI will need to allow mosquitoes to feed on human subjects. None of the mosquitoes to be used will be infected. Each group of mosquitoes will be allowed to feed on only one subject to eliminate the possibility of mosquitoes transmitting an infectious agent while taking blood meals.

One group of experiments will involve the use of *Anopheles gambiae,* a major vector of malaria in equatorial Africa. Some of the proposed work with this mosquito will be done in Kenya. Additional screening assays will be performed on the participating subjects to reduce the likelihood that they are viremic or infected with malaria at the time the studies are to be performed. The *Anopheles gambiae* will be derived from a colony first isolated in Liberia and maintained in Europe, and a derivative of the Wageningen, Netherlands colony will be used.

The mosquitoes used are RG-1. Even though *Anopheles gambiae* is exotic, it will not survive in Ohio if it escapes. Moreover, malaria is not circulating in Ohio so the risk of even transient transmission of malaria is non-existent. The other two mosquitoes to be studied are already established in nature in Ohio. From this standpoint, the risk seems minimal.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Potential Risks** (Question #3)
   - Indicate the location in Kenya where this work will be done.
   - Address whether or not monies passing through The Ohio State University will be used to fund the work done in Kenya.
   - Address whether or not additional documentation is needed to establish that the Kenyan subjects are properly enrolled in a medical surveillance plan and provide any relevant documentation.
   - Indicate which assay or assays will be used to declare the mosquitoes "test negative."
2. **Agent Acquisition** (Question #7)
   - Address whether or not any import permits are required to obtain the *Anopheles gambiae* derivative from the Wageningen, Netherlands colony.
3. **Containment Requirements** (Question #9)
   - Indicate which version of the guidelines proposed by the American Committee of Medical Entomology is being referenced.
   - Provide the relevant document.
4. **Animals** (Question #15)—Indicate the source of the chickens to be used in this study.
5. **Medical Surveillance** (Question #17)—Complete the Occupation Health Registry Questionnaire for all university personnel.

Total: 7; vote for 7; opposed 0; abstained 0

Biosafety Level: BSL-1
Type of Research: Biohazards

2005R0029 EVALUATION OF THYMUS FUNCTION IN LENTIVIRUS DISEASE, Lawrence Mathes, Veterinary Biosciences

Summary:
The PI proposes to study feline immunodeficiency virus (FIV) in order to better understand the timing and mechanisms that underlie the development of thymic dysfunction in humans during human immunodeficiency virus (HIV) infection. FIV infection in cats leads to pathological changes in the thymus similar to the effects on immune function in HIV infections.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Summary** (Question #2)—Expand the summary of the protocol beyond pathogenesis.
2. **Biohazards Transport** (Question #12)—Address the adequacy of the method of transportation for FIV-infected cell cultures or vials of viral inoculum.
3. **Animals** (Question #15b)—Check the box "contact with animal."
4. **Disinfection** (Question #18)
   - Specify the concentration of sodium hydrochloride.
   - Designate a contact time for disinfection.
1. **Spill Management** (Question #19)—Designate a contact time for ethanol or bleach in decontamination of spills.

Total: 7; vote for 7; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Biohazards

2005R0030 NOS2 SIGNALING AND FUNCTIONAL EFFECTS ON CARDIAC MYOCYTE CONTRACTILITY, Mark T. Ziolo, Physiology & Cell Biology

The protocol was tabled.

Comments:
The committee suggests that the PI rewrite and resubmit the protocol taking the following considerations into account:

1. **Risks of Exposure** (Question #15b)—Provide a response.
2. **Carcass Disposal** (Question #15d)—Indicate specific procedures to be used for the disposal of animal carcasses.
3. **Bedding Disposal** (Question #15e)—Indicate specific procedures to be used for disposal of animal bedding.
4. **Animal Waste Handling and Disposal** (Question #15f)—Indicate specific procedures used the handling and disposal of animal waste.
5. **Personnel Training** (Question #16)—Expand on training methods involved with the handling of LPS.
6. **Disinfection** (Question #18)—Indicate what is used to wipe down the counter.

7. **Spill Management** (Question #19) —Indicate what is used to wipe down the counter.
8. **Personnel Training** (Question #25)—Expand on training methods involved with the handling of LPS.

Total: 7; vote for 7; opposed 0; abstained 0

Type of Research: Biohazards

BIOHAZARDS AMENDMENT

2004R0022 TEST SYSTEMS FOR BACILLUS ANTHRACIS, Andrew J. Phipps, Veterinary Biosciences

Summary:
Andrew J. Phipps requests the PI information be changed to reflect his status as Principal Investigator.

The Committee **APPROVED** the amendment unanimously

Total: 7; vote for 7; opposed 0; abstained 0

Biosafety Level: BSL-3
Type of Research: Biohazards

PROTOCOLS APPROVED ADMINISTRATIVELY

2003R0051 BIOHAZARD SAFE PRACTICES FOR WORKING WITH FRANCISELLA SPECIES IN THE SCHLESINGER LABORATORIES (BSL-3), Larry S. Schlesinger, Internal Medicine

Administratively approved April 11, 2005

Biosafety Level: BSL-3
Type of Research: Biohazards

2003R0052 VOCAL BEHAVIOR, HABITAT USE, AND HOME RANGES OF COYOTES, Douglas A. Nelson, Evolution, Ecology, & Organismal Biology

Administratively approved April 12, 2005

Type of Research: Biohazards

2003R0060 EFFECTS OF PHOTOPERIOD ON CELLULAR AND ORGANISMAL ENERGETIC DEMANDS, Randy J. Nelson, Psychology

Administratively approved April 7, 2005

Biosafety Level: BSL-3
Type of Research: Biohazards

2003R0064 RETINAL STEM CELLS AND REGENERATION IN CHICKEN, Andy J. Fischer, Neuroscience

Administratively approved April 8, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA, Biohazards

2004R0018 STUDIES OF HERPES SIMPLEX TYPE 1 AND HUMAN CYTOMEGALOVIRUS BIOLOGY AND PATHOGENESIS, Joanne Trgovcich, Pathology

Administratively approved May 28, 2004, protocol not previously reported to IBC

Biosafety Level: BSL-2
Type of Research: Biohazards

2004R0024 INTERNATIONAL, RANDOMIZED, MULTICENTER, PHASE III STUDY IN PATIENTS WITH RELAPSING-REMITTING MULTIPLE SCLEROSIS COMPARING OVER A TREATMENT PERIOD OF 104 WEEKS:
1. DOUBLE-BLINDED THE SAFETY, TOLERABILITY, AND EFFICACY OF BETASERON/BETAFERON 250 G (8 MIU) AND BETASERON/BETAFERON 500 G (16 MIU, BOTH GIVEN SUBCUTANEOUSLY EVERY OTHER DAY,
2. RATER-BLINDED THE SAFETY, TOLERABILITY, AND EFFICACY OF BETASERON/BETAFERON S.C. EVERY OTHER DAY WITH COPAXONE 20 MG S.C. ONCE DAILY, Kottil W. Rammohan, Neurology

Administratively approved August 12, 2004

Biosafety Level: BSL-2
Type of Research: Biohazards

2004R0031 DNA PROBES FOR ACANTHAMOEBA GENOMES AND EPIDEMIOLOGY, Paul A. Fuerst, Evolution, Ecology and Organismal Biology

Administratively approved March 16, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2004R0051 GENERATION OF TRANSGENIC MICE USING LENTIVIRAL VECTORS, Anthony P. Young, Center for Molecular Neurobiology

Administratively approved Marcy 17, 2005

Biosafety Level: BSL-2
Type of Research: Animal Gene Transfer

2004R0052 OSU CCC AND CALGB LEUKEMIA TISSUE BANKS AND CALIGIURI RESEARCH LABORATORY, Michael Caligiuri, Internal Medicine

Administratively approved March 16, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

EXEMPT PROTOCOLS

2004R0004 THE EFFECT OF EXTRACELLULAR MATRIX-CELL SIGNALING MECHANISMS ON SKELETAL MUSCLE GROWTH, Sandra G. Velleman, Animal Sciences

Date of Determination: March 23, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2004R0011 DETERMINING THE ECOLOGICAL SIGNIFICANCE OF MULTIPLE MICROBIAL POPULATIONS TO SEEDLING HEALTH WITH MOLECULAR MARKERS, Brian B. McSpadden Gardener, Plant Pathology

Date of Determination: March 29, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2004R0025 GENETIC VARIATIONS AFFECTING TRANSCRIPTION AND MRNA PROCESSING, Wolfgang Sadee, Pharmacology

Date of Determination: March 24, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2004R0053 ACID-SENSING ION CHANNELS IN TRANSGENIC MICE, Candice C. Askwith, Neuroscience

Date of Determination: December 15, 2004

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2005R0004 MITOCHONDRIAL TARGETING OF ATP-SENSITIVE K CHANNELS IN ISCHEMIC PRECONDITIONING, Keli Hu, Pharmacology

Date of Determination: February 14, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2005R0015 INOSITOL PHOSPHATES PROMOTE ENDOTOXIN SHOCK, Susheela Tridandapani, Internal Medicine

Date of Determination: March 15, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2005R0016 FUNCTION OF CRMP3 IN HIPPOCAMPUS, Anne-Marie Duchemin, Psychiatry

Date of Determination: March 15, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2005R0017 HYPERTENSION PHARMACOGENETICS, Wolfgang Sadee, Pharmacology

Date of Determination: March 16, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2005R0018 CANCER CHEMOSENSITIVITY AND RESISTANCE GENE, Wolfgang Sadee, Pharmacology

Date of Determination: March 16, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2005R0021 FC RECEPTOR BIOLOGY, Clark L. Anderson, Internal Medicine

Date of Determination: March 23, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2005R0022 MECHANISMS OF BETA-GLOBIN mRNA DEGRADATION IN COOLEY'S ANEMIA, Elizabeth L. Murray, Molecular and Cellular Biochemistry

Date of Determination: March 24, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2005R0024 MOLECULAR ANALYSIS OF ACCURATE RIBOSOMAL TRANSLOCATION, Kurt L. Fredrick, Microbiology Administration

Date of Determination: March 29, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2005R0025 STRUCTURAL BIOLOGY STUDIES OF INTERLEUKIN 7 AND ITS RECEPTORS, Scott T. Walsh, Molecular & Cellular Biochemistry

Date of Determination: March 31, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2005R0027 HEAT-ACTIVATED CHANNELS: CHEMICAL SIGNALS AND REGULATION, Michael X. Zhu, Neuroscience

Date of Determination: April 7, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2005R0028 MECHANISMS FOR CONFORMATIONAL COPING, Michael X. Zhu, Neuroscience

Date of Determination: April 7, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2005R0032 ROLE OF ZAS3 IN LYMPHOCYTE SIGNALING AND SURVIVAL, Lai-Chu Wu, Molecular & Cellular Biochemistry

Date of Determination: April 11, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

CONTINUING REVIEWS APPROVED BY ADMINISTRATIVE REVIEW

2002R0030 RESTORATION OF SMN IN SPINAL MUSCULAR ATROPHY MICE AND DYSTROPHIN IN MDX MICE, Arthur H. Burghes, Molecular & Cellular Biochemistry

Administratively approved March 31, 2005

Biosafety Level: BSL-2, BSL-1-N
Type of Research: Biohazards

2002R0066 BONE MORPHOGEN THERAPY FOR EQUINE FRACTURE HEALING, Alicia Bertone, Veterinary Clinical Sciences

Administratively approved March 30, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA, Biohazards

2002R0074 HUMAN BLOOD AND TISSUE PROCESSING, Michael F. Para, Infectious Diseases

Administratively approved March 31, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2003R0006 DEVELOPMENT OF HIGH AFFINITY LIGANDS FOR PRION DETECTION, Srinand Sreevatsan, Veterinary Preventative Medicine

Administratively approved April 4, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2003R0008 TYPE IV SECRETION AND SIGNAL TRANSDUCTION IN EHRLICHIOSES, Yasuko Rikihisa, Veterinary Biosciences

Administratively approved March 30, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2003R0020 SLUG EXPRESSION DURING DMBA-INDUCED SKIN CARCINOGENESIS, Donna F. Kusewitt, Veterinary Biosciences

Administratively approved April 7, 2005

Biosafety Level: BSL-1
Type of Research: Biohazards

2003R0026 ROLE OF PROTEOGLYCANS IN SKELETAL MUSCLE GROWTH AND DEVELOPMENT, Susan G. Velleman, Animal Sciences

Administratively approved March 31, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2004R0016 BETA-GLOBIN MRNA DECAY IN ERYTHROID CELLS, Daniel R. Schoenberg, Molecular & Cellular Biochemistry

Administratively approved March 30, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2004R0017 HORMONAL REGULATION OF mRNA STABILITY, Daniel Schoenberg, Molecular & Cellular Biochemistry

Administratively approved March 30, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2004R0022 TEST SYSTEMS FOR BACILLUS ANTHRACIS, Michael Lairmore, Veterinary Biosciences

Administratively approved April 1, 2005

Biosafety Level: BSL-3
Type of Research: Biohazards

PENDING PROTOCOLS

2004R0019 BEHAVIORAL STUDIES OF ECHO-PROCESSING AND COMMUNICATION BY BATS, William P. Masters; Evolution, Ecology & Organismal Biology

Date of last communication: March 17, 2005

Type of Research: Biohazards

OTHER BUSINESS

1. Cecil Smith announced to the committee that Dr. Phil Pendergast has gone on medical leave indefinitely.

MINUTES
Institutional Biosafety Committee
12 May 2005

Revised September 23, 2005

Attendance	Members Present	Affiliation
X	Brian Ahmer	Biological Sciences
X	Angel Arroyo- Rodriguez	Ohio EPA
X	David Coplin (co-chair)	Plant Pathology
X	Lawrence A. Capitini	ULAR
NO	Long-Sheng Chang	Pediatrics
NO	Ing-Ming Chiu	Internal Medicine
X	Biao Ding	Plant Biology/ Biotechnology
X	Jyan-Chyun Jang	Horticulture and Crop Sciences
X	Joseph J. Kowalski	Veterinary Clinical Sciences
X	Stefan Niewiesk	Veterinary Biological Sciences
X	Cecil Smith (IBO)	EHS
NO	Jami St. Clair	Columbus Police Department
X	William Swoager	Microbiology
X	Kenneth Theil	OARDC
X	Marshall Williams (co-chair)	MVIMG
	Non-Voting Members Present (none)	
	Office of Responsible Research Practices	
X	Adam McClintock—Biosafety Coordinator	
X	Sandra Meadows—Human Subjects Manager	

The meeting was called to order at 10:00 am in Room 422 Research Foundation Building, and was adjourned at 11:35 pm. The Committee retained quorum for the entire meeting. Dr. Brian Ahmer arrived at 10:05 am. Dr. J.C. Jang arrived at 10:09 am. Dr. Joseph Kowalski arrived at 10:10 am. Dr. Biao Ding left the meeting at 10:40 am. Dr. Larry Capitini left the meeting at 10:55 am. Dr. J.C. Jang left the meeting at 11:32 am.

1. **Approval of Minutes**
   The Committee approved the 14 April 2005 minutes unanimously.

2. **General Amendment Form**
   The Committee reviewed and discussed a revised draft of the general amendment form for rDNA and Biohazards protocols. The following additional revisions will be made to the form, prior to initiation of use:
   1. The Occupation Health Registry Questionnaire box will be placed before the principal investigator signature.

2. The Research Foundation Help Desk contact information will be added to the form, for the purposes of technical difficulties and trouble-shooting.

Drs. Cecil Smith and Marshall Williams will make revisions to the draft of the amendment form specific to human gene transfer, prior to the June Committee meeting.

3. **Review of Application Forms**
It was brought to the attention of the Committee that the current biosafety protocol application forms contain a number of ambiguous questions and overall are lacking in efficiency. The Committee Members will review the current application forms over the course of the next month, and present suggested revisions at the June Committee meeting. Changes that should be incorporated into the revisions include the following:
    1. More direct and simplified questions that more efficiently elicit the desired information.
    2. Standardized questions to help create more efficient and thorough protocol review.
    3. Template Standard Operating Procedures such that only deviations will require explanation.

Examples of biosafety protocol applications from other institutions will be provided to Committee members prior to the June Committee meeting.

4. **Sixth year review process**
The Committee received and overview of the procedures currently being used by the Office of Responsible Research Practices for the full Committee review of non-exempt biosafety protocols every six years:
Investigators will be provided with a notification letter informing them that their protocol is approaching its date of annual review, eight weeks prior to that date. The notification letter informs the investigator of the policy change requiring the full committee review of non-exempt biosafety protocols every six years. The letter will also provide instructions for sixth year submission, and alternately, instructions for termination.

RECOMBINANT DNA DEFERRED PROTOCOLS

2005R0009 MICROBIOLOGICAL SAFETY OF FOODS OF ANIMAL ORIGIN, Jeffrey T. LeJeune, Food Animal Health Research Program

The Committee reviewed the modifications and feel that the principal investigator has not addressed all of the concerns.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Biohazards Transport** (Question #21)—Discuss how animal carcasses will be moved to the incinerator.
2. **Spill Management** (Question #28)—Lengthen contact time to between 5 and 10 minutes.

3. **Personnel Protection** (Question #33)—Indicate that work with liquid cultures will be conducted in a biosafety cabinet.
4. **Personnel Signatures** (Question #36)—Obtain signatures of personnel.
5. **Department Chair Signature** (Question#38)—Obtain signature of department chair.

Total: 12; vote for 12; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

RECOMBINANT DNA NEW PROTOCOL SUBMISSIONS

2005R0007 ROLE OF AMPK IN CHOLESTEROL HOMEOSTASIS, Kamal D. Mehta, Molecular and Cellular Biochemistry

Summary:
The principal investigator intends to study the role of adenosine monophosphate activated protein kinase (AMPK) in reducing the fat content of blood, by using E. coli and adenovirus to produce AMPK in human hepatoma HepG2 cells. The AMPK cDNA will be cloned into an adenoviral vector that can be packaged to produce an adenovirus that produces AMPK protein. Human embryo kidney cells (HEK293) will be used as the packaging cell line to produce the virus.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Host Systems** (Question #7)—The Hep_2 human embryonic cell lines derived from aborted fetuses cannot be used in research in accordance with Ohio Revised Code 2919.14. Verify that the cell lines have not been derived from aborted fetuses.
2. **Consequences of Exposure** (Question #14)—Describe the potential disease outcomes from exposure to adenovirus, E. coli and/or human cell lines.
3. **Agent Maintenance** (Question #16)—Provide a response in "other" check box.
4. **Occupational Health Issues** (Question #17)—Change response to "potential exposure could result in respiratory or enteric illness."
5. **Biohazards Transport** (Question #21)—Indicate that materials will be transported in an unbreakable, sealed, leak-proof, secondary container.
6. **Waste Disposal** (Question #22)
   - Specify that the bleaching agent will be 5% bleach, 1:20 dilution, or sodium hypochlorite at 2,500-3,750 ppm for 4 hours.
   - Indicate that treated waste will be treated as infectious waste by the Office of Environmental Health and Safety.
7. **Personnel Training** (Question #25)—Indicate that personnel will review BSL-2 policies and procedures, due to the potential health risks of E. coli and cell lines.
8. **Medical Surveillance** (Question #26)—Provide completed Occupation Health Registry Questionnaires.
9. **Disinfection** (Question #27)
   - Specify that the bleaching agent will be 5% bleach, 1:20 dilution, or sodium hypochlorite at 2,500-3,750 ppm for 4 hours.
   - Indicate that treated waste will be treated as infectious waste by the Office of

Environmental Health and Safety.

Total: 10; vote for 10; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2005R0012 FUNCTIONAL INTERPLAY BETWEEN SARCOLIPIN AND PHOSPHOLAMBAN IN SR CALCIUM HOMEOSTASIS, Gopal J. Babu, Physiology and Cell Biology

Summary:
The principal investigator intends to study the role of two calcium-pump regulators in cardiac functions and disorders by using recombinant Sarcolipin and phospholamban genes. Adenoviral-mediated gene transfer will be used to introduce the recombinant genes into adult rat cardiac myocytes. The investigator will then study the interaction between the recombinant Sarcolipin and phospholamban genes, and the myocytes.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **General**—Reconcile the dates in Question #25 and Question #34.
2. **Summary** (Question #2)—Elaborate on the summary of research.
3. **Potential Risks** (Question #3)—Remove the last sentence.
4. **IBC Review Requirements** (Question #5)—Indicate that IBC approval is required prior to initiation.
5. **Risk Group** (Question #8)—Indicate that the question is not applicable.
6. **Agent Acquisition** (Question #15)—Provide a response in "other" check box, and indicate the source of the adult rat myocytes.
7. **Agent Maintenance** (Question #16)—Provide a response in "room," and "other" check boxes.
8. **Occupational Health Issues** (Question #17)—Delete original response and replace with an indication that exposure to aerosol containing replication defective adenoviral vectors could result in respiratory disease.
9. **Containment Requirements** (Question #18)—Indicate that BSL-2 policies and procedures will be used in this research.
10. **Bloodborne Pathogen Compliance** (Question #23)—Indicate that the question is not applicable.
11. **Medical Surveillance** (Question #26)—Delete original response and indicate that all personnel will complete the Occupational Health Registry Questionnaire and participate in the University medical surveillance program.
12. **Disinfection** (Question #27)
    - Specify 10% sodium hypochlorite (4,500-7,500 ppm) will be used for the biological safety cabinet and adenoviral media to a final concentration of 1% sodium hypochlorite.
    - Indicate disinfection method for spills outside of the biosafety cabinet.
13. **Laboratory Equipment** (Question #30)—Next to "type" insert: Class II Type A biological safety cabinet
14. **Laboratory Safety Practices** (Question #32)—Check "yes" for arthropod control system.

NOTE: The biosafety cabinet certification needs to be updated.

Total: 10; vote for 10; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2005R0026 HOW DOES SARCOLIPIN REGULATE CALCIUM TRANSPORT? Mutha Periasamy, Physiology & Cell Biology

Summary:
The principal investigator hypothesizes that Sarcolipin has a corollary effect on the Sarco (end) plasmic reticulum Ca2+ ATPase (SERCA), the key regulator of cardiac contractility. Adenoviral gene transfer will be used to introduce SLN and SERCA into HEK-293 and adult rat cardiac myocytes. The investigator will then study the affects of SLN on SERCA to test the hypothesis.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Gene Source** (Question #6)—Indicate whether or not the Sarco (end) plasmic reticulum Ca2+ATPase (SERCA) is the same as phospholamban.
2. **Vectors** (Question #9)—Specify whether the pAdEasy adenoviral vector is the pAdEasy-1 or the pAdEasy-2.
3. **Disinfection** (Question #27)—Indicate the concentration of 10% sodium hypochlorite used in disinfection.

NOTE: The biosafety cabinet certification requires update

Total: 10; vote for 10; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2005R0033 ESTABLISHING STABLE CELL LINES EXPRESSING GLYCOSYLTRANSFERASES, Allan J. Yates, Pathology

Summary:
The cDNA's for glycosyltransferases will be amplified by PCR using the proper primers. PCR products will be extracted and inserted in retrovirus (pREV-TRE) vectors. A retrovirus system will be used to establish cell lines expressing glycolipids (GM3, GD3, and GD1b) according to the manufacturers' instruction (BD Biosciences). Briefly, PT67 packaging cells will be transfected with the required constructs using the calcium phosphate precipitation method (K2708001, Invitrogen). PT67 cells will be selected with the appropriate antibiotic (neomycin, hybromycin, or puromycin) for two weeks, after which the cells will be pooled and the culture media containing retrovirus particles will be centrifuged and filtered through a 0.45-µm filter. Cells will be incubated with 50% of their original media and 50% of the virus-containing media in 60-mm plastic tissue culture plates (Falcon), to deliver RNA of the genes expressing the protein of interest (GM3 synthase, GD3 synthase, GM2/GD2 synthase, and siRNA). Taken together, the investigator will deliver rDNA to cells of tissue cultures using incompetent Retrovirus particles.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Summary** (Question #2)—Elaborate on the summary to include specific aims of research.
2. **Vectors and Inserts** (Question #9)—Describe the vectors to be used.
3. **Risk Group** (Question #13)—Indicate RG-1; murine leukemia virus is inactivated by human serum and does not cause disease.
4. **Personnel Training** (Question #34)—Indicate that personnel will undergo training on an annual basis.

Total: 10; vote for 10; opposed 0; abstained 0

Biosafety Level: BSL-1
Type of Research: rDNA, Biohazards

2005R0035 CELL-MEDIATED IMMUNITY (CMI) TO ROTAVIRUS USING VACCINIA-BASED ROTAVIRUS-SPECIFIC CYTOTOXIC T CELL (CTL) ASSAY, Lijuan Yuan, Food Animal Health Research Program

Summary:
The principal investigator intends to delineate the cell-mediated immunity arm of protective immunity induced by rotavirus infection and vaccination using gnotobiotic pig model of human and porcine rotavirus infection and disease. The investigator plans to use a panel of recombinant vaccinia viruses expressing individual rotavirus antigens to assay viral protein-specific CTL responses after virulent or attenuated rotavirus infection or after vaccination with various candidate vaccines. In this manner, the investigator will be able to measure the general cell mediated immune response to rotavirus (to VP6) and to differentiate serotypic cell mediated immune responses (to Wa and RRV VP7s).

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **General**—Reconcile the two vaccinia virus constructs listed in question #3 with the three vaccinia constructs listed in question #6.
2. **Potential Risks** (Question #3)—Indicate how laboratory access will be controlled.
3. **Host Systems** (Question #7)—Describe host systems to be used.
4. **Agent Acquisition** (Question #15)—Provide the appropriate IATA permits/USDA/CDC importation approvals
5. **Agent Maintenance** (Question #16)
   - Describe the origins of the wild-type vaccinia virus and recombinant vaccinia virus constructs to be amplified.
   - Indicate that all virus propagation will be performed under a biosafety hood in a BSL-2 laboratory.
6. **Occupational Health Issues** (Question #17)—List other risk factors such as stroke and myocardial ischemic events.
7. **Biohazards Transport** (Question #21)—Describe inter-laboratory or intra-laboratory transport of vaccinia/rotavirus.
8. **Waste Disposal** (Question #22)
   - Indicate the "standard disinfectant" procedures to be used.
   - Standardize formulation of chlorine disinfectant for waste disposal and disinfection (question #27)

- Identify brand and concentration of quaternary ammonium compounds.
- Indicate the use of 10% bleach solution (5,000 to 7,500 ppm sodium hypochlorite).
- Designate a contact time for disinfection.

9. **Animals** (Question #24)—Provide information on the use of swine in the project.
10. **Medical Surveillance** (Question #26)—Indicate that vaccination is offered on an annual basis, and any refusal of vaccination will be documented.
11. **Disinfection** (Question #27)—Standardize formulation of chlorine disinfectant for disinfection with waste disposal (question #22).
12. **Personnel Signature** (Question #36)—Acquire signature for Wei Zhang.

Total: 10; vote for 10; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

RECOMBINANT DNA SIXTH YEAR REVIEW

1998R0002 STABLE DNA TRANSFORMATION OF PHYTOPHTHORA INFESTANS AND PHYTOPHTHORA SOJAE AND VIRULENCE ASSAYS ON PLANTS, Sophien Kamoun, OARDC Plant Pathology

Summary:
The principal investigator intends to determine specific genes for pathogenicity, and produce knock-out mutant genes for two species of plant pathogens, *Phytophthora infestans* and *Phytophthora sojae*, which occur naturally in Ohio. *Phytophthora infestans* causes late blight on potatoes and played a role in the Irish potato famine of the mid 19th century. *Phytophthora sojae* is a cause of root rot in soybeans. The investigator intends to mutate or construct reporter gene fusions (GUS and GFP) to various pathogenicity or avirulence genes in both species.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Vectors** (Question #7)—Specify the "classical plasmid vectors" of Phytophthora that are to be used.
2. **Personnel Training** (Question #12)
   - Ensure that personnel are familiar with the Standard Operating Procedures Biosafety Manual beyond distribution, and self-review.
   - Indicate that personnel will undergo training on an annual basis.
3. **Laboratory Equipment** (Question #17)—Specify the certification date of the biosafety cabinet.

Total: 12; vote for 12; opposed 0; abstained 0

Biosafety Level: BSL-1 / BSL-2P
Type of Research: rDNA

1998R0003 TRANSIENT EXPRESSION OF PHYTOPHTHORA AND TOBACCO GENES IN PLANTS USING POTATO VIRUS (PVX), Sophien Kamoun, OARDC Plant Pathology

Summary:
The principal investigator intends to identify and characterize genes encoding elicitors from two species of plant pathogens, *Phytophthora infestans* and *Phytophthora sojae*, and the corresponding receptor and disease resistance genes from the tobacco species, *Nicotiana*. *Phytophthora infestans* and *Phytophthora sojae* primarily cause foliar and root diseases in plants. *Phytophthora infestans* causes late blight on potatoes and played a role in the Irish potato famine of the mid 19th century. *Phytophthora sojae* is a cause of root rot in soybeans. Both pathogens occur naturally in Ohio. Potato virus X will be used as a vector and also occurs naturally in Ohio. The investigator will use use PVX to transiently express *Phytophthora* elicitor genes and known disease resistance genes from tobacco and *N. benthamiana* in related solanaceous plants (*Nicotiana* and *Lycoperiscum* spp.)

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Vectors** (Question #7)—Specify the "classical plasmid vectors" of Phytophthora that are to be used.
2. **Personnel Training** (Question #12)
   - Ensure that personnel are familiar with the Standard Operating Procedures Biosafety Manual beyond distribution, and self-review.
   - Indicate that personnel will undergo training on an annual basis.
3. **Laboratory Equipment** (Question #17)—Specify the certification date of the biosafety cabinet.

Total: 11; vote for 11; opposed 0; abstained 0

Biosafety Level: BSL-2 / BSL-2P
Type of Research: rDNA

1999R0031 INITIATION OF HSV DNA REPLICATION: UL9 INTERACTION, Deborah S. Parris, Molecular Virology, Immunology, and Medical Genetics

Summary:
The principal investigator intends to study DNA replication of the herpes simplex virus. The investigator will examine the proteins expressed from plasmid clones in E. coli or in insect cell cultures using recombinant baculoviruses. The proteins will be examined for their structure-function relationships, as well as, physical interactions of the proteins.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Potential Risks** (Question #3)
   - Replace "laminar flow hoods" with "biosafety cabinets."
   - Indicate concentration and time of exposure for Wescodyne and hypochlorite solution.
2. **Host Systems** (Question #7)—Verify the cell lines used in this protocol. Are Hela cells used?
3. **Agent Acquisition** (Question #15)—Specify the off campus source(s) of the biohazard agents.
4. **Containment Requirements** (Question #18)—Delete "Work requires Biosafety level 1," and indicate that the work requires BSL-2.

5. **Personnel Protective Equipment** (Question #19)—Provide a more specific description of the eyewear and surgical mask to be used by personnel.
6. **Biohazards Transport** (Question #21)—Specify the guidelines that are to be used for transport of the biohazard agent.
7. **Waste Disposal** (Question #22)—Indicate concentration and time of exposure for Wescodyne and hypochlorite solution.
8. **Spill Management** (Question #28)—Provide a more specific description of the eyewear and surgical mask to be used by personnel.
9. **Laboratory Equipment** (Question #30)—Provide certification data for the biosafety cabinet.
10. **Laboratory Practices** (Question #32)—Obtain a spill kit for the laboratory.

Total: 10; vote for 10; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2001R0015 GENETIC MODIFICATIONS OF PETUNIA TO DELAY FLOWER SENESCENCE, Michelle Jones, Horticulture & Crop Science

Summary:
The principal investigator is examining genetic engineering in petunias to delay senescence and create flowers with increased post-production longevity. The investigator will study two methods to delay senescence. The first method involves the manipulation of hormone synthesis or the perception of plant hormones involved in senescence, and the second involves identifying genes that are transcriptionally up or down regulated during senescence in petunias. The first method involves the investigator introducing two foreign genes into petunias, the *Agrobacterium* isopentenyl transferase gene (cytokinin synthesis) and a mutant Arabidopsis ethylene receptor. The second method involves either over - xpressing or knocking down certain genes that may be turned up or down during senescence.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Personnel Training** (Question #12)—Indicate that personnel will undergo training on an annual basis.
2. **Laboratory Space** (Question #16)—Indicate, specifically, that the *Agrobacterium* strains will not be used in the greenhouse.

Total: 10; vote for 10; opposed 0; abstained 0

Biosafety Level: BSL-1 / BSL-1P
Type of Research: rDNA

BIOHAZARDS AMENDMENTS

1999R0067 HUMAN ROTAVIRUS AND ENTERIC CALICIVIRUSES: CHARACTERIZATION, STUDIES OF DISEASE PATHOGENESIS AND IMMUNITY IN GNOTOBIOTIC PIGS AND CALVES AND DEVELOPMENT OF VACCINES, Linda J. Saif, Veterinary

Preventative Medicine

Summary:
The principal investigator's amendment request involves a two part change. First, the investigator requests the protocol title change to "Human rotaviruses, enteric calciviruses and enteric coronaviruses: characterization studies of disease pathogenesis and immunity in gnotobiotic pigs and calves and development of vaccines." The second request involves the addition of a Human Enteric Coronavirus strain HECV-4408 and its derivatives. This strain was isolated from a six year old child and propagated in HRT-18 cell culture which will be used to inoculate gnotobiotic calves. The investigator is studying this strain for its immunogenicity, pathogenesis and cross protection with bovine CoVs in gnotobiotic calves.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **General**—On the "Human Enteric Coronavirus Information Sheet," under the heading "Clinical Signs," replace the statement "suggesting low transmissibility," with a statement indicating that due to limited data, the actual transmissibility is not know.

Total: 9; vote for 9; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Biohazards

ADMINISTRATIVE APPROVALS

2003R0053 SAMPLING BLOOD FROM WILD OHIO BIRDS FOR PRESENCE OF WEST NILE VIRUS ANTIBODIES, Thomas C. Grubb, Evolution, Ecology & Organismal Biology

Date of Determination: May 3, 2005

Biosafety Level: *N/A due to field sampling*
Type of Research: rDNA, Biohazards

2004R0019 BEHAVIORAL STUDIES OF ECHO-PROCESSING AND COMMUNICATION BY BATS, William M. Masters, Evolution, Ecology & Organismal Biology

Date of Determination: May 18, 2004

Biosafety Level: BSL-2
Type of Research: Biohazards

EXEMPT PROTOCOLS

2005R0036 FUNCTIONAL ANALYSES OF THE TRANSCRIPTION FACTOR ATF, Tsonwin Hai, Neurobiotechnology Center

Date of Determination: May 3, 2005

Biosafety Level: BSL-1
Type of Research: rDNA

CONTINUING REVIEWS APPROVED ADMINSTRATIVELY

2002R0039 DEVELOPMENT OF A HUMAN LYMPHOHEMATOPOIETIC CELL PRODUCTION SYSTEM: PHASE I, Larry C. Lasky, Pathology

Date of Determination: May 1, 2005

Biosafety Level: BSL-2
Type of Research: rDNA

2002R0040 DISSECTING THE INTERACTION OF RHABDOVIRUSES WITH THEIR PLANT AND INSECT HOSTS, Saskia Hogenhout, Entomology Administration

Date of Determination: April 18, 2005

Biosafety Level: BSL-2P
Type of Research: rDNA, Biohazards

2002R0062 PCV-2 AND PMWS: CELLULAR SITES OF REPLICATION AND PATHWAYS OF CELLULAR DAMAGE, Steven Krakowka, Veterinary Biosciences

Date of Determination: April 19, 2005

Biosafety Level: BSL-1
Type of Research: Biohazards

2003R0009 GENE EXPRESSION PROFILING OF RELAPSED LYMPHOMA IN DOGS, William C. Kisseberth, Veterinary Clinical Sciences

Date of Determination: April 19, 2005

Biosafety Level: BSL-1
Type of Research: rDNA, Biohazards

2003R0025 THE IN PLANTA FUNCTIONAL ANALYSIS OF CANDIDATE EFFECTOR PROTEINS OF BACTERIAL PATHOGEN, ASTER YELLOWS PHYTOPLASMA AYWB, Saskia Hogenhout, Entomology Administration

Date of Determination: April 18, 2005

Biosafety Level: BSL-2P
Type of Research: rDNA, Biohazards

PENDING PROTOCOLS

2005R0011 ECOLOGY OF FOODBOURNE PATHOGENS ON VEGETABLES, Jeffrey T. LeJeune, OARDC Food Animal Health Research Program

Date of Last Communication: May 6, 2005

Type of Research: rDNA, Biohazards

2005R0019 INFECTIOUS BURSAL DISEASE VIRUS INFECTION STUDIES, Daral J. Jackwood, OARDC Food Animal Health Research Program

Date of Last Communication: April 29, 2005

Type of Research: Biohazards

2005R0029 EVALUATION OF THYMUS FUNCTION IN LENTIVIRUS DISEASE, Lawrence Mathes, Veterinary Biosciences

Date of Last Communication: May 5, 2005

Type of Research: Biohazards

MINUTES
Institutional Biosafety Committee
9 June 2005

Revised September 22, 2005

Attendance	Members Present	Affiliation
X	Brian Ahmer	Biological Sciences
X	Angel Arroyo- Rodriguez	Ohio EPA
X	David Coplin (co-chair)	Plant Pathology
NO	Lawrence A. Capitini	ULAR
NO	Long-Sheng Chang	Pediatrics
NO	Biao Ding	Plant Biology/ Biotechnology
NO	Jyan-Chyun Jang	Horticulture and Crop Sciences
X	Joseph J. Kowalski	Veterinary Clinical Sciences
X	Stefan Niewiesk	Veterinary Biological Sciences
X	Cecil Smith (IBO)	EHS
NO	Jami St. Clair	Columbus Police Department
NO	William Swoager	Microbiology
X	Kenneth Theil	OARDC
X	Marshall Williams (co-chair)	MVIMG

Non-Voting Members Present (none)

Office of Responsible Research Practices

X	Adam McClintock—Biosafety Coordinator
X	Liz Hanawalt—Quality Improvement Specialist

The meeting was called to order at 10:05 am in Room 422 Research Foundation Building, and was adjourned at 11:05 am. The Committee retained quorum for the entire meeting.

1. **Approval of Minutes**
   The Committee approved the 12 May 2005 minutes unanimously.

2. **New and Continuing Membership**
   The Committee chairs will consult with Dr. Guttman, and contact Dr. McGrath to solicit IBC representation from certain departments that are been having protocols reviewed without adequate representation. Additional representation is sought from Veterinary Biosciences and Human Cancer Genetics. Dr. Ing-Ming Chiu will be on sabbatical from July 1, 2005 until June 30, 2006 and will temporarily be removed from the IBC roster, effective immediately. Dr. Stefan Niewiesk will be parting with the IBC once new members have been appointed. The chairs will request that Dr. Chiu and Dr. Niewiesk provide suggestions for their replacements. New appointments are expected to be in place by the end of summer. Once new Committee members have been appointed training sessions will be planned.

3. **Human Gene Transfer Amendment Request Form**

Due to the likelihood of protocol changes post-IBC approval, but prior to IRB approval, changes are often requested before work is actually started on gene therapy projects. In general, the requested changes do not involve changes to the recombinant DNA work involved in the protocol, and it is thought that the form will aid in tracking these changes. The Committee approved the form, and minor editorial changes will be made by ORRP, similar to those in the General Recombinant DNA and/or Biohazards amendment request form.

Total: 8; vote for 8; opposed 0; abstained 0

4. **Procedure for Delinquent Responses**
   a. PA-005 Protocol Requests—The initial letter requesting that the PI submit materials to the IBC based on responses provided on PA-005's, will contain a disclaimer advising that once funding is approved, the required IBC approvals must be in place, and in the case that they are not, the approval process will not be expedited. The second notice to the PI will go out 90 days after the first notice instead of 60 days. The second letter will also contain the same disclaimer as the initial request letter. The Committee noted that the revision of the application forms, once in place, will help expedite the approval process in general.
   b. Continuing Review—The Institutional Laboratory Biosafety Manual outlines procedures for violation of biohazard policy [Section XVI.1 Violation of Biohazard Policy] These procedures will be distributed to the Committee prior to the July meeting. Additionally, once clear procedures have been established, the first notice of Continuing Review will be sent to the PI, the second notice will copy the Department Chair, and the final notice will copy the Department Chair and College Dean.

5. **Update on Gene Transfer Protocols**
   No work has begun on the gene transfer protocols that have been approved. University administration has put a hold on the projects until the proper risk management procedures are in place for insurance against institutional liability. Proposed insurance coverage is nearing the point for presentation to the Coordination Council.

GENE TRANSFER NEW PROTOCOLS

2005R0037 IN VIVO GENE DELIVERY TO GUINEA PIG CHONDROCYTES BY SELECT VIRUS VECTORS, Alicia L. Bertone, Veterinary Clinical Sciences

Summary:
The principal investigator intends to study gene therapy in guinea pigs that have had the ACL in the right knee surgically transected. Therapeutic genes will then be delivered via recombinant adeno-associated viral vectors to guinea pigs in five treatment groups. The guinea pigs will be monitored and evaluated throughout the three month treatment period. Six guinea pigs from each treatment group will be harvested at 30, 60 and 90 days. After harvest, blood and tissue samples will be retained for examination. The principal investigator hopes to obtain generalizable knowledge to better understand traumatic and osteo-arthritic cartilage damage in elderly humans and adult dogs.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Vectors and Inserts** (Question #12)
   - Specify the source of the plasmids.
   - Indicate whether or not the plasmids will be propagated in the laboratory. If

they will be propagated in the laboratory, indicate the host to be used.

2. **Risk Group** (Question #14)—Indicate Risk Group 1.
3. **Biohazards Transport** (Question #22)—Indicate that transport of rAAV outside of the laboratory will consist of a primary container, placed in a sealed, leak-proof secondary container.
4. **Risks to Personnel** (Question #25b)—Check the box 'other.'
5. **Personnel Training** (Question #26)—Indicate that training will be documented and will include list of attendees and training topics.
6. **Disinfection** (Question #28)—Indicate the use of 10% bleach [at least 5,000 ppm sodium hypochlorite].
7. **Spill Management** (Question #29)—Indicate the use of 10% bleach [at least 5,000 ppm sodium hypochlorite].
8. **Biosafety Cabinet** (Question #31a)—Add Class II Biological Safety Cabinet and indicate most recent certification date.

Total: 8; vote for 8; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Animal Gene Transfer

RECOMBINANT DNA NEW PROTOCOL SUBMISSIONS

2005R0041 CLONING AND BACULOVIRUS EXPRESSION OF ROTAVIRUS GENES, Linda J. Saif, OARDC Food Animal Health Research Program

Summary:
The principal investigator intends to study the role of inner capsid (VP2/VP6) and outer capsid (VP4/VP7) proteins in animal rotavirus resistance. cDNA of VP4 and VP7 proteins will be inserted in baculovirus vectors and gnotobiotic pigs and gnotobiotic calves will be inoculated with these recombinant proteins. The immune response to individual proteins will be studied for alternative antigens for possible rotavirus vaccines. Gnotobiotic calves and gnotobiotic pigs will also be immunized by double and triple shelled virus-like particles (VLP) of human, bovine and porcine rotaviruses. The VLP will be purified by gradient ultracentrifugation. The principal investigator hopes to gain knowledge that could contribute to the development of an effective human rotavirus vaccine and improve the efficacy of existing animal rotavirus vaccines.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **General**—There are multiple references to protocols 1999R0067 and 1999R0066; please attach copies of relevant materials to this protocol.
2. **Review Requirements** (Question #5)—Check the box 'require IBC approval before initiation.'
3. **Consequences of Exposure** (Question #14)—Cite the consequences of exposure to Rotavirus, not an existing protocol.
4. **Agent Maintenance** (Question #16)—Check 'No' for 'other' box.
5. **Occupational Health Issues** (Question #17)—Cite the consequences of exposure to Rotavirus, not an existing protocol.
6. **Biohazards Transport** (Question #21)—Indicate that inter- and/or intra-laboratory transport of biohazardous agents will consist of a primary container

placed within a sealed, leak-proof, unbreakable secondary container.

7. **Medical Surveillance** (Question #26)—Indicate that all personnel will complete the Occupational Health Registry Questionnaire.
8. **Personal Protective Equipment** (Question #33)—Indicate how sharps will be managed during the immunization of gnotobiotic calves and gnotobiotic pigs.

Total: 8; vote for 8; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Recombinant DNA/Biohazards

2005R0042 ROLE OF ANTIOXIDANTS IN INFLUENZA A VIRAL INFECTION OF LUNG EPITHELIAL CELLS IN CULTURE, Kalpana Ghoshal, Molecular & Cellular Biochemistry

Summary:
The principal investigator intends identify the molecular mechanisms used by influenza A virus to activate the expression of cellular antioxidants. Retroviral and transposon-based vectors will be used to infect lung epithelial cell line (A549) and human primary bronchial epithelial (NHBE) cells with influenza A (A/Bangkok strain). A better understanding of the mechanisms used to activate cellular antioxidants could help prevent the excessive buildup of free oxygen and nitrogen radicals (ROS and RNS), which could in turn help reduce the severity of or even prevent viral infection.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **General**—A letter must be submitted from Dr. Sheridan stating that he is aware of and approves certain parts of this protocol being done in his laboratory.
2. **Summary** (Question #2)—Briefly describe the experimental procedures used in this protocol. Is it limited to cell culture or will animals be involved?
3. **Host System** (Question #7)—Clarify the source of the cells, and if appropriate indicate proper training and laboratory practices (i.e. Bloodborne pathogen compliance training, sharps management, etc.).
4. **Biohazard** (Question #12)—Specify serotype of Influenza A (A/Bangkok strain).
5. **Consequences of Exposure** (Question #14)—Provide supporting evidence that only 'mild influenza infection' will occur.
6. **Agent Acquisition** (Question #15)
   - Check box for 'On-campus collection or researcher.'
   - Specify Dr. Sheridan's area(s) of experience with influenza, and summarize what is approved under protocol #2004A0022.
7. **Agent Maintenance** (Question #16)—Check 'No' in the unmarked boxes.
8. **Biohazards Transport** (Question #21)—Describe how infectious waste will be transported from Room 3121 to the autoclave in Room 3009.
9. **Waste Disposal** (Question #22)—Describe how infectious waste will be transported from Room 3121 to the autoclave in Room 3009.
10. **Bloodborne Pathogen Compliance** (Question #23)—If appropriate describe bloodborne pathogen compliance (see question #7)
11. **Animals** (Question #24)—Reconcile the response of 'N/A' with the reference to aerosol exposure from animals in question #33.
12. **Medical Surveillance** (Question #26)—Identify 'Dr. Jacob's group,' and the

relationship between this group, the PI, Dr. Sheridan, and Dr. Jacob (If appropriate include this group under personnel in question #35).

13. **Laboratory** (Question #29)
    - Indicate where exactly the cell culture infection will be performed (In Dr. Sheridan's laboratory 3009 Postle Hall, or 3121 Postle Hall as per the table).
    - Indicate the agency that certified Dr. Sheridan's laboratory and the level for which it is certified.
14. **Laboratory Safety Practices** (Question #32)—Check the appropriate box for 'Arthropod control program.'
15. **Personal Protective Equipment** (Question #33)
    - Reconcile the reference to infected animals with the 'N/A' response in question #24.
    - Specify the type of mask to be used by personnel.
16. **Personnel Training** (Question #34)—Indicate use of Class II Type A for consistency with question #25.

Total: 8; vote for 8; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Recombinant DNA/Biohazards

BIOHAZARDS NEW PROTOCOLS

2005R0030 BUILDING BLOCKS OF A BIOCHEMICAL CPU BASED ON DNA TRANSCRIPTION LOGIC, Mark T. Ziolo, Computer & Information Science

Discussion: The Committee reached consensus that a chemical hygiene plan will be required for your work with lipopolysaccharide and not a biohazards protocol. The protocol will be withdrawn.

Total: 8; vote for 8; opposed 0; abstained 0

2005R0034 QUANTIFICATION OF SELECT BACTERIAL SPECIES IN INFANT STOOL SAMPLES BY DENATURING GRDIENT GEL ELCTROPHORSIS AND REAL-TIME PCR METHODS, Mark Morrison, Animal Sciences

Summary:
The principal investigator will use nucleic acids extracted from healthy, human infant stool samples as a template for a variety of PCR-based assays designed to quantify and evaluate microbial diversity. Some of the chemicals used for the DNA extraction and subsequent analyses are considered hazardous. Although the samples were taken from healthy infants, they may contain enteric pathogens. The proposed containment level at BSL-2 is adequate for the work to be done.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Agent Acquisition** (Question #7)—Indicate the source of stool samples.
2. **Agent Maintenance** (Question #8)—Check 'Yes' for 'other' box.
3. **Containment Requirements** (Question #9)

- Replace 'laminar flow hood' with 'Class II Biological Safety Cabinet.
- Add "Biosafety level 2 containment, practices and procedures will be used.

Total: 8; vote for 8; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Biohazards

2005R0039 TYPE A ANIMAL INFLUENZA RESEARCH LABORATORY, Richard D. Slemons, Veterinary Preventative Medicine

Summary:
The principal investigator intends to define the natural history of type A influenza virus in avian species and identify risk factors and criteria associated with transmission of the virus from wild-bird species to poultry species. Tissue samples of the influenza isolates will be obtained from wild birds, poultry, horses and swine through various routine outbreak investigations and surveillance programs. General antigenic and genomic properties of isolates will be characterized using standard serological and polymerase chain reaction tests. The genomic analysis will be completed using standard PCR analyses on non-infectious RNA extracts from the isolates. The investigators will likely resume studies involving the screening of naturally occurring wild-bird origin type A influenza viruses for their potential to infect poultry.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Risk Group**(Question #6)—Remove reference to RG-1
2. **Agent Acquisition** (Question #7)—Check appropriate box for 'On-campus collection or researcher' and 'Other.'
3. **Agent Maintenance** (Question #8)—Check 'No' for unmarked boxes.
4. **Containment Requirements** (Question #9)—Remove reference to BSL-2.
5. **Personal Protective Equipment** (Question #10)—The Committee recommends that the procedures be reviewed and if necessary indicate use of masks or respirators.
6. **Disinfection** (Question #18)—Indicate the use of 10% Bleach [5,000-7,500 ppm sodium hypochlorite].
7. **Spill Management** (Question #19)—Indicate the use of 10% Bleach [5,000-7,500 ppm sodium hypochlorite].
8. **Biosafety Cabinet** (Question #21a)—Indicate the use of Class II Biological Safety Cabinet.

Total: 8; vote for 8; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Biohazards

ADMINISTRATIVE APPROVALS

1999R0051 FUNCTIONAL ANALYSIS OF RICE DEFENSE GENES, Guo-Liang Wang, Plant Pathology

Date of Determination: May 5, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

1999R0067 HUMAN ROTAVIRUS AND ENTERIC CALICIVIRUSES: CHARACTERIZATION, STUDIES OF DISEASE PATHOGENESIS AND IMMUNITY IN GNOTOBIOTIC PIGS AND CALVES AND DEVELOPMENT OF VACCINES, Linda J. Saif, Veterinary Preventative Medicine

Date of Determination: May 26, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2001R0015 GENETIC MODIFICATIONS OF PETUNIA TO DELAY FLOWER SENESCENCE, Michelle L. Jones, Horticulture & Crop Science

Date of Determination: May 31, 2005

Biosafety Level: BSL-1 / BSL-1 P
Type of Research: Recombinant DNA

2003R0044 BACILLUS ANTHRACIS-INDUCED INNATE IMMUNE RESPONSES, Andrew J. Phipps, Veterinary Biosciences

Date of Determination: May 26, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA, Biohazards

2003R0061 URBAN ECOLOGY OF COYOTES IN THE CHICAGO AREA, Stanley Gehrt, School of Natural Resources

Date of Determination: ay 26, 2005

Biosafety Level: *N/A due to field sampling*
Type of Research: Biohazards

2003R0062 ESTIMATING CONTACT RATES AMONG FREE-RANGING RACCOONS FOR SPATIAL MODELING OF RABIES, Stanley Gehrt, School of Natural Resources

Date of Determination: May 26, 2005

Biosafety Level: *N/A due to field sampling*
Type of Research: Biohazards

2004R0021 MEASUREMENT OF RETROVIRAL-SPECIFIC CTL RESPONSES IN ANIMAL MODELS OF HUMAN RETROVIRUSES, Michael

Date of Determination: May 26, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA, Biohazards

2005R0007 ROLE OF AMPK IN CHOLESTEROL HOMEOSTASIS, Kamal D. Mehta, Molecular and Cellular Biochemistry

Date of Determination: May 31, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA

2005R0020 MOSQUITO BITING, Woodbridge A. Foster, Entomology

Date of Determination: May 5, 2005

Biosafety Level: BSL-1
Type of Research: Biohazards

2005R0023 A5197, VERSION 2.0, 01/05/2005: A PHASE II DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED STUDY TO EVALUATE THE ANTIRETROVIRAL EFFECT OF IMMUNIZATION WITH THE MRK AD5 HIV-1 GAG VACCINE IN HIV-1 INFECTED INDIVIDUALS WHO INTERRUPT ANTIRETROVIRAL DRUG THERAPY, Susan L. Koletar, Infectious Diseases

Date of Determination: May 9, 2005

Biosafety Level: BSL-2
Type of Research: Human Gene Transfer

2005R0026 HOW DOES SARCOLIPIN REGULATE CALCIUM TRANSPORT? Mutha Periasamy, Physiology & Cell Biology

Date of Determination: May 31, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA, Biohazards

2005R0029 EVALUATION OF THYMUS FUNCTION IN LENTIVIRUS DISEASE, Lawrence Mathes, Veterinary Biosciences

Date of Determination: May 31, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2005R0035 CELL-MEDIATED IMMUNITY (CMI) TO ROTAVIRUS USING VACCINIA-BASED ROTAVIRUS-SPECIFIC CYTOTOXIC T CELL (CTL) ASSAY, Lijuan Yuan, Food Animal Health Research Program

Date of Determination: May 31, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA, Biohazards

EXEMPT PROTOCOLS

2003R0056 INVESTIGATIONS INTO DEG/ENAC CHANNEL FUNCTION, Candice Askwith, Neuroscience

Date of Determination: May 31, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2005R0044 IMPORTANCE OF PTHRP ON NORMAL OSTEOBLAST DIFFERENTIATION AND FUNCTION, Ramiro E. Toribio, Veterinary Biosciences

Date of Determination: May 31, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

CONTINUING REVIEWS APPROVED ADMINSTRATIVELY

2000R0026 INTERCELLULAR PROTEIN TRAFFICKING AND LEAF DEVELOPMENT, Biao Ding, Plant Biology

Date of Determination: May 23, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2003R0019 STUDIES OF HERPES SIMPLEX VIRUS TYPE 1 AND HUMAN CYTOMEGALOVIRUS BIOLOGY AND PATHOGENESIS, Joanne Trgovcich, Pathology

Date of Determination: May 23, 2005

Biosafety Level: BSLS-2
Type of Research: Recombinant DNA, Biohazards

2004R0020 FUNCTIONAL ANALYSIS OF SOYBEAN DEFENSE GENES, Terrence L. Graham, Plant Pathology

Date of Determination: May 10, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

PENDING PROTOCOLS

2005R0019 INFECTIOUS BURSAL DISEASE VIRUS INFECTION STUDIES, Daral J. Jackwood, OARDC Food Animal Health Research Program

Date of Last Communication: May 26, 2005

Type of Research: Biohazards

MINUTES
Institutional Biosafety Committee
14 July 2005

Revised September 22, 2005

Attendance	Members Present	Affiliation
X	Brian Ahmer	Biological Sciences
X	Angel Arroyo- Rodriguez	Ohio EPA
X	David Coplin (co-chair)	Plant Pathology
NO	Lawrence A. Capitini	ULAR
X	Long-Sheng Chang	Pediatrics
NO	Biao Ding	Plant Biology/ Biotechnology
NO	Jyan-Chyun Jang	Horticulture and Crop Sciences
NO	Joseph J. Kowalski	Veterinary Clinical Sciences
NO	Stefan Niewiesk	Veterinary Biological Sciences
X	Cecil Smith (IBO)	EHS
X	Jami St. Clair	Columbus Police Department
X	William Swoager	Microbiology
X	Kenneth Theil	OARDC
X	Marshall Williams (co-chair)	MVIMG
	Non-Voting Members Present (none)	
	Office of Responsible Research Practices	
X	Adam McClintock—Biosafety Coordinator	

The meeting was called to order at 10:00 am in Room 422 Research Foundation Building, and was adjourned at 10:55 am. The Committee retained quorum for the entire meeting.

Early Departures: Marshall Williams left at 10:45 am.

1. **Approval of Minutes**
   The Committee approved the 9 June 2005 minutes unanimously.

2. **IBCC Policy Statement**
   The IBCC Policy Statement outlines policy for biohazards violations containing language relevant specifically to incidents as opposed to compliance to policy. The Committee is currently in a position in which it can dictate consequences for violations based on compliance to policy. It has been suggested that in cases where there has been no response to requests for the submission of protocol materials or annual review forms, the investigator's department chair and/or dean will be copied on a final notice. The Committee co-chairs will confer with Dr. Guttman and Dr. Neidig as possible authorities to issue the final notice.

The Committee members agreed that it is standard practice for investigators to engage in research to gain preliminary data on an organism prior to the preparation of a grant application, and that there should be some degree of oversight involved. The current system is setup such that when funds are awarded, all required IBC/ILACUC/IRB approvals must be in place prior to those funds being released to the investigator. Throughout the communication process, language will be used such that the investigators will be made aware that approvals will not be expedited if they are not already in place prior to funds being awarded.

The co-chairs have requested that Committee members come to the next convened meeting prepared to discuss a process statement regarding non-respondence to request for submissions. In the meantime, current cases of non-respondence relating to recombinant DNA in plants and microbes that are not zoonotic pathogens will be forwarded to Dr. Coplin, while all others will go to Dr. Smith for follow-up.

RECOMBINANT DNA NEW PROTOCOL SUBMISSIONS

2002R0089 BIOCHEMISTRY OF TRNA EDITING, Juan D. Alfonzo, Microbiology

Summary:
The principal investigator intends to study transfer RNA (tRNA) and its editing enzymes in trypanosomatids. The research involves the synthesis of tRNA in the laboratory as well as the growth of cells to purify various enzymes involved in tRNA maturation. The cells that the investigator intends to grow include *Leishmania tarentolae,* which infects the Algerian gecko, *Trypanosoma brucei* (strain 29-13), a cattle pathogen and *E.coli.* Neither the tRNA, nor the cells (strains) to be used are toxic to humans. All strains to be used are non-virulent.

The Committee **DEFERRED** the biosafety plan

1. **General**—Correct Typos
   - Question #2: remove extra '"brucei" from *Trypanosoma brucei* brucei.
   - Question #8: "Thhe host of..." should read "The host of..."
   - Question #9: "puc19" should read "pUC19."
2. **Genes Used** (Question #6)—Indicate the sources of DNA and names of the genes to be cloned in the *E.coli* vectors.
3. **Host Systems** (Question #7)
   - Clarify why *Leishmania tarentolae* and *Trypanosoma brucei* are listed as vectors.
   - Provide justification for the claim that the strains of *Trypanosoma brucei* to be used are non-pathogenic. Indicate what is meant by strain numbers?
   - Will DNA be exchanged between Leishmania and Trypanosoma?

   NOTE: Unless genes are expressed in these parasites, they are not the host system.
4. **Risk Group** (Question #8)—Indicate the risk group and provide justification.
   NOTE: *Trypanosoma brucei* is classified as a cattle pathogen.
5. **Vectors** (Question #9)
   - Specify that E. coli strain K-12 will be the host.
   - List vectors to be used and indicated whether or not they are self-cloning. The vectors listed probably will not work in Leishmania and Trypanosoma. What

will be used for these genera?

6. **Consequences of Exposure** (Question #14)—Provide background on the consequences of exposure.
7. **Agent Acquisition** (Question #15)—Provide a "yes" or "no" response in each check box.
8. **Agent Maintenance** (Question #16)—Provide a "yes" or "no" response in each check box.
9. **Containment Requirements** (Question #18)
   - Indicate either BSL-1 or BSL-2, and provide justification for the containment level.

   NOTE: If the organisms are justified as RG-1, containment at BSL-1 will be appropriate.
10. **Biohazards Transport** (Question #21)—Discuss how biohazards will be transported from the main laboratory in the Biological Sciences Building 440 and 446 to the biological safety cabinet (BSC) in the teaching lab in the Biological Sciences Building 411 to the autoclave in the Biological Sciences Building 420.
11. **Personnel Training** (Question #25)—Provide detail on the content of technical and biohazard training, in-lab training, and certifications.
12. **Disinfection** (Question #27)
    - Specify the detergents to be used.
    - Revise the statement "75% ethanol and/or detergents, both will destroy the organisms listed upon contact" and provide a contact time.

    NOTE: 75% ethanol is not likely to destroy organisms upon contact.
13. **Laboratory Equipment** (Question #30a)—Indicate BSC type II-A.
    NOTE: The BSC was last certified on September 17, 1999. The Committee suggests recertification.

Total: 9; vote for 9; opposed 0; abstained 0

Type of Research: Recombinant DNA/Biohazards

2005R0052 IN-VIVO GENE TRANSFER TO CARDIAC AND NEURAL TISSUE, George E. Billman, Physiology & Cell Biology

Summary:
The principal investigator intends to directly transfect in-vivo canine neural tissue that controls the heart with a key regulatory gene, neuronal nitric oxide synthase (nNOS) encoded in a replication incompetent e1/e3 deletion Adenovirus type V vector. The investigator intends to determine whether up-regulation of this gene, in the neural tissue that controls the heart, can reverse some of the detrimental changes that are seen in nervous control of the heart after myocardial infarction.

The Committee **APPROVED** the biosafety plan

1. **NOTE:** Specify whether the Adenovirus will be propagated in the lab, or if it will continue to be acquired from the off-campus researcher.

Total: 9; vote for 9; opposed 0; abstained 0

Biosafety Level: BSL-1
Type of Research: Recombinant DNA/Biohazards

2005R0054 A FUNCTIONAL AND COMPARATIVE ANALYSIS OF THE CLOSTRIDIUM THEROCELLUM AND RUMINOCCOCCUS ALBUS GENOMES: UNDERSTANDING THE CELLULOSOME PARADIGM OF PLANT BIOMASS CONVERSION, Mark Morrison, Animal Sciences

Summary:
The principal investigator intends to study the genetics and molecular biology that underlies biomass degradation by *Clostridium thermocellum* and *Ruminococcus albus*, empowered by the genome sequence of these bacteria. The genome sequence of these bacteria has revealed additional dockerin-containing coding sequences that previously identified. The annotated sequences indicate that the spectrum of functions encoded extends beyond that glycoside hydrolases, and there is also a suite of non-cellulosomal cellulases and xylanases also encoded within the genome. The investigator hopes to gain a better understanding of the physiology of these bacteria and the cellulosome paradigm to provide new insights and opportunities for the use of fibrous crop residues for biofuel production.

The Committee **DEFERRED** the biosafety plan

1. **Summary** (Question #2)—Clarify whether the strain of ATCC 27405 is *Clostridium* or *Ruminococcus*.
2. **Genes Used** (Question #6)—Specify the "other carbohydrate active enzymes and regulatory proteins…" encoded by the genes examined.
3. **Host Systems** (Question #7)—Specify the strain *E.coli* K-12. Will genes be exchanged between Clostridium and Ruminococcus?
4. **Containment Requirements** (Question #18)—Reconcile the response referring to BSL-2 with the BSL-1 laboratory certification in question #29.
5. **Waste Disposal** (Question #22)—Indicate that needles and other sharps will be disposed of in sharps containers designed for that purpose.
6. **Disinfection** (Question #27)—Indicate a contact time for disinfection.
7. **Spill Management** (Question #28)—Incorporate spill management procedures. An example of procedures is provided below.

   Small spills will be contained using plastic-backed absorbable hood liner, paper towels, or gauze. Contaminated absorbent materials will be transferred to a lined red biohazard bag and autoclaved. The contaminated surface will be treated with a 1:10 dilution of bleach [sodium hypochlorite at 5,000 ppm], Vikron or 70% Etoh.

   Large spills will be contained by placing a barrier of paper towels around the spill after warning any other laboratory personnel in the immediate vicinity. The liquid will be absorbed with additional paper towels or granular absorbable material. The Principal Investigator should be contacted as soon as possible after the spill is contained. Laboratory personnel wearing appropriate personal protective equipment including respiratory protection will transfer the contaminated solid materials into a lined red biohazard bag for autoclaving. All contaminated surfaces will be saturated with a 1:10 dilution of bleach in water, Vikron or 70% Etoh. Aerosol formation should be kept to the absolute minimum by not spraying water or disinfectant directly onto the spill or by not using a sponge or wringing out paper towels during the cleanup. Any laboratory personnel with exposure to the agent will notify OSU Employee Health Services after the spill has been contained

and any contaminated personal protective equipment and clothing has been removed. Contaminated personal protective equipment and clothing will be placed into a red biohazardous bag and autoclaved prior to being laundered or disposal.

Total: 9; vote for 9; opposed 0; abstained 0

Type of Research: Recombinant DNA/Biohazards

RECOMBINANT DNA AMENDMENTS

2003R0040 RECOMBINANT DNA AND BIOHAZARD SAFE PRACTICE FOR THE GUNN LABORATORIES (BSL-3), John S. Gunn, Molecular Virology, Immunology & Medical Genetics

Summary:
The principal investigator intends to engage in research involving the transfer of antibiotic resistant genes into *Francisella tularensis*, a select agent. This modification would give the investigator the ability to introduce selectable plasmids into the agent or induce chromosomal gene disruptions. The proposed genes for this work encode for resistance to erythromycin and kanamycin, neither of which are drugs of choice for the treatment of patients with tularemia. These transfers should not compromise the drug control of the disease agent.

The Committee **APPROVED** the amendment

Total: 9; vote for 9; opposed 0; abstained 0

Biosafety Level: BSL-3
Type of Research: Recombinant DNA/Biohazards

BIOHAZARDS NEW PROTOCOLS

2005R0045 PREDISPOSING FACTORS AND TREATMENT FOR POST-TRANSPLANT LYMPHOPROLIFERATIVE DISORDER, Anne M. VanBuskirk, Surgery

Summary:
The principal investigator intends to collect human peripheral blood cells from individuals who tested Epstein Barr Virus+ (EBV) and introduce them to immunosuppressed mice. The investigator intends to identify individuals who are at risk for developing a type of cancer known as post-transplant lymphoproliferative disorder (PTLD), and to identify possible treatments. The incidence of PTLD is 1% to 10% of all transplant patients and the mortality rate of those that have developed PTLD is about 87%. The populations of interest are individuals that have undergone organ transplants, and other individuals that are risk of developing EBV-associated lymphomas, such as HIV/AIDS patients. Overarchingly, the investigator hopes that the results of these studies will help lead to better identification of those as risk of developing PTLD and improve treatments and survivability of PTLD.

The Committee **DEFERRED** the biosafety plan

1. **Summary** (Question #2)—Elaborate to include the experimental approach and procedures to be used.
2. **Agent Acquisition** (Question #7)—Provide relevant documentation concerning the use of human subjects for the blood collected from human volunteers (i.e. IRB approval letter).
3. **Exposure Risks** (Question #15b)—Specify the procedures used in reference to the "appropriate care" taken to avoid inadvertent injection of human tumor cells into investigators.
14. **Other Risks** (Question #15c)
    - Indicate what happens to injected mice, including any relevant post mortem procedures and/or sample collection.
    - Indicate any risk for sharps incidents and if any, how the risk will be reduced.
    - Describe any instrument disinfection or transport of specimens from the vivarium back to the laboratory.
    - Indicate whether or not specimens collected from mice will be manipulated in the laboratory and if so, describe these procedures including how potential contamination will be treated.
4. **Medical Surveillance** (Question #17)—Replace "etc." with specific immunizations.
5. **Personnel Signatures** (Question #27)—Acquire the signatures of personnel.
6. **Chair Signature** (Question #29)—Acquire the signature of the department chair.

Total: 9; vote for 9; opposed 0; abstained 0

Type of Research: Biohazards

2005R0048 INCIDENCE, SIGNIFICANCE, AND CONTROL OF LISTERIA MONOCYTOGENES IN THE HOME ENVIRONMENT, Jeffrey T. LeJeune, OARDC Food Animal Health Research Program

Summary:
The principal investigator hypothesizes that dairy farm women of childbearing age are at increased risk for pregnancy loss due to the presence of pathogenic strains of *Listeria monocytogenes* isolated from the dairy farm home environment. The investigator intends to engage in microbiological testing of cattle and the farm home for *Listeria monocytogenes*, survey farmers and their physicians regarding their attitudes and knowledge of farm related zoonoses*, and use guinea pigs as a model to study the pregnancy outcomes after exposure to human pathogenic *Listeria monocytogenes*. Listeria spp. will be cultured from various biological and environmental sources using traditional microbiological methods. The guinea pigs will be challenged via feed that has been inoculated with broth cultures of *Listeria monocytogenes*.

The Committee **DISAPPROVED** the biosafety plan

1. **Summary** (Question #2)
    - Indicate how cultures of *Listeria monocytogenes* will be concentrated, and the precautions to be used during concentration.
    - Indicate how the guinea pigs are to be handled.
    - Indicate how contaminated cages and feed bins will be treated for disinfection.

- Indicated whether the animals will be challenged on a single occasion, or if the agent will be added to feed on numerous occasions.

2. **Potential Risks** (Question #3)
   - Indicate whether or not there is any increased risk to laboratory personnel that are pregnant or are considering pregnancy.
   - Indicate whether or not there is a potential risk of the agent spreading into the surrounding environment from feed dust.
   - Indicate whether or not laboratory personnel will be exposed to the spiked feed source, and any risks associated with such exposure.
3. **Agent Acquisition** (Question #7)—Provide details regarding reception of the organism from off-site locations.
4. **Agent Maintenance** (Question #8)—Provide a "yes" or "no" response for "room".
5. **Personal Protective Equipment** (Question #10)—Indicate the personal protective equipment that will be used for sample collection from cattle and/or home.
6. **Biohazards Transport** (Question #12)—Describe the transport conditions for samples collected from cattle and/or home, contaminated bedding and carcasses to the incinerator.
7. **Waste Disposal** (Question #13)—Indicate how contaminated items from the BSL-2 hood will be handled and disinfected prior to transport to the autoclave and incinerator.
8. **Bloodborne Pathogen Compliance** (Question #14)
   - Indicate how the human fecal samples will be obtained and transported to the laboratory.
   - Indicate whether or not this protocol has IRB approval for the use of human fecal samples.*
9. **Other Risks to Humans** (Question #15c)
   - Indicate whether or not the challenged guinea pigs are pregnant and if so the likelihood of the fetuses to be aborted.
   - Indicate whether or not there is an increased risk to laboratory personnel from exposure to aborted fetuses.
10. **Carcass Disposal** (Question #15d)—Indicate how the carcasses will be transported from the animal room to the incinerator.
11. **Bedding Disposal** (Question #15e)—Indicate how the bedding will be transported from the animal room to the incinerator.
12. **Medical Surveillance** (Question #17)—Ensure that all laboratory personnel have current Occupation Health Registry Questionnaires on file, and participate in a medical surveillance program.
13. **Spill Management** (Question #19)—Specify concentration of bleach.
14. **Personal Protective Equipment** (Question #24)—Indicate the use of respiratory protection when working with animals.

***NOTE:** Survey work and research involving human subjects requires IRB approval prior to initiation. Please contact Peggy Mihalko, Biomedical IRB Administrator at 614-688-7920, or mihalko.1@osu.edu.

Total: 8; vote for 8; opposed 0; abstained 0

Type of Research: Biohazards

BIOHAZARDS APPROVAL VIA ELECTRONIC BALLOT

2005R0040 COMPOUNDS IN IMMUNE ENHANCEMENT, John F. Sheridan, Oral Biology

Summary:
The principal investigator intends engage in research to determine if an orally administered product affects the immune response to viral infection, and if it enhances survival to an influenza viral infection. Mice will be fed the propriety substance for one-month. After the one-month feeding period, the mice will be anesthetized and infected via nasal instillation with a solution of saline and influenza APR/8. After infection, the mice will be sacrificed via compressed CO_2 asphyxiation in a vivarium. The lungs and spleen will be excised in the vivarium and placed into tissue culture media and will then be transported to the laboratory.

Approved via electronic ballot on June 13, 2005

Total: 5; vote for 5; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Biohazards

2005R0053 INTERSPECIES TRANSMISSION OF INFLUENZA A VIRUS, Yehia M. Saif, OARDC Food Animal Health Research Program

Summary:
The principal investigator intends to engage in a series of experiments to identify the molecular attributes that allow influenza viruses to spread from one species to another. The investigator has isolated two H_3N_2 influenza A viruses from turkey breeder flocks in Ohio and Illinois. The investigator will sequence part of the viral genome before and after interspecies transmission to pinpoint molecular markers that allow the virus to cross the species barrier. Results of this research would have the potential to allow for the determination of which influenza viruses are in circulation that have the potential to spread across species barriers. This would allow for the development of better prevention and control strategies.

Approved via electronic ballot on June 22, 2005

Total: 5; vote for 5; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Biohazards

PROTOCOLS APPROVED ADMINISTRATIVELY

1991R0051 CLONING AND BACULOVIRUS EXPRESSION OF ROTAVIRUS GENES, Linda J. Saif, OARDC Food Animal Health Research Program

Administratively approved on June 29, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA/Biohazards

1999R0031 INITIATION OF HSV DNA REPLICATION: UL9 INTERACTION, Deborah S. Parris, Molecular Virology, Immunology, and Medical Genetics

Administratively approved on June 13, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA/Biohazards

2005R0009 MICROBIOLOGICAL SAFETY OF FOODS OF ANIMAL ORIGIN, Jeff LeJeune, OARDC Food Animal Health Research Program

Administratively approved on June 8, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA/Biohazards

2005R0012 FUNCTIONAL INTERPLAY BETWEEN SARCOLIPIN AND PHOSPHOLAMBAN IN SR CALCIUM HOMEOSTASIS, Gopal J. Babu, Physiology and Cell Biology

Administratively approved on July 6, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA/Biohazards

2005R0019 INFECTIOUS BURSAL DISEASE VIRUS INFECTION STUDIES, Daral J. Jackwood, OARDC Food Animal Health Research Program

Administratively approved on June 6, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2005R0033 ESTABLISHING STABLE CELL LINES EXPRESSING GLYCOSYLTRANSFERASES, Allan J. Yates, Pathology

Administratively approved on June 8, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA/Biohazards

2005R0037 IN VIVO GENE DELIVERY TO GUINEA PIG CHONDROCYTES BY SELECT VIRUS VECTORS, Alicia L. Bertone, Veterinary Clinical Sciences

Administratively approved on June 26, 2005

Biosafety Level: BSL-2
Type of Research: Animal Gene Transfer

2005R0047 CAMPYLOBACTER ECOLOGY, TRANSMISSION, AND PREVALENCE IN CHICKENS AND TURKEYS, Teresa Y. Morishita, Veterinary Preventative Medicine

Administratively approved on June 27, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

ANNUAL REVIEWS APPROVED ADMINSTRATIVELY

1999R0074 PEPTIDE DEFORMYLASE: MECHANISM AND INHIBITOR DESIGN, Dehua Pei, Chemistry

Administratively approved on June 22, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2000R0002 REGULATION OF GENE EXPRESSION DURING ORGANOGENESIS, Helen M. Chamberlin, Molecular Genetics

Administratively approved on June 8, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2000R0015 METABOLIC ENGINEERING OF FLAVONOID BIOSYNTHESIS, Erich Grotewold, Plant Cell & Molecular Biology

Administratively approved on June 2, 2005

Biosafety Level: BSL-1 / BSL-1-P
Type of Research: Recombinant DNA

2000R0017 ROLE OF CHROMATIN REMODELERS IN B AND T CELL DEVELOPMENT, Said Sif, Molecular & Cellular Biochemistry

Administratively approved on June 7, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA

2000R0048 THE ROLE OF P75 SIGNALING IN APOPTOSIS OF NEURONS FOLLOWING INJURY IN VIVO, Sung O. Yoon, Molecular & Cellular Biochemistry

Administratively approved on June 30, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2000R0049 MOLECULAR MECHANISMS OF HTLV-1 INFECTION AND DISEASE, Michael D. Lairmore, Veterinary Biosciences

Administratively approved on June 29, 2005

Biosafety Level: BSL-3
Type of Research: Biohazards

2001R0002 PLANT TRANSCRIPTIONAL ACTIVATION MECHANISMS AND THE GENES CONTROLLED IN RESPONSE TO ENVIRONMENTAL STIMULI, Eric J. Stockinger, Horticulture & Crop Science

Administratively approved on July 6, 2005

Biosafety Level: BSL-1 / BSL-1-P
Type of Research: Recombinant DNA

2001R0004 AN INTEGRATIVE APPROACH TO STUDY VIROID MOVEMENT, Biao Ding, Plant Cell & Molecular Biology

Administratively approved on June 7, 2005

Biosafety Level: BSL-2 / BSL-2-P
Type of Research: Recombinant DNA

2001R0027 ABERRANT DNA METHYLATION IN ACUTE MYELOID LEUKEMIA, Christoph Plass, Molecular Virology, Immunology & Medical Genetics

Administratively approved on June 23, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2002R0044 METABOLISM AND MOBILIZATION OF CARBON AND NITROGEN IN SOYBEAN NODULES, John G. Streeter, Horticulture & Crop Science

Administratively approved on July 7, 2005

Biosafety Level: BSL-1 / BSL-1-P
Type of Research: Recombinant DNA

2002R0051 INVESTIGATION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES, Jiyan Ma, Molecular & Cellular Biochemistry

Administratively approved on July 5, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA

2002R0054 TRANSIENT KINETIC AND DYNAMICAL STUDIES OF A LESION BYPASS DNA

POLYMERASE, Zucai Suo, Biochemistry

Administratively approved on June 6, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2002R0055 URACIL-DNA GLYCOSYLASE: A NOVEL TARGET FOR HIV-1 THERAPY, Marshall V. Williams, Molecular Virology, Immunology & Medical Genetics

Administratively approved on June 9, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2002R0057 STRUCTURAL STUDIES OF RECA-DNA COMPLEXES, Charles E. Bell, Molecular & Cellular Biochemistry

Administratively approved on June 16, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2002R0059 HUMAN BLOOD, TISSUE, AND RANDOM SOURCE MATERIALS, Christoph Plass, Molecular Virology, Immunology & Medical Genetics

Administratively approved on June 23, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2002R0068 IMMUNE DISEASE RESEARCH, Daniel J. Birmingham, Nephrology

Administratively approved on June 30, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2002R0069 IMMUNE DISEASE RESEARCH, Bradley H. Rovin, Internal Medicine

Administratively approved on July 5, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA

2002R0086 REGULATION OF APOPTOSIS IN BREAST CANCER CELLS, Andrea I. Doseff, Pulmonary/Critical Care

Administratively approved on June 12, 2005

Biosafety Level: BSL-2

Type of Research: Recombinant DNA

2002R0087 REGULATION OF THE APOPTOTIC PATHWAY BY TH1/TH2 CYTOKINES, Andrea I. Doseff, Pulmonary/Critical Care

Administratively approved on June 12, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA

2003R0039 RECOMBINANT DNA AND BIOHAZARD SAFE PRACTICE FOR THE GUNN LABORATORIES (BSL-2), John S. Gunn, Molecular Virology, Immunology & Medical Genetics

Administratively approved on June 7, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA/Biohazards

2003R0040 RECOMBINANT DNA AND BIOHAZARD SAFE PRACTICE FOR THE GUNN LABORATORIES (BSL-3), John S. Gunn, Molecular Virology, Immunology & Medical Genetics

Administratively approved on June 7, 2005

Biosafety Level: BSL-3
Type of Research: Recombinant DNA/Biohazards

2004R0030 BUILDING BLOCKS OF A BIOCHEMICAL CPU BASED ON DNA TRANSCRIPTION LOGIC, Mario Lauria, Computer Science & Engineering

Administratively approved on July 7, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

AMENDMENTS APPROVED ADMINSTRATIVELY

2000R0048 THE ROLE OF P75 SIGNALING IN APOPTOSIS OF NEURONS FOLLOWING INJURY IN VIVO, Sung O. Yoon, Molecular & Cellular Biochemistry

Administratively approved on June 30, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2001R0036 BIOFILM MECHANISMS IN LISTERIA MONOCYTOGENES, Hua Wang, Food Science & Technology

Administratively approved on June 14, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2003R0019 STUDIES OF HERPES SIMPLEX VIRUS TYPE 1 AND HUMAN CYTOMEGALOVIRUS BIOLOGY AND PATHOGENESIS, Joanne Trgovcich, Pathology

Administratively approved on June 21, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA

2003R0045 MYCOBACTERIUM TUBERCULOSIS STUDIES, Joanne Turner, Internal Medicine

Administratively approved on June 14, 2005

Biosafety Level: BSL-3
Type of Research: Biohazards

EXEMPT PROTOCOLS

2005R0049 THE EPSTEIN-BARR VIRUS ENCODED DUTPASE INDUCES IMMUNE DYSFUNCTION, Marshall V. Williams, Molecular Virology, Immunology & Medical Genetics

Determined exempt on June 9, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2005R0050 URACIL-DNA GLYCOSYLASE: ROLE IN INDUCING IMMUNE DYSREGULATION, Marshall V. Williams, Molecular Virology, Immunology & Medical Genetics

Determined exempt on June 9, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

PENDING PROTOCOLS

2005R0042 ROLE OF ANTIOXIDANTS IN INFLUENZA A VIRAL INFECTION OF LUNG EPITHELIAL CELLS IN CULTURE, Kalpana Ghoshal, Molecular & Cellular Biochemistry

Date of Last Communication: June 21, 2005

Type of Research: Recombinant DNA/Biohazards

MINUTES
Institutional Biosafety Committee
8 September 2005

Attendees	Subcommittee rDNA	Bio	HGT	Members Present	Affiliation
X		X		Brian Ahmer	Biological Sciences
X	X			Angel Arroyo- Rodriguez	Ohio EPA
X	X			David Coplin (co-chair)	Plant Pathology
NO		X	X	Lawrence A. Capitini	ULAR
NO	X	X	X	Long-Sheng Chang	Pediatrics
X	X			Biao Ding	Plant Bio / Biotech
X	X			Jyan-Chyun Jang	Horticulture & Crop Science
X		X		Joseph J. Kowalski	Veterinary Clinical Science
X	X	X	X	Cecil Smith (IBO)	EHS
NO		X		Jami St. Clair	Columbus PD
NO		X		William Swoager	Microbiology
NO		X		Kenneth Theil	OARDC
X			X	Marshall Williams (co-chair)	MVIMG
				Responsible Research Practices	
X				Adam McClintock—IBC Coordinator	
X				John Yocom—ILACUC Administrator	
X				Amanda Trainor—ILACUC QIS	

The meeting was called to order at 10:07 am in Room 422 of the Research Foundation Building, and was adjourned at 10:37 am. The Committee retained quorum for the entire meeting.

1. **Approval of Minutes**
   The Committee approved the 11 August 2005 minutes unanimously.

   Total: 8; vote for 8; opposed 0; abstained 0

2. **Draft of Investigator Notice of Non-Compliance**
   The Committee reviewed a notice of non-compliance that was drafted by the co-chairs of the IBC. The letter will be issued to investigators when Annual Review materials are not received in the Office of Responsible Research Practices sixty days after the initial request has been made. The letter gives instructions on the steps necessary to remain compliant and outlines the consequences of non-compliance. A hardcopy of the letter will be forwarded to investigators with signatures, signature stamps, or electronic signatures of each of the three co-chairs. The Committee voted unanimously to adopt the letter; however no timeline was discussed for implementation.

   Total: 8; vote for 8; opposed 0; abstained 0

RECOMBINANT DNA NEW PROTOCOL SUBMISSIONS

1999R0048 ANALYSIS OF POST-TRANSCRIPTIONAL CONTROL MECHANISMS IN RETROVIRUS SYSTEMS, Kathleen Boris-Lawrie, Veterinary Biosciences

Summary:
The principal investigator intends to identify and characterize post-transcriptional regulatory mechanisms in the cell that are involved in gene expression. Specifically, the investigator intends to characterize the biochemical mechanisms of a new post-transcriptional control element that has been discovered in selected retroviruses and cellular proto-oncogene RNA. The investigator will also explore the related issue of post-transcriptional control elements in virus replication, and the results will be used to enhance translation in lentiviral vector systems.

The Committee **APPROVED** the biosafety plan

NOTE:

1. Please reference disinfectant as "Chlorine 1% for 10 minutes" in question #27.

Total: 8; vote for 8; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Recombinant DNA, Biohazards

1999R0066 DETECTION, CHARACTERIZATION, PATHOGENESIS AND IMMUNITY TO ENTERIC VIRUSES OF SWINE AND CATTLE, Linda J. Saif, OARDC—Food Animal Health Research Program

Summary:
New enteric and respiratory viral strains are being identified or emerging, and the current failure of several viral vaccines requires development of new tests for their diagnosis. The principal investigator intends to engage in research using gnotobiotic pigs and calves, colostrums-deprived claves and conventional seronegative pigs as models to study the detection, isolation and antigenic and molecular characterizations of enteric and respiratory viral strains. Animal studies will focus on disease pathogenesis and immunity. The results of this line of research could aid in the development of more effective viral vaccines, and prevention and control methods of enteric and respiratory virus in susceptible animal host species.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Potential Risks** (Question #3)
   - Indicate that the cDNA of full length human enteric/respiratory coronaviruses cannot be classified as RG-1. The entire range of risks of a cDNA isolate cannot be known with certainty.
   - Provide evidence that deletions and/or mutations of animal pathogens do not extend the host ranges.

Total: 8; vote for 8; opposed 0; abstained 0

Biosafety Level: BSL-2 / ABSL-2
Type of Research: Recombinant DNA, Biohazards

2005R0060 MYOFIBRILLAR DETERMINANTS OF STRIATED MUSCLE RELAXATION, Jack A. Rall, Physiology & Cell Biology

Summary:
The principal investigator intends to study the role of cardiac troponin C in cardiac muscle relaxation. The investigator will construct recombinant adenoviruses carrying the wild-type and mutant human cardiac troponin C. Then, either the wildtype or mutated troponin C DNA will be introduced to the troponin C gene in adult rat ventricular myocytes. Contraction and relaxation will be observed to determine molecular mechanisms involved in cardiac contraction and relaxation. The results have the potential to help treat cardiac disorders.

The Committee **APPROVED** the biosafety plan

NOTE:

1. Please indicate in question #21 that inter-laboratory and intra-laboratory transport of the biohazardous agents will be in sealed non-breakable containers.
2. Please indicate in questions #25 and #34 that training will include the *NIH Guidelines for Research Involving Recombinant DNA Molecules*.
3. Please indicate in question #28 that larges spills [>150mL] will be contained with absorbent material. Sodium hypochlorite 10% will be added to the absorbent material for 30 minutes, and waste will be disposed of in biohazards waste stream.

Total: 8; vote for 8; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Recombinant DNA, Biohazards

RECOMBINANT DNA AMENDMENTS

1991R0051 CLONING AND BACULOVIRUS EXPRESSION OF ROTAVIRUS GENES, Linda J. Saif, OARDC—Food Animal Health Research Program

Summary:
The principal investigator has several active protocols under which similar lines of research are being conducted involving human rotaviruses, enteric calciviruses and enteric coronaviruses. The investigator is proposing to combine four related protocols into a single protocol. The IBC has reviewed the four protocols and feels that the request is appropriate.

The Committee **APPROVED** the amendment to the biosafety plan

Total: 8; vote for 8; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Recombinant DNA, Biohazards

1999R0066 DETECTION, CHARACTERIZATION, PATHOGENESIS AND IMMUNITY TO ENTERIC VIRUSES OF SWINE AND CATTLE, Linda J. Saif, OARDC Food Animal Health Research Program

Summary:
The principal investigator has several active protocols under which similar lines of research are being conducted involving the detection, pathogenesis and immunity to enteric and respiratory viruses in swine and cattle. The investigator is proposing to combine four related protocols into a single protocol. The IBC has reviewed the four protocols and feels that the request is appropriate pending the receipt of modifications to the umbrella protocol (#1999R0066), which was also reviewed at the current IBC meeting.

The Committee **APPROVED** the amendment to the biosafety plan

NOTE:
1. Approval of the amendment request is contingent upon the approval of the modifications to the protocol itself.

Total: 8; vote for 8; opposed 0; abstained 0

Biosafety Level: BSL-2 / ABSL-2
Type of Research: Recombinant DNA, Biohazards

BIOHAZARDS NEW PROTOCOLS

2005R0061 INHIBITION OF RESPIRATORY SYNCYTIAL VIRUS BY LEFLUNOMIDE IN COTTON RATS. W. James Waldman, Pathology

Summary:
The principal investigator intends to explore the efficacy of leflunomide in the treatment of respiratory syncytial virus (RSV). Leflunomide is an anti-inflammatory agent that has been approved for treatment of rheumatoid arthritis, and it was discovered several years ago to have strong antiviral activity against certain types of virus. Recently it has been discovered that leflunomide inhibits the production of RSV. The investigator will test the ability of leflunomide to inhibit the production and dissemination of RSV in infected cotton rats, and evaluate the drug's ability to reduce inflammatory lung injury caused by RSV. Leflunomide, which can be administered orally and has been approved for treatment in humans, could easily be translated into clinical treatment for RSV pending the results of the study.

The Committee **APPROVED** the biosafety plan

NOTE:
1. Specify in question #19 that in the case of large spills, contaminated clothing and personal protective equipment will be removed and disposed of prior to seeking medical attention.

Total: 8; vote for 8; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Biohazards

PROTOCOLS APPROVED ADMINISTRATIVELY

2002R0080 GENE EXPRESSION PROFILES OF HUMAN CARTILAGE AND BONE, Alicia

Bertone, Veterinary Biosciences

Date of Determination: August 23, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2002R0081 GENE EXPRESSION PROFILES OF ARTHRITIC HUMAN CARTILAGE AND BONE, Alicia Bertone, Veterinary Biosciences

Date of Determination: August 23, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2002R0085 GUIDELINES FOR WORKING WITH HUMAN WHITE CELLS AND BRONCHALVEOLAR CELLS IN THE LABORATORY, Larry Schlesinger, Internal Medicine

Date of Determination: May 20, 2003—not previously reported to the Committee

Biosafety Level: BSL-2
Type of Research: Recombinant DNA, Biohazards

2003R0010 MONITORING THE ELECTRICAL ACTIVITY AT THE SURFACE OF THE CORTEX OF THE BRAIN, David Q. Beversdorf, Neurology

Date of Determination: August 23, 2005

Biosafety Level: ABSL-2
Type of Research: Biohazards

2005R0043 ONCOLYTIC HSV TARGETING TO THE P16 TUMOR SUPPRESSOR PATHWAY, E. Antonio Chiocca, Neurosurgery

Date of Determination: September 1, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA, Biohazards

2005R0051 INVESTIGATION OF DNA MEHYLTRANSFERASE 3B IN HEMATOPOIETIC CELLS, Laura Rush, Veterinary Biosciences

Date of Determination: August 29, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2005R0055 BONE METASTASIS MODELS IN THE NUDE MOUSE AND RAT, Tom Rosol, Veterinary Biosciences

Date of Determination: August 29, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2005R0056 MYCOBACTERIA AND MACROPHAGE INTERACTIONS, William P. LaFuse, Molecular Virology, Immunology & Molecular Genetics

Date of Determination: August 29, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA, Biohazards

2005R0065 EFFECTS OF 1.25$(OH)_2D_3$, AND PIROXICAM IN COMBINATION WITH MEDIUM CHAIN TRIGLYCERIDES ON CANINE URINARY BLADDER CANCER: A MOUSE MODEL STUDY, Nongnuch Inpanbutr, Veterinary Biosciences

Date of Determination: August 22, 2005

Biosafety Level: BSL-1
Type of Research: Biohazards

ANNUAL REVIEWS APPROVED ADMINSTRATIVELY

2000R0052 RAPID GENERATION OF GENETICALLY MODIFIED SKIN MODELS, Donna F. Kusewitt, Veterinary Biosciences

Date of Determination: August 29, 2005

Biosafety Level: n/a (protocol involves chemical hazards, BSL not assigned)
Type of Research: Biohazards

2002R0038 ENGINEERED HEMATOPOIETIC CELL SELF-RENEWAL AND DEATH, Larry C. Lasky, Pathology

Date of Determination: August 22, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA, Biohazards

2002R0050 RESEARCH PROGRAM ON EHRLICHIA CANIS ANTIGENS, Yasuko Rikihisa, Veterinary Biosciences

Date of Determination: August 17, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2002R0052 OVEREXPRESSION OF CALCIUM TRANSPORT PROTEINS USING ADENOVIRAL VECTORS IN CARDIOMYOCYTES, Muthu Periasamy, Physiology & Cell Biology

Date of Determination: August 29, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA, Biohazards

2002R0067 ESCHERICHIA COLI RESEARCH, Elliot D. Crouser, Internal Medicine

Date of Determination: August 15, 2005

Biosafety Level: BSL-1
Type of Research: Biohazards

2003R0010 MONITORING THE ELECTRICAL ACTIVITY AT THE SURFACE OF THE CORTEX OF THE BRAIN, David Q. Beversdorf, Neurology

Date of Determination: September 1, 2005

Biosafety Level: ABSL-2
Type of Research: Biohazards

2003R0041 MANIPULATION OF PLANT SIGNALING BY BACTERIAL EFFECTOR PROTEINS, David Mackey, Horticulture & Crop Science

Date of Determination: August 9, 2005

Biosafety Level: BSL-1P
Type of Research: Recombinant DNA

2003R0042 FUNCTIONAL GENOMICS OF PANTOEA STEWARTII, David L. Coplin, Plant Pathology

Date of Determination: August 15, 2005

Biosafety Level: BSL-1P
Type of Research: Recombinant DNA

2004R0029 MOLECULAR AND CELLULAR BIOLOGY OF TRYPANOSOMATID PROTOZOA, Bradford S. McGwire, Internal Medicine

Date of Determination: August 22, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA, Biohazards

2004R0034 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, Yiqing Xu, Hematology & Oncology

Date of Determination: August 29, 2005

Biosafety Level: BSL-2
Type of Research: Human Gene Transfer

2004R0041 HTLV-1 TRANSFORMED T CELL LINES, Stefan Niewiesk, Veterinary Bioscience

Date of Determination: August 15, 2005

Biosafety Level: BSL-1
Type of Research: Biohazards

AMENDMENTS PPROVED ADMINSTRATIVELY

2002R0083 GENETIC, MOLECULAR, AND DEVELOPMENTAL ANALYSIS OF VARIATION IN TOMATO FRUIT MORPHOLOGY, Esther K. Vanderknaap, Horticulture

Date of Determination: September 1, 2005

Biosafety Level: BSL-1 / BSL-1P
Type of Research: Recombinant DNA

2003R0041 MANIPULATION OF PLANT SIGNALING BY BACTERIAL EFFECTOR PROTEINS, David Mackey, Horticulture & Crop Science

Date of Determination: August 9, 2005

Biosafety Level: BSL-1P
Type of Research: Recombinant DNA

EXEMPT PROTOCOLS APPROVED ADMINISTRATIVELY

2003R0033 HOMEOSTATIC CONTROL OF FCR-MEDIATED MACROPHAGE FUNCTIONS, Susheela Tridandapani, Internal Medicine

Date of Determination: August 23, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2005R0013 MECHANISMS OF BLASTIC TRANSFORMATION OF CHRONIC MYELOGENOUS LEUKEMIA (CML): ROLE OF RNA BINDING PROTEINS, Danilo Perotti, Molecular Virology, Immunology & Medical Genetics

Date of Determination: August 22, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA, Biohazards

2005R0062 STRUCTURE AND GENESIS OF TAU FILAMENTS, Jeff A. Kuret, Molecular & Cellular Biochemistry

Date of Determination: August 10, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2005R0063 TRIGGERS AND ENHNACERS OF TAU FIBIRILLIZATION, Jeff A. Kuret, Molecular & Cellular Biochemistry

Date of Determination: August 15, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

PENDING PROTOCOLS

1999R0058 STUDIES ON INFECTIOUS BURSAL DISEASE VIRUS, Yehia M. Saif, OARDC Food Animal Health Research Program

Date of Last Communication: August 18, 2005

Type of Research: Biohazards

MINUTES
Institutional Biosafety Committee
11 August 2005

Attendance	Members Present	Affiliation
X	Brian Ahmer	Biological Sciences
NO	Angel Arroyo- Rodriguez	Ohio EPA
X	David Coplin (co-chair)	Plant Pathology
NO	Lawrence A. Capitini	ULAR
NO	Long-Sheng Chang	Pediatrics
NO	Biao Ding	Plant Biology/ Biotechnology
X	Jyan-Chyun Jang	Horticulture and Crop Sciences
X	Joseph J. Kowalski	Veterinary Clinical Sciences
X	Stefan Niewiesk	Veterinary Biological Sciences
X	Cecil Smith (IBO)	EHS
X	Jami St. Clair	Columbus Police Department
X	William Swoager	Microbiology
X	Kenneth Theil	OARDC
X	Marshall Williams (co-chair)	MVIMG

Non-Voting Members Present (none)

Office of Responsible Research Practices

X	Adam McClintock—Biosafety Coordinator

The meeting was called to order at 10:00 am in Room 422 Research Foundation Building, and was adjourned at 11:19 am. The Committee retained quorum for the entire meeting.

Late Arrivals:

1. Brian Ahmer 10:03 am
2. J.C. Jang 10:16 am

Early Departures:

1. Dave Coplin 11:03 am
2. J.C. Jang 11:03 am

1. **Approval of Minutes**
   The Committee approved the 14 July 2005 IBC minutes unanimously.

   Total: 8; vote for 8; opposed 0; abstained 0

2. **NABC Recommendations**
   The NABC has recently released a draft of its Recommendations for Management Practices for Field Trials with Transgenic Plants, and the Director of OARDC is our representative to NABC and he has requested that the IBC comment on the recommendations. Currently, approval for field testing of transgenic plants must come from various federal agencies. Historically the IBC has not been involved in oversight of such field trials and has reviewed very few of them. PIs are

therefore encouraged to deal with the agencies directly and inform the IBC of their decisions. Different agencies may be involved depending on the particular transgenes, plant or method of construction. Plants that are noxious weeds, exotic to the US or those constructed by the use of plant pathogens must receive approval from APHIS; those that have pesticidal properties must receive EPA approval, and those that are used as components of food products or to produce pharmaceuticals must receive FDA approval. Many other plants have fallen between the cracks. The new NABC Recommendations urge that a greater role in oversight be taken at the institutional level for all non-commercially released plants that have not received federal approval. A major drawback to such oversight at the institutional level at OSU is the lack of the proper regulatory framework and expertise in field releases.

The IBC was concerned at the institutional level with the current absence of an oversight-committee with the proper expertise to review such protocols. The consensus of the Committee is that if the institution is to review protocols for field testing of transgenic plants that a separate oversight committee should be formed. The current IBC lacks the expertise to review such protocols required by the NABC recommendation, and the addition of an IBC subcommittee to compensate for the lack of expertise would create a number of problems. Primarily if these members were added to the current NIH-approved IBC then we would have a big problem in maintaining a quorum at meetings. This is because the materials reviewed by the current IBC would be of little interest to the new members. The best solution would be to form a completely separate IBC-F that conforms to the NABC recommendations, but not the NIH Guidelines. This could be under the aegis of the ORRP and include the Institutional Biosafety Officer and the current plant molecular biology experts on the IBC.

3. **Process Statement**
The Committee continued discussion on the process to be used for investigators who have been unresponsive to requests for materials. IBC procedures dated July 24, 1995 were distributed to the Committee prior to the meeting, with Section II "PROCEDURES TO BE TAKEN TO MONITOR RECOMBINANT DNA RESEARCH AND ASSURE COMPLIANCE" being of main interest. Section II of this document outlined procedures to ensure compliance, used by the IBC prior to the realignment of the IBC into the subcommittees. These procedures include a series of notification and reminder letters, a request for the principal investigator to present an explanation before the IBC, and steps to contact responsible University officials.

The Committee suggested the utilization of two separate categories of notification letters. One category will be targeted at investigators engaging in research involving biohazardous agents, while the second will be sent to investigators engaging in rDNA research not involving biohazards. While there are numerous checks and balances in place to ensure compliance for research involving biohazardous agents, no such mechanism currently exists for purely rDNA research. It has been discussed at prior Committee meetings that reminder notifications will be forwarded to responsible officials such as department chairs, and college deans, however the Committee suggests that a more effective route may be a reminder that funding can be withheld if all approvals are not in place at the time of award. The Committee co-chairs agreed to draft these notification letters prior to the September 8th Committee meeting.

RECOMBINANT DNA DEFERRED PROTOCOLS

2002R0089 BIOCHEMISTRY OF TRNA EDITING, Juan D. Alfonzo, Microbiology

Discussion:

The Committee reviewed the modifications and feel that the principal investigator has addressed all major concerns. Minor editorial concerns are noted below.

The Committee **APPROVED** the biosafety plan

NOTE:

1. Spell out *Escherichia coli* in question #2.
2. Indicate in question #31 that the BSC type II-A is in room #411 of the Biological Sciences Building not room #446.
3. Acquire personnel signatures in question #36.

Total: 10; vote for 10; opposed 0; abstained 0

Biosafety Level: BSL-1
Type of Research: Recombinant DNA/Biohazards

2005R0054 A FUNCTIONAL AND COMPARATIVE ANALYSIS OF THE CLOSTRIDIUM THEROCELLUM AND RUMINOCCOCCUS ALBUS GENOMES: UNDERSTANDING THE CELLULOSOME PARADIGM OF PLANT BIOMASS CONVERSION, Mark Morrison, Animal Sciences

Discussion:
The Committee reviewed the modifications and feel that the principal investigator has addressed all major concerns. Minor concerns are noted below.

The Committee **APPROVED** the biosafety plan

NOTE:

1. The Committee recommends a contact time of at least two minutes for disinfection and spill management.

Total: 10; vote for 10; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Recombinant DNA/Biohazards

RECOMBINANT DNA NEW PROTOCOL SUBMISSIONS

2005R0043 ONCOLYTIC HSV TARGETING TO THE P16 TUMOR SUPPRESSOR PATHWAY, E. Antonio Chiocca, Neurosurgery

Summary:
The principal investigator intends to use several recombinant strains of herpes simplex virus type-1 (HSV-1) vectors targeting the p16 tumor suppressor pathways in attempts to selectively enter and kill brain tumor cells. Such brain cancers are currently incurable and typically result in death around one year after diagnosis. The investigator hopes to contribute to additional treatment options for these brain cancers. In the past 35 plus years, only two new chemotherapy drugs have received Food and Drug Administration approval. If successful, the investigator hopes to further this line of research in clinical trials.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Summary** (Question #2)
   - Indicate how the MGH2 (rHSVQ1-P4502B1-CE), rQNestin34.5, and rHSVQ1 vectors will target the p16 pathways.
   - Describe what tumor cells that will be injected into mice or indicate the animal model to be used.
2. **Host Systems** (Question #7)—Clarify the statement that Vero cells will be used as a host, while "mice and rats" are listed under question #24a. If mice and rats are to be used, please provide a description of the work in the summary in question #2.
3. **Risk Group** (Question #13)—Indicate that the recombinant herpes simplex virus type-1 (HSV-1) vectors are Risk Group 2 agents. Although attenuated and less virulent, the HSV-1 vectors are not replication deficient.
4. **Consequences of Exposure** (Question #14)
   - Indicate how the attenuated HSV-1 will be grown in the Vero, since it is stated that the attenuated virus can replicate efficiently only in cancer cells.
   - Correct the last sentence to read "Intracranial injection of similar vector (G207, up to 10^7 PFU) did not exhibit any marked toxicity in phase I clinical trials."
5. **Agent Acquisition** (Question #15)—Indicate if and how the recombinant HSV-1 vectors will be propagated.
6. **Biohazards Transport** (Question #21)—Indicate how materials will be transported between laboratories.
7. **Animal Carcass Disposal** (Question #24d)—Indicate that animal carcasses will be treated as infectious waste and will be placed in a Biohazard burn box as per university policy.
8. **Animal Bedding Disposal** (Question #24e) —Indicate that animal bedding will be treated as infectious waste and will be placed in a Biohazard burn box as per university policy.
9. **Animal Waste Disposal** (Question #24f) —Indicate that animal waste will be treated as infectious waste and will be placed in a Biohazard burn box as per university policy.
10. **Personnel Training** (Question #25)—Indicate the personnel training will include biosafety level 2 practices and procedures and review of *NIH Guidelines for Research Involving Recombinant DNA Molecules*.
11. **Spill Management** (Question #28)—Incorporate spill management procedures. An example of procedures is provided below.

    Small spills will be contained using plastic-backed absorbable hood liner, paper towels, or gauze. Contaminated absorbent materials will be transferred to a lined red biohazard bag and autoclaved. The contaminated surface will be treated with a 1:10 dilution of bleach [sodium hypochlorite at 5,000 ppm], STERIS LpH se, or 70% Etoh contact time of ten minutes.

    Large spills will be contained by placing a barrier of paper towels around the spill after warning any other laboratory personnel in the immediate vicinity. The liquid will be absorbed with additional paper towels or granular absorbable material. The Principal Investigator should be contacted as soon as possible after the spill is contained. Laboratory personnel wearing appropriate personal protective equipment including respiratory protection will transfer the contaminated solid materials into a lined red biohazard bag for autoclaving. All contaminated surfaces

will be saturated with a 1:10 dilution of bleach in water, STERIS LpH se or 70% Etoh. Aerosol formation should be kept to the absolute minimum by not spraying water or disinfectant directly onto the spill or by not using a sponge or wringing out paper towels during the cleanup. Any laboratory personnel with exposure to the agent will notify OSU Employee Health Services after the spill has been contained and any contaminated personal protective equipment and clothing has been removed. Contaminated personal protective equipment and clothing will be placed into a red biohazardous bag and autoclaved prior to being laundered or disposal.

12. **Biosafety Cabinet** (Question #30a)—Specify type of biosafety cabinet.

Total: 10; vote for 10; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Recombinant DNA/Biohazards

2005R0051 INVESTIGATION OF DNA MEHYLTRANSFERASE 3B IN HEMATOPOIETIC CELLS, Laura J. Rush, Veterinary Biosciences

Summary:
The principal investigator intends to obtain a cloned methyltransferase gene to re-clone it into hematopoietic cells. The specific gene (DNMT3b) is one of the genes responsible for adding methyl groups to cytosines in DNA promoters which leads to inactivation of transcription of the affected gene. The investigator hypothesizes that the over-expression of the methyltransferase genes from a promoter that is expressed only in hematopoietic cells that it will silence tumor suppressor genes in cell cultures and transgenic mice. The investigator anticipates that subsets of the transgenic mice will develop leukemia or lymphoma. The investigator hopes that the results will be useful in determining if mehtylation of specific genes is sufficient for the development of leukemia or lymphoma.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Host Systems** (Question #6)
   - Clarify the constructions.
   - Clarify the origins of replication for the plasmid (does it only have a bacterial origin?).
2. **Vectors & Inserts**(Question #7)
   - Explain why the insert is being re-cloned into the TOPPO pc DNA3.1 vector.
   - Indicate whether or not this only for tissue culture.
   - Indicate if stably transformed tissue culture lines will be selected or if these experiments only involve transient expression.
3. **Exemption Under *NIH Guidelines*** (Question #10)
   - Indicate how the transgenic mice will be produced. Will the Vav/DNMT3b construct will be microinjected into eggs that will be transplanted into female mice.
   - Indicate where the transgenic mice will be housed.
4. **Personnel Training** (Question #24)—Indicate that annual training will include the *NIH Guidelines* and the OSU Biosafety Manual.

Total: 10; vote for 10; opposed 0; abstained 0

Biosafety Level: BSL-1 / BSL-1N
Type of Research: Recombinant DNA

2005R0056 MYCOBACTERIA AND MACROPHAGE INTERACTIONS, William P. LaFuse, Molecular Virology, Immunology & Molecular Genetics

Summary:
Macrophages play a critical role in resistance to intracellular pathogens, and when activated by INF-γ, macrophages increase killing of mycobacterium. Macrophages infected by mycobacterium, however, tend to respond poorly to INF-γ. The principal investigator intends to study the mechanisms by which mycobacterium inhibit gene expression induced by INF-γ in macrophages. The investigator will infect tissue cultures of mouse macrophage cell lines, and mouse peritoneal macrophages with *Mycobacterium avium* and *Mycobacterium tuberculosis* and examine the effect on gene induction and signaling pathways. In addition to investigating the inhibition of gene expression induced by INF-γ in macrophages, the project will also explore the roles of iron metabolism, protein expression involved in iron transport and the expression of the hormone hepcidin, which regulates iron transport within the body.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Genes Used** (Question #6)—Provide examples of the genes of interest referenced as mouse cDNA.
2. **Host Systems** (Question #7)—List cell lines referenced in question #9 as host systems.
3. **Agent Acquisition** (Question #15) Provide a "yes" or "no" response in each check box.
4. **Agent Maintenance** (Question #16) Provide a "yes" or "no" response in each check box.
5. **Personnel Training** (Question #25)—Indicate that training will include the *NIH Guidelines for Research Involving Recombinant DNA Molecules.*
6. **Disinfection** (Question #26)—Indicate the bleach [sodium hypochlorite at a concentration of 5,000-7,500 ppm] will be diluted at 1:10 not 1:100.
7. **Spill Management** (Question #27)—Indicate the bleach [sodium hypochlorite at a concentration of 5,000-7,500 ppm] will be diluted at 1:10 not 1:100.
8. **Biosafety Cabinet** (Question #30a)—Provide the latest date of certification for the Type II BSC. Biosafety cabinets must receive recertification at least every 12 months.
9. **Laboratory Safety Practices** (Question #32)—Generate a spill kit.
10. **Personnel Protective Equipment** (Question #33)—Indicate the specific type of "mask" to be used [type of respiratory protection, i.e. N-95].

Total: 10; vote for 10; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Recombinant DNA/Biohazards

2005R0057 MOLECULAR STUDIES AND INFECTIOUS CLONES OF INFECTIOUS BURSAL DISEASE VIRUSES, Daral J. Jackwood, OARDC-Food Animal Health Research Program

Summary:
The principal investigator intends to create infectious clones of infectious bursal disease virus (IBDV) in order to study the molecular basis for antigenic changes in IBDV. The investigator will create clones of the IBDV genome, make specific nucleotide mutations in the clones and rescue virus in vitro. The rescued virus will be used to vaccinate chickens so that phenotypic changes in their antigenicity can be identified. The vaccinated birds will be challenged with the pathogenic IBDV strains, and then sacrificed. At necropsy, bursa tissue and blood samples will be collected for examination. Although IBDV is Risk Group 1 agent, the work will be conducted using BSL-2 containment to prevent the accidental release of the virus or its clones into the environment.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Genes Used** (Question #6)—Specify the nature of the mutated infectious clones, and indicate if the site-directed mutations might alter either anitigenicity or virulence in a manner that could be of concern to the poultry industry.
2. **Biohazards Transport** (Question #21)—Indicate how the chickens will be transported to the necropsy room after they are euthanized.
3. **Waste Disposal** (Question #22)—Describe how infectious waste will be transported to the autoclave or incinerator.
4. **Personnel Training** (Question #25)—Indicate the training will include the *NIH Guidelines for Research Involving Recombinant DNA Molecules.*
5. **Disinfection** (Question #27)—Describe how Horsfall and Bauer isolation units be decontaminated.
6. **Personnel Training** (Question #34)—Indicate the training will include the *NIH Guidelines for Research Involving Recombinant DNA Molecules.*

Total: 10; vote for 10; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Recombinant DNA/Biohazards

BIOHAZARDS DEFERRED PROTOCOLS

2005R0045 PREDISPOSING FACTORS AND TREATMENT FOR POST-TRANSPLANT LYMPHOPROLIFERATIVE DISORDER, Anne M. VanBuskirk, Surgery

Summary:
The Committee reviewed the modifications and feel that the principal investigator has addressed all concerns.

The Committee **APPROVED** the biosafety plan

Total: 8; vote for 8; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Biohazards

BIOHAZARDS NEW PROTOCOLS

1999R0058 STUDIES ON INFECTIOUS BURSAL DISEASE VIRUS, Yehia M. Saif, OARDC Food Animal Health Research Program

Summary:
Infectious Bursal Disease caused by the RNA virus Infectious Bursal Disease Virus (IBDV), is one of the most economically important diseases infecting chickens and turkeys. The principal investigator intends to characterize isolates of IBDV in search of variant strains. Groups of chickens will be inoculated with uncharacterized strains of IBDV and chickens from the group will be bled and euthanized at various points post-inoculation. After euthanized the birds will be examined for macroscopic and microscopic lesions; and sera will be tested for antibodies. Other groups of chickens will be vaccinated with a known immunogenic type of the virus and then challenged with an unknown immunogenic type. The birds will be examined for clinical signs such as lesions and virus shedding; proper positive and negative controls will be maintained and examined.

The Committee **DEFERRED** the biosafety plan

1. **Potential Risks** (Question #3)
   - Explain why the imported samples of inactivated Infectious Bursal Disease Virus (IBDV) are necessary, and cannot be acquired domestically.
   - Provide a copy of the USDA permit.
   - Indicate the "extraneous agents" for which the U.S samples of IBDV will be examined.
   - References to "biosafety hood" should be replaced with "biosafety cabinet".
2. **Waste Disposal** (Question #13)—Indicate whether or not the autoclaves and incinerator have been certified.
3. **Animal Carcass Disposal** (Question #15d)—Describe how the animal carcasses will be transported to the incinerator.
4. **Animal Waste Disposal** (Question #15f)—Reconcile the statement in this question with the statement in question #2 indicating that all waste will be incinerated.
5. **Personnel Training** (Question #16)—Indicate the specific training sessions that personnel will be required to attend.
6. **Medical Surveillance** (Question #17)—Indicate when the Occupation Health Registry Questionnaires will be completed.
7. **Laboratory Space** (Question #20)—Provide a date for most recent laboratory inspections.
8. **Biosafety Cabinet** (Question #21a)—Specify the type of biosafety cabinet.

Total: 8; vote for 8; opposed 0; abstained 0

Type of Research: Biohazards

1999R0064 ASCARDIA LARVAE MIGRATION ASSOCIATED WITH TRANSOVARIAL TRANSMISSION IN TURKEYS, Teresa Y. Morishita, Veterinary Preventative Medicine

Summary:
The principal investigator did not provide any protocol details, and the Committee has requested a detailed account of the protocol procedures to be used.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Summary** (Question #2)—Provide a detailed description of the protocol procedures to be used.
2. **Biohazard** (Question #5)—List the agents to be used and include reference to zoonotic agents endemic to turkeys.
3. **Agent Acquisition** (Question #7)—Provide shipping details of agents.
4. **Biohazards Transport** (Question #12) —Provide shipping details from off-camps sources.
5. **Animals** (Question #15c)—Provide examples of potential zoonotic agents endemic to turkeys.
6. **Personnel Training** (Question #16)—Indicate that personnel will be trained in the awareness of Salmonella and Campylobacter.
7. **Medical Surveillance** (Question #17)—Ensure that all laboratory personnel will submit an Occupation Health Registry Questionnaire and personnel coming in contact with turkeys will be enrolled in the medical surveillance program for animal handlers.
8. **Disinfection** (Question #18)
   - Indicate whether or not organic material will be removed before disinfectant is applied.
   - Specify a concentration and contact time for sodium hypochlorite.
9. **Spill Management** (Question #19)—Incorporate spill management procedures. An example of procedures is provided below.

   Small spills will be contained using plastic-backed absorbable hood liner, paper towels, or gauze. Contaminated absorbent materials will be transferred to a lined red biohazard bag and autoclaved. The contaminated surface will be treated with a 1:10 dilution of bleach [sodium hypochlorite at 5,000 ppm], or 70% Etoh contact time of ten minutes.

   Large spills will be contained by placing a barrier of paper towels around the spill after warning any other laboratory personnel in the immediate vicinity. The liquid will be absorbed with additional paper towels or granular absorbable material. The Principal Investigator should be contacted as soon as possible after the spill is contained. Laboratory personnel wearing appropriate personal protective equipment including respiratory protection will transfer the contaminated solid materials into a lined red biohazard bag for autoclaving. All contaminated surfaces will be saturated with a 1:10 dilution of bleach in water, or 70% Etoh. Aerosol formation should be kept to the absolute minimum by not spraying water or disinfectant directly onto the spill or by not using a sponge or wringing out paper towels during the cleanup. Any laboratory personnel with exposure to the agent will notify OSU Employee Health Services after the spill has been contained and any contaminated personal protective equipment and clothing has been removed. Contaminated personal protective equipment and clothing will be placed into a red biohazardous bag and autoclaved prior to being laundered or disposal.

10. **Personnel Training** (Question #25)—Indicate that all laboratory personnel will be trained to include biosafety practices and procedures.

NOTE:
1. Signatures must be acquired from and when they become available.

Total: 8; vote for 8; opposed 0; abstained 0

Biosafety Level: BSL-1
Type of Research: Biohazards

2005R0055 BONE METASTASIS MODELS IN THE NUDE MOUSE AND RAT, Tom Rosol, Veterinary Biosciences

Summary:
Bone metastasis increases morbidity and mortality in advanced stages of various cancers. The principal investigator intends to use mouse and rat animal models to increase understanding of the interaction between these cancers and the bone microenvironment. The investigator proposes to inject mice and rats with human and animal cancer cells. The investigator will then study the biological mechanisms responsible for tumor growth in the bone microenvironment and the resulting tumor induced skeletal complications.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Biohazards** (Question #5)
   - Indicate the potential of the human or animal cancer cells containing human pathogens, and specify these potential pathogens.
   - Provide evidence that the cell lines are stabilized.
2. **Risk Group** (Question #6)—Indicate Risk Group 2. Due to the potential for cancer cells to contain other agents, they are typically treated as Risk Group 2 agents.
3. **Biohazards Transport** (Question #12)—Describe inter-laboratory transport of hazardous materials.
4. **Waste Disposal** (Question #13)—Describe disposal procedures for liquid waste.
5. **Personnel Training** (Question #16)—Indicate that all laboratory personnel will be trained to include biosafety practices and procedures.
6. **Disinfection** (Question #18)—Specify a contact time for the disinfectant.
7. **Spill Management** (Question #19)—Specify a contact time for the disinfectant.
8. **Biosafety Cabinet** (Question #21a)—Specify the type of biosafety cabinet.

Total: 8; vote for 8; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Biohazards

ADMINISTRATIVE APPROVALS

Protocols

2005R0034 QUANTIFICATION OF SELECT BACTERIAL SPECIES IN INFANT STOOL SAMPLES BY DENATURING GRADIENT GEL ELCTROPHORESIS AND REAL-TIME PCR METHODS, Mark Morrison, Animal Sciences

Date of Determination: July 8, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2005R0039 2005R0039 [Biohazards]—TYPE A ANIMAL INFLUENZA RESEARCH LABORATORY, Richard D. Slemons, Veterinary Preventative Medicine

Date of Determination: July 8, 2005

Biosafety Level: BSL-1
Type of Research: Biohazards

2005R0042 2005R0042 [rDNA, Biohazards]—ROLE OF ANTIOXIDANTS IN INFLUENZA A VIRAL INFECTION OF LUNG EPITHELIAL CELLS IN CULTURE, Kalpana Ghoshal, Molecular & Cellular Biochemistry

Date of Determination: July 21, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA/Biohazards

Continuing Reviews

2001R0014 HAMSTER ORAL CANCER: A MODEL FOR P16 GENE TRANSFER, Christopher M. Weghorst, School of Public Health

Date of Determination: July 26, 2005

Biosafety Level: BSL-2 / BSL-2N
Type of Research: Recombinant DNA

2002R0047 THE CELLULAR STRESS RESPONSE IN VIRAL ENCEPHALITIS, Michael J. Oglsebee, Veterinary Biosciences

Date of Determination: July 18, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA

2002R0053 OPIOID RECEPTOR REGULATION, Wolfgang Sadee, Pharmacology

Date of Determination: July 27, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA/Biohazards

2002R0072 MICROBIOLOGICAL SAFETY OF FOODS OF ANIMAL ORIGINS, Jeffrey T. LeJeune, OARDC—Food Animal Health Research Program

Date of Determination: August 2, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2002R0083 GENETIC, MOLECULAR, AND DEVELOPMENTAL ANALYSIS OF VARIATION IN TOMATO FRUIT MORPHOLOGY, Esther K. Vanderknaap, Horticulture

Date of Determination: July 15, 2005

Biosafety Level: BSL-1 / BSL-1P
Type of Research: Recombinant DNA

2003R0031 GROWTH OF BACILLUS CEREUS AND ISOLATION OF DNA, RNA AND PROTEIN, Michael Ibba, Microbiology

Date of Determination: August 4, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2004R0019 BEHAVIORAL STUDIES OF ECHO-PROCESSING AND COMMUNICATION BY BATS, William M. Masters, Evolution, Ecology & Organismal Biology

Date of Determination: April 7, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2004R0024 INTERNATIONAL, RANDOMIZED, MULTICENTER, PHASE III STUDY IN PATIENTS WITH RELAPSING-REMITTING MULTIPLE SCLEROSIS COMPARING OVER A TREATMENT PERIOD OF 104 WEEKS:

1 DOUBLE-BLINDED THE SAFETY, TOLERABILITY, AND EFFICACY OF BETASERON/BETAFERON 250 G (8 MIU) AND BETASERON/BETAFERON 500 G (16 MIU, BOTH GIVEN SUBCUTANEOUSLY EVERY OTHER DAY,
2 RATER-BLINDED THE SAFETY, TOLERABILITY, AND EFFICACY OF BETASERON/BETAFERON S.C. EVERY OTHER DAY WITH COPAXONE 20 MG S.C. ONCE DAILY, Kottil Rammohan, Neurology

Date of Determination: July 12, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

Amendments

2002R0051 INVESTIGATION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES, Jiyan Ma, Molecular & Cellular Biochemistry

Date of Determination: July 15, 2005

Biosafety Level: BSL-2
Type of Research: Recombinant DNA

EXEMPT APPROVALS

2003R0046 STUDIES OF NEW FAMILY OF METALLOCARBOXYPEPTIDASE, Michael K. Chan, Biohchemistry

Date of Determination: April 21, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2005R0058 IL-15 CHARACTERIZATION THROUGH EXPERIMENTAL IMMUNOLOGY, Michael Caligiuri, Internal Medicine

Date of Determination: July 27, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

2005R0059 INORGANIC NUCLEASES, James A. Cowan, Chemistry

Date of Determination: July 28, 2005

Biosafety Level: BSL-1
Type of Research: Recombinant DNA

MINUTES
Institutional Biosafety Committee
13 October 2005

Attendees	Subcommittee rDNA	Bio	HGT	Members Present	Affiliation
X		X		Brian Ahmer	Biological Sciences
X	X			Angel Arroyo- Rodriguez	Ohio EPA
NO	X			David Coplin (Co-Chair)	Plant Pathology
NO		X	X	Lawrence A. Capitini	ULAR
X	X	X	X	Long-Sheng Chang	Pediatrics
NO	X			Biao Ding	Plant Biology / Biotechnology
NO	X			Jyan-Chyun Jang	Horticulture & Crop Science
NO		X		Joseph J. Kowalski	Veterinary Clinical Science
X	X	X	X	Cecil Smith (IBO)	Environmental Health & Safety
NO		X		Jami St. Clair	Columbus Police Department
X		X		William Swoager	Microbiology
X		X		Kenneth Theil	OARDC
X			X	Marshall Williams (Co-Chair)	MVIMG
				Responsible Research Practices	
X				Adam McClintock	Biosafety Coordinator
X				John Yocom	ILACUC Administrator
X				Todd Guttman	Research Foundation

The meeting was called to order at 10:06 am in Room 422 Research Foundation Building, and was adjourned at 10:54 am. The Committee retained quorum for the entire meeting.

Approval of Minutes

1. The Committee approved the 8 September 2005 minutes unanimously.

   Total: 7; vote for 7; opposed 0; abstained 0

RECOMBINANT DNA NEW PROTOCOL SUBMISSIONS

1996R0005 1.) LYMPHOCYTE ACTIVATION IN HTLV REPLICATION, 2.) EXPRESSION OF MOLECULAR CLONES OF HTLV-I, 3.) TRAINING IN MOLECULAR VIROLOGY IN HTLV-I PATHOGENS IN RABBITS, Michael D. Lairmore, Veterinary Bioscience

Summary:
Human T-Lymphotropic Virus type 1 (HTLV-1) is the cause of adult T-cell leukemia/lymphoma (ATLL) and a chronic degenerative myelopathy. The cellular mechanisms involved in the replication and function of the virus, however, are not well characterized. The principal investigator intends to identify amino acids in proteins that are crucial to the activation process of T-lymphocytes, and study their mechanisms of activity

in the establishment and control of HTLV-1 infection. The investigators will induce selective mutations in key genes for select amino acids. The results of these mutations will be tested in vivo using infectious clones to infect rabbits.

The Committee **REQUIRES MODIFICATIONS** to the protocol.

1. **Protocol Summary** (Question #2)—Please expand on the in vivo and in vitro procedures.

Total: 7; vote for 7; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2005R0046 DNA REPAIR AND HUMAN DISEASE, Richard Fishel, Molecular Virology, Immunology & Medical Genetics

Summary:
The principal investigator intends to study the genetics, regulation, mechanisms, and consequences of human DNA repair, primarily in the pathogenesis of cancer and HIV infection, as well as, the role of DNA repair in accurate meiotic chromosome segregation and fertility. The investigators will use numerous homologous genes from yeast, mouse and human most of which are involved in mismatch repair. A variety of vectors will be used including E.coli, baculovirus mammalian vectors and an HIV vector. The HIV vector contains less than 10% of the viral genome, is self-inactivating, and is replication defective. Mice are involved in the research; however, the investigator provides no real description of how they will be used.

The Committee **REQUIRES MODIFICATIONS** to the protocol.

1. **Protocol Summary** (Question #2)—Please indicate how mice will be used in the research.
2. **Biohazards Transport** (Question #21)—Please indicate that all materials will be placed in a sealed, leak-proof, unbreakable container for inter-laboratory transport.
3. **Waste Disposal** (Question #22)—Please specify a contact time for disinfection of biohazardous waste.
4. **Animals Used** (Question #24b, 24c)—Please provide more information about possible risks to personnel.
5. **Animals Used** (Question #24d, 24e, 24f)—Please indicate that animal carcasses, animal bedding, and animal waste will be handled as infectious waste.
6. **Personnel Training** (Question #25)—Please include biosafety training (i.e. personal protective equipment, biological safety cabinets, biological agents used in the lab, etc.) as a part of the laboratory personnel training program
7. **Medical Surveillance** (Question #26)
   - Please provide more information regarding the "radiation badges and rings".
   - Please ensure that all laboratory personnel complete the Occupational Health Registry Questionnaire.
8. **Disinfection** (Question #27)—Please clarify the reference to 10% bleach, and indicate a contact time for each disinfectant.

Total: 7; vote for 7; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2005R0069 MECHANISM OF DRUG ADDICTION, Howard Gu, Pharmacology

Summary:
Cocaine is an extremely addictive drug that has been popularly abused throughout the 1980s and 90s, with estimates of use at nearly 1% of the United States population above 12 years of age. The principal investigator intends to study the mechanisms underlying cocaine addiction. The investigator intends to test a transgenic line of mice against wild-type mice for sensitivity to cocaine addiction. The transgenic mice have been genetically modified to remove transporters of various neurotransmitters associated with sensitivity to cocaine. The investigator hopes to reveal specific information regarding the mechanisms of addiction which may lead to more adequate prevention and treatment techniques. Overall the protocol provides only a vague description, of the specific vectors to be used, and the associated safety precautions.

The Committee **DEFERRED** the biosafety plan

1. **Protocol Summary** (Question #2)—Please provide a detailed description of the mouse line bearing the functional dopamine transporter (DAT) that has been modified for increased sensitivity to cocaine inhibition.
2. **Potential Risks** (Question #3)—Please describe the "modified vaccinia" referenced in the section. If a viral vector is being used, please provide a detailed description of the viral vector (Section #9 and 9b), safety precautions (Section #3), and medical surveillance for laboratory personnel (Section #26).
3. **Review Requirements** (Question #4)—Please provide a response to the question. (refer to section III of the NIH Guidelines).
4. **Host Systems** (Question #7)—Please correct reference to "Hela cells" to read **"HeLa"**.
5. **Animals Used** (Question #24b)—Please specify the exposure risks to the investigators and animal care personnel for the items check in the section.
6. **Animals Used** (Question #24d, 24e, 24f)—Please indicate that animal carcasses, animal bedding, and animal waste will be handled as infectious waste.
7. **Laboratory Space** (Question #29)—The laboratory space must be certified for BSL-2 practices prior to the initiation of the experiments.

Total: 7; vote for 7; opposed 0; abstained 0

Type of Research: rDNA, Biohazards

BIOHAZARDS NEW PROTOCOLS

2005R0067 FUNCTIONAL FETAL CARDIAC MAGNETIC RESONANCE, Orlando Simonetti, Cardiovascular Medicine

Summary:
The principal investigator intends to study magnetic resonance imaging (MRI) techniques

by examining the fetuses of pregnant sheep. The investigators hope that the results can be used to develop new methods for the use of MRI to monitor fetal heart and blood vessels. New methods could include the early detection and pre- and postnatal treatment of illnesses and abnormalities that can prove devastating and even fatal to fetuses and neonates. The investigator intends to regularly transport pregnant ewes into a populated hospital to use an MRI machine located there. While the sheep will be acquired from a herd tested seronegative for Coxiella burnetii, it is nearly impossible to identify a herd as completely free of Q-fever. The risk of exposure creates a threat to laboratory personnel, hospital employees, and hospital patients. The protocol lacks important information including procedures for the isolation of sheep during transport, disinfection procedures to be used and a contingency plan in the vent of spontaneous abortion. An adequate plan should also address methods to minimize the number of individuals in contact with the sheep. Within the last 30 years, there have been at least three well documented cases of significant outbreaks of Q-fever involving similar studies at major medical centers. As such, thought should be given to the possibility of using an MRI machine which is located in the same facility as the sheep are to be housed.

The Committee **DEFERRED** the biosafety plan

1. **General**—The Committee requests additional information regarding the portions of the research to be conducted at the Ross Heart Hospital as follows:
   - Please indicate whether or not the procedures could be done using the MRI machine located in Wiseman Hall.
   - Please indicate what members of the administrative staff of the Ross Heart Hospital have been made aware of the proposed research, and indicate how they have been notified.
   - Please provide a detailed description of the affected environment at the Ross Heart Hospital to include route to be used for transport from Wiseman Hall to the hospital, points of entry to be used, route to be used for transport to the MRI machine, and methods used to minimize exposure to patients in the hospital.
   - Please indicate whether or not animals could be transported outside.
   - Please provide a contingency plan in the event of spontaneous abortion.
   - Address methods to minimize the number of individuals in contact with the sheep.
2. **Protocol Summary** (Question #2)—Please specify the target animals, and indicate whether or not they will be sacrificed in course of study.
3. **Potential Risks** (Question #3)—Please indicate medical supervision procedures.
4. **Personal Protective Equipment** (Question #10)—The Committee suggests that personal protective equipment (PPE) include respiratory PPE such as N95 Respirators.
5. **Biohazards Transport** (Question #12)
   - Please indicate specific details of the transport to be conducted by ULAR personnel.
   - Please indicate the type of cart to be used to transport the animals from Wiseman Hall to the Ross Heart Hospital.

   NOTE: Researchers at OARDC uses Rubbermaid ® laundry carts with some sort of covering for the transport of large animals.
6. **Animals Used** (Question #15d)—Please indicate that animal carcasses will be treated as infectious waste.

7. **Spill Management** (Question #19)—The Committee suggests masks and eyewear be included as part of protective coating during spill cleanup.
8. **Safety Procedures** (Question #24)
   - Indicate whether or not the animals will be kept in isolation prior to being included in the study.
   - Indicate whether or not the Coxiella burnetii has the potential to form a spore-like state.
   - Indicate if the disinfectant Roccal-D is effective against a spore-like stage of the agent.
9. **Personnel** (Question #26)—Please provide a different description of personnel experience, such as type of biosafety experience not particularly to specific agent (i.e. training for work involving aerosol, training for work with RG3 agents, training in BSL-2 laboratory practices, etc.).
10. **Personnel Signatures** (Question #27)—Please provide signatures of personnel.
11. **Department Chair Signature** (Question #29)—Please provide signature of the department chair.

Total: 7; vote for 7; opposed 0; abstained 0

Type of Research: Biohazards

2005R0068 INCIDENCE, SIGNIFICANCE AND CONTROL OF LISTERIA MONOCYTOGENES IN THE HOME ENVIRONMENT, Jeffrey T. LeJeune, OARDC—Food Animal Health Research Program

Summary:
The principal investigator intends to study *Listeria monocytogenes* in the farm home environment. The investigator hypothesizes that women of childbearing age living in the "farm home" environment are at an increased risk for pregnancy loss due to pathogenic strains of *L. monocytogenes*. The investigator proposes to conduct microbiological testing of cattle, human farm residents and their homes, administer a survey to farmers and their physicians questioning their attitudes and knowledge of farm related zoonoses, and using a guinea pig model to test pregnancy outcomes after exposure to human pathogenic *L. monocytogenes*. The protocol has several deficiencies including an inadequate description of how the spiked feed will be kept, distributed and prevented from contaminating the surrounding environment; descriptions relating to how animals, cultures and pathogens will be kept and secured; and disinfection and cleanup procedures to be used throughout the course of the study. The study will also require an approved IRB protocol for the distribution of a survey and the collection of human fecal samples.

The Committee **REQUIRES MODIFICATIONS** to the protocol.

1. **Protocol Summary** (Question #2)—Please expand on the description of the experimental procedures.
   NOTE: The involvement of human subjects requires IRB approval prior to the initiation of research. Please contact Peggy Mihalko, Biomedical IRB Administrator at 614-688-7920, or mihalko.1@osu.edu.
2. **Potential Risks** (Question #3)
   - Please indicate how the feed will be spiked using the concentrated bacterial suspension.

- Please indicate the nature of the food and whether or not there is potential for surrounding areas to be contaminated by pathogens via feed dust.
- Please indicate methods to be used to prevent the spread of potentially infectious material (i.e. feed dust, placenta, aborted fetal tissue, etc.).
- Please describe how the animals will be kept in isolation (separate room? environmentally separated cages, etc.?).
- Describe disinfection and cleanup procedures to be used after the collection of field samples of bovine fecal specimens.

3. **Agent Acquisition** (Question #7)—Please spell out the abbreviation "ODH".
4. **Storage Requirements** (Question #11)—Indicate where the cultures, and specimens will be stored, and specify the reference to "under lock".
5. **Animals Used** (Question #15d, 15e, 15f)—Indicate that infected animal carcasses, bedding, and waste will be placed in burn boxes for disposal by Environmental Health & Safety. The incinerator at this location is not permitted to burn infectious waste.
6. **Personnel Training** (Question #16)—The Committee suggests that laboratory personnel take blood borne pathogen training as a precaution.
7. **Disinfection** (Question #18)—Please reconcile the discrepancy of concentrations of sodium hypochlorite in sections 18 and 19.
8. **Laboratory Space** (Question #20)—Please indicate where the guinea pigs will be housed.
9. **Locations** (Question #22)
   - Please correct the typo "FARRP" to read "FARHP" where necessary.
   - Please indicate where the incinerator is located.

Total: 7; vote for 7; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Biohazards

2005R0070 XENOGRAFT AND TRANSGENIC MOUSE MODELS OF CANCER, William C. Kisseberth, Veterinary Clinical Sciences

Summary:
The principal investigator intends to create mouse xenograft models of cancer using human and animal tumor tissue and cell lines. Tumor tissue and cell lines will be derived from client owned animals (dog, cat, horse and cow) from the OSU Veterinary Teaching Hospital. Human breast tumor samples will be acquire from the OSU-Cooperative Human Tissue Network. It appears that the tumor tissue and cell lines will then be injected into immunodeficient mice, however, this is not made clear in the protocol description. The tumors that are grown in the immunodeficient mice will be characterized biochemically, morphologically and tested for DNA hypermethylation. The protocol lacks specific descriptions of the general and experimental procedures to be used.

The Committee **REQUIRES MODIFICATIONS** to the protocol.

1. **Protocol Summary** (Question #2)—Please expand on the description of the protocol summary to include specific procedures, and the involvement of mice **NOTE:** If transgenic mice are being produced please resubmit this protocol on the Recombinant DNA and Biohazards application form, which can be found online at

http://www.orrp.osu.edu/biosafety/forms.cfm.

2. **Potential Risks** (Question #3)—Indicate any potential blood borne pathogens in the tumor samples, and explain the possible route(s) of infection.
3. **Risk Group** (Question #6)—Due to the possibility of blood borne pathogens, please indicate RG-2.
4. **Personal Protective Equipment** (Question #10)—Please indicate that respiratory personal protective equipment will be used.
5. **Biohazards Transport** (Question #12)
   - Please indicate that all materials will be placed in a sealed, leak-proof, unbreakable container for inter-laboratory transport.
   - Please provide details of how the standards will be met for shipping of tissues.
6. **Waste Disposal** (Question #13)—The Committee suggests that unused tissue be placed directly into biohazard waste containers to avoid creating splashes involved with disinfection.
7. **Blood Borne Pathogen Compliance** (Question #14)
   - Please specify the dilution and contact time for the disinfectant used for surface disinfection.
   - Please provide more details about potential blood borne pathogens and exposure.
8. **Animals Used** (Question #15b)—Risk exposure should include "feces", "blood", and "animal bite or scratch".
9. **Animals Used** (Question #15d)—Please indicate that animal carcasses will be treated as infectious waste and placed in a biohazard waste container.
10. **Animals Used** (Question #15e, 15f)—Indicate that bedding and animal waste will be handled by ULAR staff.
11. **Personnel Training** (Question #16)—Please indicate that personnel will receive blood borne pathogen training.
12. **Medical Surveillance** (Question #17)—Please indicate that all personnel will complete the Occupational Health Registry Questionnaire and medical surveillance program.
13. **Disinfection** (Question #18)—Please replace "chlorine compound" with **"sodium hypochlorite"**.
14. **Laboratory Equipment** (Question #21a)—Please verify the type of biosafety cabinet contained in the laboratory.
15. **Personnel Protection** (Question #24)—Please replace the reference to "when needed" to indicate specifically when personnel protective equipment will be used.
16. **Personnel Training** (Question #16)—Please indicate that personnel will receive blood borne pathogen training.

Total: 7; vote for 7; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Biohazards

PROTOCOLS APPROVED ADMINISTRATIVELY

1999R0058 STUDIES ON INFECTIOUS BURSAL DISEASE VIRUS, Yehia M. Saif, OARDC Food Animal Health Research Program

Administratively approved on September 26, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

1999R0064 ASCARDIA LARVAE MIGRATION ASSOCIATED WITH TRANSOVARIAL TRANSMISSION IN TURKEYS, Teresa Y. Morishita, Veterinary Preventative Medicine

Administratively approved on September 1, 2005

Biosafety Level: BSL-1
Type of Research: Biohazards

1999R0066 DETECTION, CHARACTERIZATION, PATHOGENESIS AND IMMUNITY TO ENTERIC VIRUSES OF SWINE AND CATTLE, Linda J. Saif, OARDC Food Animal Health Research Program

Administratively approved on September 26, 2005

Biosafety Level: BSL-2 / ABSL-2
Type of Research: rDNA, Biohazards

2005R0057 MOLECULAR STUDIES AND INFECTIOUS CLONES OF INFECTIOUS BURSAL DISEASE VIRUSES, Daral J. Jackwood, OARDC-Food Animal Health Research Program

Administratively approved on September 7, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

ANNUAL REVIEWS APPROVED ADMINSTRATIVELY

2002R0078 MITIGATION OF SUBCLINICAL SALMONELLA SHEDDING IN RABBITS, Thomas E. Wittum, Veterinary Preventative Medicine

Administratively approved on September 19, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2002R0079 ROLE OF EPITHELIUM IN REGULATION INFECTION OF MACROPHAGES BY HIV, Mark D. Wewers, Pulmonary / Critical Care

Administratively approved on September 28, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2002R0085 GUIDELINES FOR WORKING WITH HUMAN WHITE CELLS AND BRONCHALVEOLAR CELLS IN THE LABORATORY, Larry Schlesinger, Internal

Medicine

Administratively approved on September 9, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2003R0029 PREVALENCE OF BAYLIS ASCARIS IN URSINE SPECIES, Teresa Y. Morishita, Veterinary Preventative Medicine

Administratively approved on September 21, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2003R0045 MYCOBACTERIUM TUBERCULOSIS STUDIES, Joanne Turner, Internal Medicine

Administratively approved on September 7, 2005

Biosafety Level: BSL-3
Type of Research: Biohazards

2004R0031 DNA PROBES FOR ACANTHAMOEBA GENOMES AND EPIDEMIOLOGY, Paul A. Fuerst, Evolution, Ecology & Organismal Biology

Administratively approved on September 30, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2004R0038 INTRACELLULAR CALCIUM SIGNALING IN HEART, Sandor Gyorke, Physiology & Cell Biology

Administratively approved on September 19, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2004R0039 A NEW PARADIGM FOR FIBROSIS: MONOCYTE ACTIVATION OF TGF AND INTRACELLULAR PATHWAYS REGULATING MONOCYTE SURVIVAL, Clay B. Marsh, Internal Medicine

Administratively approved on September 14, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2004R0043 LESIONAL CHEMOTHERAPEUTIC MANAGEMENT FOR ORAL AIDS-KS, Susan R. Mallery, Oral Pathology

Administratively approved on September 9, 2005

Biosafety Level: BSL-1
Type of Research: Biohazards

2004R0047 PHYSIOLOGICAL IMPLICATIONS OF OPIOID RECEPTOR REGULATION, Laura M. Bohn, Pharmacology

Administratively approved on September 29, 2005

Biosafety Level: BSL-1
Type of Research: rDNA

AMENDMENTS PPROVED ADMINSTRATIVELY

2002R0085 GUIDELINES FOR WORKING WITH HUMAN WHITE CELLS AND BRONCHALVEOLAR CELLS IN THE LABORATORY, Larry Schlesinger, Internal Medicine

Administratively approved on September 9, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2004R0024 INTERNATIONAL, RANDOMIZED, MULTICENTER, PHASE III STUDY IN PATIENTS WITH RELAPSING-REMITTING MULTIPLE SCLEROSIS COMPARING OVER A TREATMENT PERIOD OF 104 WEEKS:

1 DOUBLE-BLINDED THE SAFETY, TOLERABILITY, AND EFFICACY OF BETASERON/BETAFERON 250 G (8 MIU) AND BETASERON/BETAFERON 500 G (16 MIU, BOTH GIVEN SUBCUTANEOUSLY EVERY OTHER DAY,
2 RATER-BLINDED THE SAFETY, TOLERABILITY, AND EFFICACY OF BETASERON/BETAFERON S.C. EVERY OTHER DAY WITH COPAXONE 20 MG S.C. ONCE DAILY, Kottil Rammohan, Neurology

Administratively approved on September 30, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2004R0038 1. INTRACELLULAR CALCIUM SIGNALING IN HEART, Sandor Gyorke, Physiology & Cell Biology

Administratively approved on September 19, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

EXEMPT PROTOCOLS

2005R0066 PROFILING MICROBIAL COMMUNITIES TO INCREASE METABOLIZEABLE PROTEIN AND PREVENT MILK FAT DEPRESSION IN DIARY CATTLE FED RUMENSIN, Jeffery L. Firkins, Animal Sciences

Determined exempt on September 9, 2005

Biosafety Level: BSL-1
Type of Research: rDNA

MINUTES
Institutional Biosafety Committee
08 December 2005

Attendees	Subcommittee rDNA	Bio	HGT	Members Present	Affiliation
X		X		Brian Ahmer	Biological Sciences
	X			Angel Arroyo- Rodriguez	Ohio EPA
X	X			David Coplin (Co-Chair)	Plant Pathology
		X	X	Lawrence A. Capitini	ULAR
	X	X	X	Long-Sheng Chang	Pediatrics
	X			Biao Ding	Plant Biology / Biotechnology
X	X			Jyan-Chyun Jang	Horticulture & Crop Science
X		X		Joseph J. Kowalski	Veterinary Clinical Science
X	X	X	X	Cecil Smith (IBO)	Environmental Health & Safety
		X		Jami St. Clair	Columbus Police Department
X		X		William Swoager	Microbiology
X		X		Kenneth Theil	OARDC
X			X	Marshall Williams (Co-Chair)	MVIMG
				Responsible Research Practices	
X				Kelli Cyrus	Biosafety Coordinator
X				Adam McClintock	Biomedical IRB Coordinator

The meeting was called to order at 10:05 am in Room 422 Research Foundation Building, and was adjourned at 10:57. The Committee retained quorum for the entire meeting. J.C. Jang left at 10:44 am.

1. **Approval of Minutes**
   The Committee approved the October 13, 2005 minutes unanimously.

GENE TRANSFER NEW PROTOCOLS

2001R0045 ELF3 REGULATION OF TUMOR PROGRESSION AND METASTASIS IN HUMAN BREAST CANCER, Lisa Yee, Surgery

Summary:
ETS binding proteins help regulate the transcription of genes that encode for growth factors, tumor suppressor genes, oncogenes, and extracellular matrix proteases. These factors—such as ELF3 and ETS2—likely play a role in controlling tumor growth and progression, including the malignant tendencies of breast cancer cells. The investigators hypothesize that ELF3 inhibits breast cancer developments by repressing certain enzymes that are important for tumor cell invasion and metastasis. The investigators have constructed two adenoviral expression vectors that they will use to test this hypothesis. One vector contains full length cDNA for ELF3, and the second in antisense orientation. Additionally, the investigators will use a third, empty vector as a control.

Invasive breast cancer cell lines that do not express ELF3 will be infected with either the adenoviral ELF3 expression vector or the control vector, and will be tested in vitro assays

for decreased invasiveness as a result of ELF3 expression. Noninvasive breast cancer cell lines that express ELF3 under basal conditions will be infected with either the antisense ELF3 vector or the control vector, and will be tested in vitro assays for increased invasiveness as a result of the inhibition of ELF3 expression. To determine the effect of ELF3 expression on breast cancer, nude mice will be injected with xenografts of an invasive metastatic breast cancer cell line, transfected with the ELF3 expression vector or the control vector, and then observed for tumor latency, growth and metastases.

The investigators also intend to create a transgenic mouse model to determine whether the overexpression of ELF3 helps prevent breast cancer development and progression. Transgenic mice will be created by using a promoter that targets high level expression of transgenes to the mammary gland in mice. Transgenic mice with 5 to 10 times higher than normal levels of ELF3 will be identified and bred with transgenic mice that are known to develop breast cancer at high frequencies (greater than 90%) and low latency (3 to 6 months). The investigators hope that the combination of high incidence, low latency, and high ELF3 expression will allow the investigators to quickly determine the effect of ELF3 in inhibiting tumor growth and progression.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Introduction of DNA** (Question #8)—Clarify how pronuclear injections will be used to generate transgenic mice using adenoviral vectors.
2. **DNA Acquisition** (Question #16)—It appears that the adenoviral vectors have already been obtained. Revise the check boxes to reflect only those materials that will be acquired.
3. **Animals** (Question #25d, e, f)—Indicate the all animal materials will be handled per ULAR protocols and that animal carcasses will be treated as infectious waste.
4. **Medical Surveillance** (Question #27)—Indicate how it will be ensured that all laboratory personnel have up-to-date Occupation Health Registry Questionnaires on file with Environmental Health & Safety.
5. **Spill Management** (Question #29)
   - List the disinfectant to be used for all spills, and indicate a contact time.
   - Based on the response in this section, it appears that retroviral vectors will be used in the project. Revise the protocol summary (Question #2) to reflect the use of retroviral vectors.
6. **Laboratory Space** (Question #30)—Specify the location in which nude mice will be housed.

Total: 8; vote for 8; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Animal Gene Transfer

RECOMBINANT DNA DEFERRED PROTOCOLS

2005R0069 MECHANISM OF DRUG ADDICTION, Howard Gu, Pharmacology

Discussion:
Cocaine is an extremely addictive drug that has been popularly abused throughout the 1980s and 90s, with estimates of use at nearly 1% of the United States population above 12

years of age. The principal investigator intends to study the mechanisms underlying cocaine addiction. The investigator intends to test a transgenic line of mice against wild-type mice for sensitivity to cocaine addiction. The transgenic mice have been genetically modified to remove transporters of various neurotransmitters associated with sensitivity to cocaine. The investigator hopes to reveal specific information regarding the mechanisms of addiction which may lead to more adequate prevention and treatment techniques.

The Committee discussed the revisions to the deferred protocol and feel that the principal investigator has adequately addressed the prior concerns.

The Committee **APPROVED** the biosafety plan

Total: 8; vote for 8; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

RECOMBINANT DNA NEW PROTOCOL SUBMISSIONS

2005R0076 ROLE OF EUKARYOTIC-TYPE SERINE/THREONINE KINASE (STK) AND SERINE/THREONINE PHOSPHATASE (STP OR PPPL) IN GROUP A STREPTOCOCCAL (GAS) PATHOGENESIS, Vijay Pancholi, Pathology

Summary:
Group A Streptococcus (GAS, *S. pyogenes*) causes a variety of human diseases, such as mild pharyngitis, skin diseases, and autoimmune diseases. It has recently been discovered that the presence of eukaryotic-type/Ser/Thr kinase (ESTK) and protein phosphate (ESTP) in prokaryotes plays in important role in prokaryotic metabolic processes and signal transduction pathways. Sequence analyses of the GAS genome have revealed that a single gene encodes for each ESTK and ESTP and are annotated STK and pppL, respectively. There is little known about the role of STK and pppL in the pathogenesis of GAS, however, the investigators hypothesize that they play a significant role. The investigators have identified, characterized and cloned STK and pppL specific genes, produced corresponding recombinant proteins and generated STK and pppL specific polyclonal antibodies. They will use these cloned genes, recombinant proteins, and polyclonal antibodies to test the virulence of mutant strains that have altered surface proteins and cell division profiles. Virulence of the mutant strains will be tested in vitro using human pharyngeal cells and neutrophils. The investigators then propose to verify the in vitro findings with in vivo mouse intraperitoneal and nasopharyngeal models. The investigators hope to gain a better understanding of novel signaling molecules in bacterial pathogenesis and particularly GAS pathogenesis.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Protocol Summary** (Question #2)—The IBC review requirement section (Question #5) indicates that IRB approval is required for this research, which would indicate a human source for the neutrophils, and pharyngeal cells. Clarify the source of the neutrophils and pharyngeal cells.
2. **IBC Review Requirements** (Question #5)—Revise the response to this section if necessary based on the clarifications made in the protocol summary.

3. **Genes to be Used** (Question #6)—Indicate whether or not the genes have already been cloned in a vector (pET14B).
4. **Host Systems** (Question #7)—Clarify the constructs that will be used to make mutants to be introduced into *S. pyogenes*.
5. **Biohazards Transport** (Question #21)—Indicate that live culture will be kept in a non-breakable screw-capped tube during transport.
6. **Bloodborne Pathogen Compliance** (Question #23)—Revise the section accordingly to reflect clarifications made in the protocol summary, if materials are derived from a human source.
7. **Personnel Training** (Question #25)
   - Provide an outline of topics to be covered during training sessions.
   - Indicate that all laboratory personnel will undergo bloodborne pathogen training.
8. **Biosafety Cabinet** (Question #30a)—Provide the most recent certification date for the biological safety cabinet.
   NOTE: Biosafety cabinets must receive recertification at least every 12 months.

Total: 8; vote for 8; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2005R0082 ECOLOGY OF FOODBOURNE PATHOGENS ON VEGETABLES, Jeff LeJeune, Food Animal Health Research Program

Summary:
The principal investigator proposes to study the interaction between plant pathogens and the enteropathogens (*E. coli* O157) in the phylosphere of tomato plants, in both the laboratory and natural setting. A red fluorescent mark will be inserted into the plant pathogens, and *E. coli* O157 is labeled with a fluorescent green marker. These markers will allow the investigator to observe the interactions of the pathogens in the in vitro studies and differentiate each pathogen from each other and other epiphytic microorganisms during the in vivo studies. *Xanthomonas campestris vesicatoria* and *Pseudomonas syringae syringae* will be grown in a minimal media along with *E. coli* O157 in order to determine nutrient use and interaction between the pathogens. The plant pathogens will also be co-inoculated onto tomato plants with *E. coli* O157. The plant pathogens will be inoculated directly onto the tomato plants and the *E. coli* will be spot inoculated. At different intervals, portions of the infected plants will be removed, prepared and dilutions will be plated on media and observed by confocal microscopy to determine the amounts of plant pathogens and enteropathogens that are present. The investigator hopes that the results of these studies can help to determine how the presence of plant pathogens affects the growth of foodborne pathogens.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **General**—Provide a flow chart indicating the work to be done in each location and how materials will be transported from location to location.
2. **Protocol Summary** (Question #2)
   - Further characterize the strain of *E. coli* O157 that is described as non-toxigenic.

- Provide more details about the techniques to be used for inoculation (i.e. how the *Pseudomonas syringae syringae* and *Xanthomnas campestris vesicatoria* be applied to tomato plants, how spot inoculation of *E coli* occur, etc.).
- Indicate how portions of the infected plants will be prepared and dilutions plated (i.e. will this involve homogenization, where will this be done, will this be done in a Biosafety cabinet, etc.).
- It seems that the leaves will be ground with the possibility of aerosol formation; indicate where this will be done, how aerosol formation will be minimized, and any hazards associated with the formation of an aerosol.
- Indicate how access to the greenhouse will be restricted.

3. **Potential Risks** (Question #3)—Indicate the toxins that have been deleted from the strain of *E. coli* O157 to make the strain non-pathogenic.
4. **Risk Group** (Question #9)—Indicate whether or not the strain of *E. coli* is debilitated enough to be classified as RG-1.
5. **Consequences of Exposure** (Question #14)—Describe the potential for this non-toxigenic strain of *E. coli* to become toxigenic by picking up bacteriophages that may be present in the normal human flora.
6. **Containment Requirements** (Question #18)
   - Indicate the location of the room where the growth chambers will be maintained.
   - Indicate who approved the room at BSL-2 / BSL-2-P.
   - Describe the structure of the growth chambers.
7. **Biohazards Transport** (Question #21)—Indicate how the slides and contaminated plants will be disposed of, upon completion of the experiment, and whether or not the microscope will be disinfected after use.
8. **Waste Disposal** (Question #22)—Clarify how the pick up of waste will be arranged with Environmental Health & Safety.
9. **Medical Surveillance** (Question #25)
   - Describe the potential for *E. coli* O157 to become toxigenic, colonize in laboratory workers, and transfer to members of their household.
   - Indicate whether or not medical surveillance will include monitoring for diarrheic illness.
10. **Disinfection** (Question #27)—Clarify the disinfection process to include a more precise indication of the bleach concentration, and a specific contact time.
11. **Laboratory Space** (Question #29)
    - Clarify the greenhouse location where work will be done; there is not a greenhouse for the School of Natural Resources, but there is a Williams Hall Greenhouse that is shared by both the School of Natural Resources and Horticulture & Crop Sciences.
    - Indicate how the School of Natural Resources was notified of the work that will be done in their location, or how they will notified if they have not yet been notified.
12. **Personnel** (Question #35)—Indicate whether or not plant pathologists will be handling specimens that are potentially infected with *E. coli* O157, and if so how they will be advised of the risks associated with working with bacterial pathogens.

NOTE: The Committee specified that the original reviewers will receive the modifications for review and approval.

Total: 8; vote for 8; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

BIOHAZARDS DEFERRED PROTOCOLS

2005R0067 FUNCTIONAL FETAL CARDIAC MAGNETIC RESONANCE, Orlando Simonetti, Cardiovascular Medicine

Summary:
The principal investigator intends to study magnetic resonance imaging (MRI) techniques by examining the fetuses of pregnant sheep. The investigators hope that the results can be used to develop new methods for the use of MRI to monitor fetal heart and blood vessels. New methods could include the early detection and pre- and postnatal treatment of illnesses and abnormalities that can prove devastating and even fatal to fetuses and neonates. The investigator intends to regularly transport pregnant ewes into a populated hospital to use an MRI machine located there. While the sheep will be acquired from a herd tested seronegative for Coxiella burnetii, it is nearly impossible to identify a herd as completely free of Q-fever. The risk of exposure creates a threat to laboratory personnel, hospital employees, and hospital patients. Within the last 30 years, there have been at least three well documented cases of significant outbreaks of Q-fever involving similar studies at major medical centers.

The investigator has taken several steps to minimize these risks of exposure. The sheep will be anesthetized and transported from their housing location to the location of the MRI in a van by ULAR personnel. They will be transported from the van through the loading dock, to the MRI unit in a hydraulic cart covered by a surgical drape. The sheep's body will be contained within a plastic bag during the MRI procedure. In the case of spontaneous abortion, the materials will be disinfected appropriately and treated as infectious waste. Hospital administration has been made aware of and has approved of the use of their facilities, and the experimental procedures will be done outside of normal patient hours when not patients will be around. Additionally, the minimal number of laboratory personnel required will be used to carry out the procedure.

The Committee discussed the revisions to the deferred protocol and feel that the principal investigator has adequately addressed the prior concerns.

The Committee **APPROVED** the biosafety plan

Total: 8; vote for 8; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Biohazards

BIOHAZARDS NEW PROTOCOLS

2005R0078 IN VITRO DRUG SCREENING: HUMAN CANCER CELLS, Esperanza J Carcache de Blanco, Pharmacy

Summary:
The principal investigator intends to develop in vitro bioassay protocols to study the effectiveness of potential chemotherapeutic agents in cancer treatment. At least 3 human cancer cell lines will be cultured to confluency. The investigator will then use an in vitro drug screening method that will measure the cellular protein content of adherent and suspension cultures by staining the cells and extracting the dye for the determination of optical density. The investigator hypothesizes that the application of bioassay-directed isolation techniques has the potential to produce chemically diverse compounds that have a high potential for the development of new chemotherapeutic techniques and chemoprevention agents.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **General** – Revise throughout to correct for typos and grammatical errors.
2. **Protocol Summary** (Question #2)
   - Specify the source(s) for the "plant component samples" and bioassays, and indicate any potential risks associated with the materials derived form those sources.
   - Specify the cancer cell lines that will be used, and address any potential risks associated with exposure to those cell lines.
3. **Containment Requirements** (Question #9)—Indicate that BSL-2 practices and procedures will be used.
4. **Medical Surveillance** (Question #17)—Clearly indicate whether or not laboratory employees (and other personnel) are at risk, and whether or not they will be enrolled. The current statement "All employees at risk… are to automatically be enrolled…" is an open ended statement.
5. **Laboratories Space** (Question #20)—Provide a response to the section to indicate where the work will take place, and the containment level for which the laboratory space has been approved.

Total: 7; vote for 7; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Biohazards

2005R0079 IN VITRO ANTICANCER DRUG SCREENING: HUMAN CANCER CELLS, Hee-Byung Chai, Med. Chem. & Pharmacognosy

Summary:
The investigator intends to use a small panel of in vitro bioassays, constituted of two cell based assays, in order to conduct research to develop new antineoplastic drugs from plant sources. Human cancer cells will be cultured to confluency and will then be harvested by trypsinization. The investigator will measure the cellular protein content of adherent and suspension cultures by staining the cells and extracting the dye for the determination of optical density.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **General** – Revise throughout to correct for typos and grammatical errors.
2. **Protocol Summary** (Question #2)

- Specify the source(s) for the bioassays, and indicate any potential risks associated with the materials derived form those sources.
- Specify the cancer cell lines that will be used, and address any potential risks associated with exposure to those cell lines.

3. **Containment Requirements** (Question #9)—Indicate that BSL-2 practices and procedures will be used.
4. **Medical Surveillance** (Question #17)—Clearly indicate whether or not laboratory employees (and other personnel) are at risk, and whether or not they will be enrolled. The current statement "All employees at risk… are to automatically be enrolled…" is an open ended statement.
5. **Disinfection** (Question #18)—The last sentence in the section appears to be incomplete. Please revise to include the additional information to this section.
6. **Laboratories Space** (Question #20)—Provide a response to the section to indicate where the work will take place, and the containment level for which the laboratory space has been approved.

Total: 7; vote for 7; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Biohazards

PROTOCOLS APPROVED ADMINISTRATIVELY

1996R0005 1.) LYMPHOCYTE ACTIVATION IN HTLV REPLICATION, 2.) EXPRESSION OF MOLECULAR CLONES OF HTLV-I, 3.) TRAINING IN MOLECULAR VIROLOGY IN HTLV-I PATHOGENS IN RABBITS, Michael D. Lairmore, Veterinary Bioscience

Administratively approved on November 1, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2005R0046 DNA REPAIR AND HUMAN DISEASE, Richard Fishel, Molecular Virology, Immunology & Medical Genetics

Administratively approved on November 3, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2005R0070 XENOGRAFT AND TRANSGENIC MOUSE MODELS OF CANCER, William C Kisseberth, Veterinary Clinical Sciences

Administratively approved on November 15, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

ANNUAL REVIEWS APPROVED ADMINSTRATIVELY

2002R0058 DYNAMICS OF THE ACTIN CYTOSKELETON IN OSTEOCLASTS, Beth S. Lee, Physiology & Cell Biology

Administratively approved on November 1, 2005

Biosafety Level: BSL-1
Type of Research: rDNA

2002R0073 ADVANCED SURGICAL TECHNIQUES AND DEVICE TRAINING, Robert Michler, Surgery

Administratively approved on October 11, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2002R0082 STRESS, IMMUNITY AND CHOLINERGIC SYSTEMS, Gary G. Berntson, Psychology

Administratively approved on November 1, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2003R0032 EVALUATING AND MITIGATING POSSIBLE EFFECTS OF GENE FLOW FROM TRANSGENIC, NATURAL RUBBER-PRODUCING SUNFLOWERS, Allison Snow, Evolution, Ecology & Organismal Biology

Administratively approved on November 2, 2005

Biosafety Level: BSL-1P
Type of Research: rDNA

2003R0050 BIOHAZARD SAFE PRACTICES FOR WORKING WITH MYCOBACTERIA SPECIES IN THE SCHLESINGER LABORATORIES, Larry S Schlesinger, Internal Medicine

Administratively approved on November 28, 2005

Biosafety Level: BSL-3
Type of Research: Biohazards

2003R0052 VOCAL BEHAVIOR, HABITAT USE, AND HOME RANGES OF COYOTES, Douglas A. Nelson, Evolution, Ecology & Organismal Biology

Administratively approved on November 1, 2005

Biosafety Level: ABSL-2
Type of Research: Biohazards

2003R0053 SAMPLING BLOOD FROM WILD OHIO BIRDS FOR PRESENCE OF WEST NILE

VIRUS ANTIBODIES, Thomas C. Grubb, Evolution, Ecology & Organismal Biology

Administratively approved on October 18, 2005

Biosafety Level:
Type of Research: rDNA, Biohazards

2003R0057 RECOMBINANT DNA AND BIOHAZARDS SAFE PRACTICES FOR THE WEWERS LABORATORIES, Mark D Wewers, Pulmonary/Critical Care

Administratively approved on November 28, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2004R0018 STUDIES OF HERPES SIMPLEX TYPE 1 AND HUMAN CYTOMEGALOVIRUS BIOLOGY AND PATHOGENESIS, Joanne Trgovcich, Pathology

Administratively approved on October 10, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2004R0056 CHARACTERIZATION OF COTTON RAT RECEPTORS FOR MEASLES VIRUS, Stefan Niewiesk, Veterinary Biosciences

Administratively approved on November 28, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2004R0057 BOVINE LEUKEMIA VIRUS VECTOR, Stefan Niewiesk, Veterinary Biosciences

Administratively approved on November 28, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2005R0001 ROLES OF NOTCH SIGNALING IN THE SEGMENTATION CLOCK, DEVELOPMENT AND DISEASE, Susan E. Cole, Molecular Genetics

Administratively approved on November 1, 2005

Biosafety Level: BSL-1
Type of Research: rDNA

AMENDMENTS PPROVED ADMINSTRATIVELY

1991R0051 HUMAN ROTAVIRUSES, ENTERIC CALCIVIRUSES AND

ENTERIC/RESPIRATORY CORONAVIRUSES: CHARACTERIZATION, STUDIES OF DISEASE PATHOGENESIS AND IMMUNITY IN GNOTOBIOTIC PIGS AND CALVES AND DEVELOPMENT OF VACCINES, Linda J. Saif, OARDC Food Animal Health Research Program

Administratively approved on November 2, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

1999R0066 DETECTION, CHARACTERIZATION, PATHOGENESIS AND IMMUNITY TO ENTERIC VIRUSES OF SWINE AND CATTLE, Linda J. Saif, OARDC Food Animal Health Research Program

Administratively approved on November 2, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2000R0017 ROLE OF CHROMATIN REMODELERS IN B AND T CELL DEVELOPMENT, Said Sif, Molecular & Cellular Biochemistry

Administratively approved on November 28, 2005

Biosafety Level: BSL-2
Type of Research: rDNA

2001R0004 AN INTEGRATIVE APPROACH TO STUDY VIROID MOVEMENT, Biao Ding, Plant Cell & Molecular Biology

Administratively approved on November 1, 2005

Biosafety Level: BSL-2/BSL-2P
Type of Research: rDNA

2002R0011 MYOFIBROBLASTS AND FIBROSIS AFTER CARDIAC TRANSPLANT, Arthur R. Strauch, Physiology & Cell Biology

Administratively approved on November 1, 2005

Biosafety Level: BSL-2
Type of Research: rDNA

2002R0047 THE CELLULAR STRESS RESPONSE IN VIRAL ENCEPHALITIS, Michael J. Oglesbee, Veterinary Biosciences

Administratively approved on October 11, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2002R0051 INVESTIGATION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES, Jiyan Ma, Molecular & Cellular Biochemistry

Administratively approved on November 1, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2002R0053 OPIOID RECEPTOR REGULATION, Wolfgang Sadee, Pharmacology

Administratively approved on November 28, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2002R0057 STRUCTURAL STUDIES OF RECA-DNA COMPLEXES, Charles E. Bell, Molecular & Cellular Biochemistry

Administratively approved on November 1, 2005

Biosafety Level: BSL-1
Type of Research: rDNA

2002R0066 BONE MORPHOGEN THERAPY FOR EQUINE FRACTURE HEALING, Alicia Bertone, Veterinary Clinical Sciences

Administratively approved on November 28, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2002R0073 ADVANCED SURGICAL TECHNIQUES AND DEVICE TRAINING, Benjamin Sun, Surgery

Administratively approved on October 14, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2003R0062 ESTIMATING CONTACT RATES AMONG FREE-RANGING RACCOONS FOR SPATIAL MODELING OF RABIES, Stanley D. Gehrt, School of Natural Resources

Administratively approved on November 1, 2005

Biosafety Level:
Type of Research: Biohazards

2003R0064 RETINAL STEM CELLS AND REGENERATION IN CHICKEN, Andy J. Fischer, Neuroscience

Administratively approved on November 3, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2004R0018 STUDIES OF HERPES SIMPLEX TYPE 1 AND HUMAN CYTOMEGALOVIRUS BIOLOGY AND PATHOGENESIS, Joanne Trgovcich, Pathology

Administratively approved on October 10, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2004R0020 FUNCTIONAL ANALYSIS OF SOYBEAN DEFENSE GENES, Terry L. Graham, Plant Biotechnology

Administratively approved on November 3, 2005

Biosafety Level: BSL-1
Type of Research: rDNA

2004R0059 THE ROLE OF MPS1P PROTEIN KINASE IN MITOTIC SPINDLE FUNCTION AND GENETIC INSTABILITY, Harold Fisk, Molecular Virology, Immunology & Medical Genetics

Amendment #1—Administratively approved on November 1, 2005
Amendment #2—Administratively approved on November 1, 2005

Biosafety Level: BSL-1
Type of Research: rDNA

2005R0053 INTERSPECIES TRANSMISSION OF INFLUENZA A VIRUS, Yehia M. Saif, OARDC Food Animal Health Research Program

Administratively approved on October 14, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2005R0056 MYCOBACTERIA AND MACROPHAGE INTERACTIONS, William P. Lafuse, Molecular Virology, Immunology & Medical Genetics

Administratively approved on November 3, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2005R0057 MOLECULAR STUDIES AND INFECTIOUS CLONES OF INFECTIOUS BURSAL DISEASE VIRUSES, Daral J. Jackwood, Food Animal Health Research Program

Administratively approved on November 28, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

EXEMPT PROTOCOLS

2005R0071 ECOLOGY OF TETRACYCLINE RESISTANCE ORIGINATING FROM FOOD ANIMAL PRODUCTION SYSTEMS, Mark Morrison, Animal Sciences

Determined exempt on November 1, 2005

Biosafety Level: BSL-1
Type of Research: rDNA

2005R0072 COMPREHENSIVE EXAMINATION OF INTESTINAL MICROFLORA OF TURKEYS, Mark Morrison, Animal Sciences

Determined exempt on November 1, 2005

Biosafety Level: BSL-1
Type of Research: rDNA

2005R0073 ROLE OF SPHINGOSINE KINASE AND MULTIPLE EDG RECEPTORS IN GILMOA CELL GROWTH, James R. Van Brocklyn, Pathology

Determined exempt on November 1, 2005

Biosafety Level: BSL-1
Type of Research: rDNA

2005R0074 CHARACTERIZING THE EFFECTS OF SARA NULLIZYGOSITY IN VIVO, Michael B, Weinstein, Molecular Genetics

Determined exempt on November 1, 2005

Biosafety Level: BSL-1
Type of Research: rDNA

2005R0075 DISCOVERY AND CHARACTERIZATION OF NOVEL MICROBIAL POPULATIONS AND INTERACTIONS CONTRIBUTING TO THE SUPPRESSION OF CORN AND SOYBEAN DISEASES, Brian McSpadden Gardner, Plant Pathology

Determined exempt on October 27, 2005

Biosafety Level: BSL-1
Type of Research: rDNA

MINUTES
Institutional Biosafety Committee
12 January 2006

Attendees	Subcommittee rDNA	Bio	HGT	Members Present	Affiliation
X		X		Brian Ahmer	Biological Sciences
X	X	X		Angel Arroyo- Rodriguez	Ohio EPA
X	X			David Coplin (Co-Chair)	Plant Pathology
		X	X	Lawrence A. Capitini	ULAR
X	X	X	X	Long-Sheng Chang	Pediatrics
X	X			Biao Ding	Plant Biology / Biotechnology
	X			Jyan-Chyun Jang	Horticulture & Crop Science
X		X		Joseph J. Kowalski	Veterinary Clinical Science
	X	X	X	Cecil Smith (IBO)	Environmental Health & Safety
X	X	X		Jami St. Clair	Columbus Police Department
X		X		William Swoager	Microbiology
X	X	X		Kenneth Theil	OARDC
X	X	X	X	Marshall Williams (Co-Chair)	MVIMG
				Responsible Research Practices	
X				Kelli Cyrus	Biosafety Coordinator
X				Adam McClintock	Biomedical IRB Coordinator

The meeting was called to order at 10:02 AM in Room 422 Research Foundation Building, and was adjourned at 10:52 AM. The Committee retained quorum for the entire meeting.

Late Arrivals:

1. Biao Ding

1. Approval of Minutes

The Committee approved the December 8, 2005 minutes unanimously.

RECOMBINANT DNA NEW PROTOCOL SUBMISSIONS

1994R0007 RECOMBINANT DNA AND BIOHAZARD SAFE PRACTICES FOR THE KNOELL LABORATORY, Daren L. Knoell, Pharmacy

Summary:

The principal investigator intends to clone and express genes from the zinc transporter family, including SLC39A1~14 and SLC30A1~10. The full-length genes and DNA fragments containing promoters for these genes will be isolated using *E. coli* K12 strains. Standard recombinant DNA techniques will be employed to generate recombinant proteins for biochemical studies or to transfect or transduce mammalian cells using a replication defective adenoviral vector to study the mechanisms of function. The investigators will also conduct site-directed mutagenesis studies with the genes inserted into expression vectors to investigate the structure and function of genes and proteins of interest.

The Committee **DEFERRED** the biosafety plan

1. **General**—Revise the protocol title so that it is more specific and it is clear what experimental system is covered.
2. **Protocol Summary** (Question #2)
   - Describe all the genes that will be used in this study and give more details concerning the adenoviral vector.
   - Indicate that the proposal is limited to E. coli and the replication defective adenoviral vector.
3. **Genes** (Question #6)
   - Please correct the typo "zinc **transport** family" to read "zinc **transporter** family".
   - Describe the genes cloned from CARD, NOD, and PYRIN family as discussed in Question #9 (i.e. are they all of human origin?).
4. **Host Systems** (Question #7)—Describe the source of human epithelial cells and biosafety concerns associated with these cells.
5. **Vectors & Inserts** (Question #9)—Provide more information regarding the mammalian genes described in this section and how they are used in this study.
6. **Viral Vectors** (Question #9b)
   - Provide a more in depth description of the adenoviral vectors indicating their risk group and the source of the human genes that will be cloned.
   - Specify the packaging cell line that will be used; HEK293 is not a packaging cell line.
   - Revise the last sentence of the section to read "...commercial resource available to **transduce**..." instead of "...commercial resource available to **transfect**..."; the use of recombinant adenovirus should be referred to as "transduce or infect" but not "transfect".
   - Specify whether or not retroviral vectors will be used during the course of this project.
7. **Viral Genome** (Question #10)—Specify the percentage of the viral genome in the adenoviral vectors.
8. **Consequences of Exposure** (Question #14)—Revise this section to include recombinant adenoviral vector as a biohazard; the adenoviral vector should be handled BSL-2 containment, not E. coli.
9. **Agent Maintenance** (Question #16)–Revise the typo in the first checkbox to "**X**" not "**?**".
10. **Waste Disposal** (Question #22)—Please indicate that the biohazardous material be treated as infectious waste and placed in burn boxes for pick-up by the Office of Environmental Health and Safety.
11. **Bloodborne Pathogen Compliance** (Question 23)–Clarify how laboratory personnel will come into contact with blood products that will require bloodborne pathogen compliance training; this section indicates that personnel will undergo bloodborne pathogen compliance training but does not specify when personnel will be in contact with blood products.

Total: 10; vote for 10; opposed 0; abstained 0

Type of Research: rDNA, Biohazards

1997R0017 ROLE OF HTLV REX IN VIRAL REPLICATION AND TRANSFORMATION, Patrick

L. Green, Veterinary Biosciences

Summary:
The investigator plans to continue studying the role of the Rex protein in the regulation of viral gene expression and the overall biology of the HTLV. Specifically the investigator plans to define the biochemical properties of Rex-2 mutants, to determine the role of Rex-2 phosphoryation in viral replication and cellular transformation, to examine the effects of Rex-2 in viral persistence, and to develop an HTLV that replicates independent of Rex to directly access the role of Rex in cellular transformation. Standard molecular biology techniques will be used. Subgenomic HTLV-1 and HTLV-2 plasmids that contain less than 2/3 of their parental genomes and are replication defective will be cloned utilizing E. coli K12 strain and commercially available expression plasmids. Only expression plasmids containing the full-length proviruses are infectious. Small amounts of HTLV-1 and HTLV-2 are considered as risk group 2. Various human cell lines and human peripheral blood mononuclear cells will be used in transfection experiments. Animal experiments using rabbit for *in vivo* HTLV-1 and HTLV-2 infection and potential therapeutics will also be performed.

The Committee **APPROVED WITH MODIFICATIONS** the biosafety plan

1. **Protocol Summary** (Question #2)
   - Provide details about how the rabbits are being used in this study.
2. **Host Systems** (Question #7)—Specify whether or not rabbits are being used as a host system.
3. **Consequences of Exposure** (Question #14)—
   - Please discuss the consequences of infection with HTLV.
   - Please specify that peripheral blood mononuclear cells will be used in this study and discuss the safety precautions associated with the use of these agents.
4. **Occupational Health Issues** (Question #17)—Discuss the consequences of infection with HTLV infection.
5. **Disinfection** (Question #27)—Indicate that the bleach being used for disinfection will be at a minimum concentration of 10%.
6. **Spill Management** (Question #28)—Indicate that the bleach being used for spill management will be at a minimum concentration of 10%.
7. **Laboratory Space** (Question #29)—Revise this section to indicate where animals will be housed and the maximum animal-containment level for which the location is approved.

Total: 10; vote for 10; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2005R0080 USE MURINE RETROVIRAL-GENE TRANSFER/BONE MARROW TRANSPLANTATION TO STUDY THE BONE MARROW STEM CELL ORIGIN OF SOLID CANCER, Sanford H Barsky, Pathology

Summary:
The principle investigator proposes to study and understand the bone marrow stem cell

origin of solid cancers. The investigator intends to test whether breast cancer and lung cancer can be transferred by introducing "genetically marked" bone marrow derived from tumor-prone transgenic mice or wild-type healthy mice into either unmarked tumor-prone transgenic mice or normal healthy mice, respectively. By using an *ex vivo* method to label, a recombinant retrovirus carrying a GFP or luciferase expression unit will be used to genetically mark bone marrow cells. The labeled bone marrow cells will then be injected into lethally irradiated recipient mice by intravenous tail. The investigator hypothesizes that the cancer will develop in the recipient mice from the donor-derived bone marrow stem cells. The hypothesis will be tested by observing the recipient mice for 4-8 months.

The Committee **DEFFERED** the biosafety plan

1. **General**
   - Please proofread the application and correct for typos throughout.
   - Include information about the use of human cancer cell lines, the potential for them to be infected with unspecified human pathogens, and the risk of exposure to laboratory personnel
   - Provide information regarding the use of infectious agents on animals and address the safety issues for personnel exposed to these agents.
   - Indicate that infected animal waste will be treated as infectious waste and will be place in burn boxes for pick-up by the Office of Environmental Health and Safety.
2. **IBC Application Form**—Complete the IBC Recombinant DNA/Biohazards application form to incorporate the concerns described below:
3. **Protocol Summary** (Question #2)—Provide a better description detailing how the mice will be infected with cancer cells.
4. **Genes** (Question #5)—List the specific genes that will be used in the experiment.
5. **Host Systems** (Question #6)—Please provide the source of the packaging cell line and the MMLV vector used in this study.
6. **Disinfection** (Question #14)—Please specify a contact time for disinfection.
7. **Spill Management** (Question #15)—Incorporate spill management procedures. An example of procedures is provided below.

   Small spills will be contained using plastic-backed absorbable hood liner, paper towels, or gauze. Contaminated absorbent materials will be transferred to a lined red biohazard bag and autoclaved. The contaminated surface will be treated with a 1:10 dilution of bleach [sodium hypochlorite at 5,000 ppm], STERIS LpH se, or 70% Etoh contact time of ten minutes.

   Large spills will be contained by placing a barrier of paper towels around the spill after warning any other laboratory personnel in the immediate vicinity. The liquid will be absorbed with additional paper towels or granular absorbable material. The Principal Investigator should be contacted as soon as possible after the spill is contained. Laboratory personnel wearing appropriate personal protective equipment including respiratory protection will transfer the contaminated solid materials into a lined red biohazard bag for autoclaving. All contaminated surfaces will be saturated with a 1:10 dilution of bleach in water, STERIS LpH se or 70% Etoh. Aerosol formation should be kept to the absolute minimum by not spraying water or disinfectant directly onto the spill or by not using a sponge or wringing out paper towels during the cleanup. Any laboratory personnel with exposure to the

agent will notify OSU Employee Health Services after the spill has been contained and any contaminated personal protective equipment and clothing has been removed. Contaminated personal protective equipment and clothing will be placed into a red biohazardous bag and autoclaved prior to being laundered or disposal.

8. **Laboratory Space** (Question #16)—Please indicate the maximum physical containment of the laboratory/greenhouse and the date of last inspection.
9. **Locations** (Question #18)—Please provide the room number where the autoclave is located.

Total: 10; vote for 10; opposed 0; abstained 0

Type of Research: rDNA, Biohazards

2005R0081 EPIGENETIC CHANGES IN LUNG CANCER, Gregory Otterson, Internal Medicine

Summary:
The principle investigator intends to study epigenetic events that alter the functional aspects of cancer, specifically thoracic malignancies. The investigator proposes to re-introduce "recombinant elements" into cell lines. These "recombinant elements" are microRNAs and are re-introduced using adenovirus vectors into the tumor cell lines. The investigator then intends to analyze the effect on downstream events, specifically cell viability, apoptosis, cell cycle, soft agar cloning, and sensitivity to chemotherapy and/or radiation.

The Committee **DEFERRED** the biosafety plan

1. **General**—Include information about the use of adenoviral vectors and the risk of exposure to laboratory personnel.
2. **IBC Application Form**—Complete the IBC Recombinant DNA/Biohazards application form to incorporate the concerns described below:
3. **Protocol Summary** (Question #2)—Specify which genes will be cloned.
4. **Potential Risks** (Question #3)—Please specify the recombinant genes involved in the project.
5. **Genes** (Question #5)—Please specify the genes and organisms from which the DNA/genes are taken.
6. **Vectors and Inserts** (Question #7)
   - Please specify the packaging system used to make the virus.
   - Provide a description of the plasmid vectors that are mentioned in this project; indicate whether or not E. coli K-12 will be used to maintain and grow the plasmid DNA.
   - Please provide a description of the replication deficient adenoviral vectors.
7. **NIH Guidelines** (Question #10)—Please indicate any or all of your experiments that are exempted by the *NIH Guidelines* and cite the relevant sections of the *Guidelines* that establish the exemption. If not applicable, state not applicable.
8. **Disinfection** (Question #14)—Indicate that the bleach being used for disinfection will be at a minimum concentration of 10%.

Total: 10; vote for 10; opposed 0; abstained 0

Type of Research: rDNA, Biohazards

2005R0084 MYCOBACTERIA-MACROPHAGE INTERACTIONS IN IRON METABOLISM AND MACROPHAGE ACTIVATION, William P. Lafuse, Molecular, Virology, Immunology, and Medical Genetics

Summary:
Pulmonary tuberculosis, called *Mycobacterium tuberculosis*, is a global health concern. *Mycobacterium tuberculosis* induces an immunological response in the lungs that leads to the formation of ganulomas as the host attempts to restrict the spread of the bacterium in this tissue. Iron is necessary for this intracellular growth as the bacterium grows within the host's pulmonary macrophages. Hepcidin, a protein produced by the liver and macrophages, has a role in regulating iron uptake and release. The principle investigator intends to determine if hepcidin is produced by macrophages in the granuloma in response to *Mycobacterium tuberculosis* and whether expression of the iron transport proteins changes during mycobacteria infection and formation of the granuloma. *In vivo* experiments will be conducted examining the expression of hepcidin and iron transport during a Mycobacteria infection in mice. In addition, *in vitro* experiments will also be conducted in which mouse macrophages and macrophage cell lines will be infected with *Mycobacterium tuberculosis* and treated with cytokines to examine the mechanisms that the bacterium uses to block the induction of IFN-γ, a protein known to activate macrophages for increased killing of bacteria.

The Committee **APPROVED WITH MODIFICATIONS** the biosafety plan

1. **General**
   - The PA-005 associated with this project indicates that radioisotopes are being used; please indicate how radioisotopes are involved in this project.
   - Please properly cite the complete title, date and/or version of the BSL-3 operating manual that referred to in several sections of the protocol (i.e. sections #19, 20, 22, 24d, 24e, 28, 33, 34).
2. **Protocol Summary** (Question #2)—Provide a more detailed description of the experiments that will be conducted (the specific route of inoculation, whether or not lung tissue specimens will be collected, how cell cultures will be inoculated, how mice will be manipulated after infection).
3. **Genes** (Question #6)
   - Specify the cytokine genes that will be used during this project.
   - Specify all the genes that will be cloned.
4. **Vectors and Inserts** (Question #9)
   - Please correct the typo "**luciferasee**" to read "**luciferase**".
   - Provide a more detailed description of the vectors to be used.
5. **Consequences of Exposure** (Question #14)
   - List pulmonary tuberculosis as a potential consequence of exposure.
   - Specifically state that all individuals are at risk of infection, with AIDS patients being at a higher risk.
6. **Agent Acquisition** (Question #15)—Please check appropriate boxes either 'yes' or 'no'.
7. **Agent Maintenance** (Question #16)—Please check appropriate boxes either 'yes' or 'no'.
8. **Protective Equipment** (Question #19)—Indicate that lab coats will be worn as

personal protective equipment, and specify the type of eye protection that will be used.

9. **Biohazard Transport** (Question #21)
   - Indicate how the bacterium is transported from where it will be grown to the area where mice will be exposed.
   - Specifically state that infected mice will not be transported outside the BSL-3 facility.
   - Indicate how infected tissues will be transported for the granuloma studies.
10. **Animal Waste** (Question #24f)—Please describe the disposal of animal waste.
11. **Training** (Question #25)—Indicate that bloodborne pathogen training will be required for all personnel working on this project.
12. **Disinfection** (Question #27)
    - Please correct the typo "**tuberculoidal**" to read "**tuberculocidal**".
    - Specify the tuberulocidal disinfectants to be used in the laboratory and when treating tissues and necropsy instruments contaminated with the bacterium.
    - Provide a clearer indication of the concentration of bleach to be used for disinfection.
13. **Spill Management** (Question #28)—Describe the appropriate disinfectant that will be used for spill management.
14. **Laboratory Space** (Question #29)
    - Specifically indicate the type of work that will be done in Graves Hall.
    - Specify where mice will be housed.
15. **Laboratory Space** (Question #30)—Clearly indicate what work that will be done in Graves Hall 2178 (BSL-2), and what will be done in the Biosciences Building 517 and 521 (BSL-3).
16. **Personnel Training** (Question #34)—Please correct the typo in the last sentence of the section to read "**signed**" instead of "**sighed**".

Total: 10; vote for 10; opposed 0; abstained 0

Biosafety Level: BSL-3
Type of Research: rDNA, Biohazards

BIOHAZARDS NEW PROTOCOLS

2005R0087 PATHOGENESIS, INTERSPECIES TRANSMISSION, AND VACCINE STUDY OF INFLUENZA A VIRUSES, Chang Won Lee, Food Animal Health Research Program

Summary:
The principle investigator intends characterize low pathogenicity avian influenza virus isolates. The investigators will laboratory work which will involve creating infectious clones of full-length DNA using reverse genetics. Using new methods in biotechnology, the investigators hope to attenuate the virus and create a more effective vaccine. The research will also include animal studies involving chickens and turkeys to assess interspecies transmission. Other aims of the study include the development of advanced vaccine or preventive treatment (including companion diagnostic testing) and assessing the effect of vaccines on antigenic drift of the avian influenza virus.

The Committee **DEFERRED** the biosafety plan

1. **General**—Clearly indicate how recombinant DNA is being used in this study.
2. **IBC Application Form**—Complete the IBC Recombinant DNA/Biohazards application to incorporate the concerns described below:
3. **Protocol Summary** (Question #2)—Please provide more detail about the experimental procedures (including how studies are conducted involving turkeys and chickens, the routes and location of inoculation, how data will be collected on interspecies transmission and a concise but complete overview of the experiments to be conducted).
4. **Potential Risks** (Question #3)
   - Provide a rationale for strains being created using reverse genetics.
   - While these viruses are not currently a threat to human health, provide an assessment of the risks of these agents to the poultry industry in Ohio.
5. **Biohazards** (Question #5)—Specify the subtypes of avian influenza that will be used in this project.
6. **Agent Acquisition** (Question #7)—Indicate how the low pathogenic viruses will be created, and specify the higher pathogenic viruses from which they will be created.
7. **Waste Disposal** (Question #13)—Please indicate that the biohazardous material be treated as infectious waste and placed in burn boxes for pick-up by the Office of Environmental Health and Safety.
8. **Animals** (Question #15)—Provide more information about the pathogenesis study; it is implied that animals will be sacrificed and specimens collected and transported back to the laboratory for analysis.
9. **Animals**
   - Provide a detailed description of potential risks to humans that may result from exposure to animals or animal wastes.
   - (Question #15f)—Provide a detailed description of the process by which the animal waste will handled, "sterilized", and how the materials will be disposed of afterwards.
10. **Personnel Training** (Question #16)—Specify the "University Training Session" that will be required.
11. **Disinfection** (Question #18)—Provide a clear but concise description of the procedures that will be used to disinfect the rooms.
12. **Laboratory Space** (Question #20)
    - Please indicate where the chickens and turkeys will be housed.
    - Schedule an inspection for the certification of the laboratory space to be used in this study.
13. **Personnel** (Question #26)—Complete the "Experience" column, indicating the background of each member of the research team.

Total: 10; vote for 10; opposed 0; abstained 0

Type of Research: rDNA, Biohazards

PROTOCOLS APPROVED ADMINISTRATIVELY

2005R0076 ROLE OF EUKARYOTIC-TYPE SERINE/THREONIN KINASE (STK) AND SERINE/THREONINE PHOSPHATASE (STP OR PPPL) IN GROUP A STREPTOCOCCAL (GAS) PATHOGENESIS, Vijay Pancholi, Pathology

Date of last communication: January 4, 2006

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2005R0077 EFFECTS OF MELATONIN ON THE DEVELOPMENT OF IMMUNE FUNCTION, Randy J. Nelson, Psychology

Administratively approved on January 3, 2006

Biosafety Level: BSL-1
Type of Research: Biohazards

2005R0078 IN VITRO DRUG SCREENING: HUMAN CANCER CELLS, Esperanza Carcache de Blanco, Pharmacy

Administratively approved on January 3, 2006

Biosafety Level: BSL-2
Type of Research: Biohazards

2005R0079 AN IN VITRO ANTICANCER DRUG SCREENING: HUMAN CANCER CELL LINE, Hee-Byung Chai, Pharm CBO/Coll

Administratively approved on January 3, 2006

Biosafety Level: BSL-2
Type of Research: Biohazards

ANNUAL REVIEWS APPROVED ADMINSTRATIVELY

1990R0015 OTITIS MEDIA WITH EFFUSION: HUMAN AND ANIMAL STUDIES, Thomas Demaria, Otolaryngology

Administratively approved on December 15, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2002R0027 REGULATION OF NEUROTRANSMITTER RECEPTORS, MEMBRANE TRANSPORTERS, ION EXCHANGERS, AND ION CHANNELS, Wolfgang Sadee, Pharmacology

Administratively approved on November 7, 2005

Biosafety Level: BSL-1
Type of Research: Biohazards

2002R0080 GENE EXPRESSION PROFILES OF HUMAN CARTILAGE AND BONE, Alicia Bertone, Veterinary Clinical Sciences

Administratively approved on December 19, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2002R0081 GENE EXPRESSION PROFILES OF ARTHRITIC HUMAN CARTILAGE AND BONE, Alicia Bertone, Veterinary Clinical Sciences

Administratively approved on December 19, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2003R0013 CHARACTERIZATION OF PLANT RNASE P AND EXAMINATION OF ITS UTILITY AS A FUNCTIONAL GENOMICS TOOL, Venkat Gopalan, Biochemistry

Administratively approved on January 3, 2006

Biosafety Level: BSL-1 & BSL-1P
Type of Research: rDNA

2003R0051 BIOHAZARD SAFE PRACTICES FOR WORKING WITH FRANCISELLA SPECIES IN THE SCHLESINGER LABORATORIES, Larry S Schlesinger, Internal Medicine

Administratively approved on November 28, 2005

Biosafety Level: BSL-3
Type of Research: Biohazards

2003R0054 CELL-ASSOCIATED FIV: VAGINAL PROTECTION AND TRANSMISSION, Mary Jo Burkhard, Veterinary Biosciences

Administratively approved on November 7, 2005

Biosafety Level: BSL-2

Type of Research: Biohazards

2004R0026 MOLECULAR MECHANISMS OF VASCULAR ALPHA2 -ADRENOCEPTOR EXPRESSION AND TRAFFICKING, Maqsood Chotani, Internal Medicine

Administratively approved on December 20, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2004R0035 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, Amit Agrawal, Department of Otolaryngology

Administratively approved on November 7, 2005

Biosafety Level: BSL-2
Type of Research: Human Gene Transfer

2004R0045 EVOLUTION OF SNAKE VENOM, H. L. Gibbs, Evolution, Ecology, & Organismal Biology

Administratively approved on November 7, 2005

Biosafety Level: BSL-1
Type of Research: Biohazards

2004R0046 A PHASE I STUDY OF ADV-TK + VALACYCLOVIR GENE THERAPY IN COMBINATION WITH STANDARD RADIATION THERAPY FOR MALIGNANT GLIOMAS, E. Antonio Chiocca, Department of Neurological Surgery

Administratively approved on December 20, 2005

Biosafety Level: BSL-2
Type of Research: Human Gene Transfer

2004R0048 CONTROL OF FOODBOURNE PATHOGENS, Ahmed Yousef, Food, Science, & Technology

Administratively approved on November 7, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2004R0050 RETICULOSPINAL CONTROL OF REACHING, John Buford, School of Allied Medical Professions

Administratively approved on January 3, 2006

Biosafety Level: BSL-2
Type of Research: Biohazards

2004R0051 GENERATION OF TRANSGENIC MICE USING LENTIVIRAL VECTORS, Anthony P Young, Center for Molecular Neurobiology

Administratively approved on November 7, 2005

Biosafety Level: BSL-2
Type of Research: Animal Gene Transfer

2004R0053 ACID-SENSING ION CHANNELS IN TRANSGENIC MICE, Candice Askwith, Pathology

Administratively approved on December 15, 2005

Biosafety Level: BSL-1
Type of Research: rDNA

2004R0058 TUMOR SUPPRESSOR GENE RECOMBINANT EXPERIMENTS, Kay Huebner, Molecular Virology, Immunology and Medical Genetics

Administratively approved on January 3, 2006

Biosafety Level: BSL-1
Type of Research: Animal Gene Transfer

2004R0059 THE ROLE OF MPS1P PROTEIN KINASE IN MITOTIC SPINDLE FUNCTION AND GENETIC INSTABILITY, Harold Fisk, Molecular Genetics

Administratively approved on November 7, 2005

Biosafety Level: BSL-1
Type of Research: Biohazards

AMENDMENTS PPROVED ADMINSTRATIVELY

1999R0053 FUNCTION AND ASSEMBLY OF CO2 ASSIMILATORY ENZYMES, F. Robert Tabita, Microbiology

Administratively approved on January 3, 2006

Biosafety Level: BSL-1
Type of Research: rDNA

2000R0017 ROLE OF CHROMATIN REMODELERS IN B AND T CELL DEVELOPMENT, Said Sif, Molecular & Cellular Biochemistry

Administratively approved on December 22, 2005

Biosafety Level: BSL-2
Type of Research: rDNA

2000R0019 THE ROLE OF P75 SIGNALING IN APOPTOSIS OF NEURONS FOLLOWING INJURIES IN VIVO, Sung Yoon, Molecular & Cellular Biochemistry

Administratively approved on December 20, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2002R0051 INVESTIGATION OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES, Jiyan Ma, Molecular & Cellular Biochemistry

Administratively approved on January 3, 2006

Biosafety Level: BSL-2
Type of Research: rDNA

2003R0053 SAMPLING BLOOD FROM WILD OHIO BIRDS FOR PRESENCE OF WEST NILE VIRUS ANTIBODIES, Thomas C. Grubb, Evolution, Ecology, & Organismal Biology

Administratively approved on December 19, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2003R0054 CELL-ASSOCIATED FIV: VAGINAL PROTECTION AND TRANSMISSION, Mary Jo Burkhard, Veterinary Biosciences

Administratively approved on November 7, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2004R0039 A NEW PARADIGM FOR FIBROSIS: MONOCYTE ACTIVATION OF TGF AND INTRACELLULAR PATHWAYS REGULATING MONOCYTE SURVIVAL, Clay Marsh, Internal Medicine

Administratively approved on December 20, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2004R0048 CONTROL OF FOODBOURNE PATHOGENS, Ahmed Yousef, Food, Science, & Technology

Administratively approved on November 7, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

2004R0051 GENERATION OF TRANSGENIC MICE USING LENTIVIRAL VECTORS, Anthony P Young, Center for Molecular Neurobiology

Administratively approved on November 7, 2005

Biosafety Level: BSL-2
Type of Research: Animal Gene Transfer

2005R0012 FUNCTIONAL INTERPLAY BETWEEN CARCOLIPIN AND PHOSPHOLAMBAN IN SR CALCIUM HOMEOSTASIS, Gopal Babu, Physiology & Cell Biology

Administratively approved on November 7, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2005R0045 PREDISPOSING FACTORS AND TREATMENT FOR POST-TRANSPLANT LYMPHOPROLIFERATIVE DISORDER, Anne VanBuskirk, Surgery

Administratively approved on December 15, 2005

Biosafety Level: BSL-2
Type of Research: Biohazards

EXEMPT PROTOCOLS

2005R0083 SCREENING OF S1P RECEPTOR BINDING COMPOUNDS, James Van Brocklyn, Pathology

Administratively approved on December 15, 2005

Biosafety Level: BSL-1
Type of Research: rDNA

PENDING PROTOCOLS

2001R0045 ELF3 REGULATION OF TUMOR PROGRESSION AND METASTASIS IN HUMAN BREAST CANCER, Lisa Yee, Surgery

Date of last communication: January 4, 2006

Type of Research: Animal Gene Transfer

2005R0082 ECOLOGY OF FOODBOURNE PATHOGENS ON VEGETABLES, Jeff LeJeune, Food Animal Health Research Program

Date of last communication: January 4, 2006

Type of Research: rDNA, Biohazards

MINUTES
Institutional Biosafety Committee
09 February 2006

Attendees	Subcommittee rDNA	Bio	HGT	Members Present	Affiliation
X		X		Brian Ahmer	Biological Sciences
X	X	X		Angel Arroyo- Rodriguez	Ohio EPA
X	X			David Coplin (Co-Chair)	Plant Pathology
X		X	X	Lawrence A. Capitini	ULAR
	X	X	X	Long-Sheng Chang	Pediatrics
X	X			Biao Ding	Plant Biology / Biotechnology
X	X			Jyan-Chyun Jang	Horticulture & Crop Science
X		X		Joseph J. Kowalski	Veterinary Clinical Science
X	X	X	X	Cecil Smith (IBO)	Environmental Health & Safety
X	X	X		Jami St. Clair	Columbus Police Department
X		X		William Swoager	Microbiology
X	X	X		Kenneth Theil	OARDC
X	X	X	X	Marshall Williams (Co-Chair)	MVIMG
				Responsible Research Practices	
X				Kelli Cyrus	Biosafety Coordinator
X				Adam McClintock	Biomedical IRB Coordinator

The meeting was called to order at 2:03 pm in Room 422 Research Foundation Building, and was adjourned at 3:00 pm. The Committee retained quorum for the entire meeting.

Late Arrivals:

1. Joseph Kowalski 2:07

1. **Approval of Minutes**
   The Committee approved the January 12, 2006 minutes unanimously.

2. **Current IBC Issues**
   The committee reviewed a notice of current IBC changes drafted by Dr. Cecil Smith. The notice discussed recent administrative changes requiring the Institutional Biosafety Committee to physically meet once a month. The noticed emphasized that cancellation of meetings due to a lack of quorum cannot occur. Therefore, the committee discussed that members should find alternates if a colleague is available and willing. The committee also discussed the option of reducing the number of committee members to meet the minimum requirements for holding committee meetings. Alternates should still be found as quorum will still need to be met. The notice also addressed a revision of the Institutional Biosafety Charter to reflect conflict of interest procedures. The revised charter will be discussed and voted upon at the March Meeting. Lastly, the notice addressed future changes in the PA-005 requirements and procedures. The committee has not come to a resolution at this time.

RECOMBINANT DNA MODIFICATIONS REQUIRED

2005R0082 ECOLOGY OF FOODBOURNE PATHOGENS ON VEGETABLES, Jeff LeJeune, Food Animal Health Research Program

Summary:
The principal investigator proposes to study the interaction between plant pathogens and the enteropathogens (*E. coli* O157) in the phylosphere of tomato plants, in both the laboratory and natural setting. A red fluorescent mark will be inserted into the plant pathogens, and *E. coli* O157 is labeled with a fluorescent green marker. These markers will allow the investigator to observe the interactions of the pathogens in the in vitro studies and differentiate each pathogen from each other and other epiphytic microorganisms during the in planta studies. *Xanthomonas campestris pv. vesicatoria* and *Pseudomonas syringae pv. syringae* will be grown in a minimal media along with *E. coli* O157 in order to determine nutrient use and interaction between the pathogens. The plant pathogens will also be co-inoculated onto tomato plants with *E. coli* O157. The plant pathogens will be inoculated directly onto the tomato plants and the *E. coli* will be spot inoculated. At different intervals, portions of the infected plants will be removed, prepared and dilutions will be plated on media and observed by confocal microscopy to determine the amounts of plant pathogens and enteropathogens that are present. The investigator hopes that the results of these studies can help to determine how the presence of plant pathogens affects the growth of foodborne pathogens.

The Committee **APPROVED WITH MODIFICATIONS** the biosafety plan

1. **General**—Specify in the Flow Chart where the MCIC is located.
2. **Protocol Summary** (Question #2)
   - As the AsRed marker is considered safe and standard, to avoid having to get APHIS approval, all inoculations should be done in the Selby Hall headhouse rather than the Selby Hall greenhouse and plants should be kept in growth chambers.
   - Provide information by describing or referencing the *E. coli* strain containing a GFP vector.
3. **IBC Review Requirements** (Question #5)—Indicate that work with RG2 agents requires IBC approval prior to the initiation of research.
4. **Containment Requirements** (Question #18)—Post a sign in Room 35 of Selby Hall indicating limited access to the room.
5. **Training** (Question #25)—Remove the statement 'if required' in the second sentence so the phrase reads "The PI will annually assess and update biosafety training for all personnel. Indicate that training will be required for all personnel working on this project.
6. **Laboratory Space** (Question #29)
   - Please update the table to exclude Williams Hall.
   - Provide a containment level for the Plant Pathology Growth Chambers.
   - Provide documentation for the BSL-2P containment level for Selby Hall, room 237.
7. **Personnel Training** (Question #34)—Remove the statement 'if required' so the phrase reads "The PI will annually assess and update biosafety training for all personnel. Indicate that training will be required for all personnel working on this project

Discussion:
The Committee reviewed the modifications and feel that the principal investigator has not addressed all of the concerns.

Total: 12; vote for 12; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

RECOMBINANT DNA NEW PROTOCOL SUBMISSIONS

1999R0059 EHRLICHIAL RESEARCH, Yasuko Rikihisa, Veterinary Biosciences

Summary:
Ehrlichiosis is an acute or chronic disease caused by infection of men or animals by the bite of infected ticks or trematodes. The principle investigator intends to examine the mechanism of the disease Ehrlichiosis and develop effective vaccines. The study will clone and express various candidate genes from the bacteria *Ehrlichia eqingii*, *Ehrlichia chaffeensis*, *Anaplasma phagocytophilum*, and *Neorickettsia sennetsu*. The purpose of this study is to evaluate the bacteria's' biological function in culture, make antibodies to determine localization, and test various candidates in mice, dogs, or horses. These studies will determine whether the vaccines confer protection against Ehrlichiosis.

The Committee **DEFERRED** the biosafety plan

1. **Protocol Summary** (Question #2)
   - Provide more detail to specify which genes will be cloned to include the risk group classification for specific species.
   - Specify the source of the bacteria and exactly which species will be used.
   - Indicate what genes will be cloned and whether or not they will be used to make knock-out mutants.
2. **Potential Risks** (Question #3)—Provide a control plan for escaped experimental animals; section 3 indicates that if experimentally infected animals are released, they may serve as reservoirs for the wild animal infection.
3. **IBC Review Requirements** (Question #5)—Provide a response to this section based on the clarifications made to the protocol.
4. **Genes** (Question #6)
   - Provide further detail as to which species are being used and whether or not they make toxins.
   - Provide detail as to which genes are the candidate genes, and the total DNA that will be cloned into *E. coli*.
5. **Vectors and Inserts** (Question #9)
   - Provide a list of inserts to be used in this study.
   - Clarify whether or not you will be making a "shotgun" library.
   - Provide details on how the mutants will be made.
6. **Agent Acquisition** (Question #15)—Indicate who will be responsible for collecting field samples.
7. **Occupational Health Issues** (Question #17)—Provide explanation of the

occupational health issues associated with field sampling. If no occupational health issues exist, state that there are no occupational health issues.

8. **Containment Requirements** (Question #18)—Remove disinfection comments from this section.
9. **Protective Equipment** (Question #19)—Revise this section to reflect feces as a potential hazard; If the agent is found in the feces of lab animals, respiratory protection is appropriate with any procedures done outside the confines of the biological hood.
10. **Biohazards Transport** (Question #21)—Indicate that infected cells will be kept in a non-breakable screw-capped tube during transport.
11. **Waste Disposal** (Question #22)—Provide detail regarding the waste disposal including the time for autoclaving.
12. **Bloodborne Pathogen Compliance** (Question #23)—Indicate that those with exposed to Bloodborne Pathogens (i.e. those exposed to potentially contaminated blood) will report to Employee Health Services.
13. **Animals** (Question 24 d,e,f)
    - Revise this section to reflect feces as an exposure risk and provide a time for autoclaving in the appropriate sections.
    - Indicate that the biohazardous material be treated as infectious waste and placed in burn boxes for pick-up by the Office of Environmental Health and Safety.
14. **Medical Surveillance** (Question #26)—Indicate how it will be ensured that all laboratory personnel have up-to-date Occupation Health Registry Questionnaires on file with Environmental Health & Safety.
15. **Disinfection** (Question #27)
    - The committee suggests revising the protocol to use a more effective disinfectant rather than 3% hydrogen peroxide.
    - Indicate how 70% ethanol will be disposed of after disinfection.
16. **Spill Management** (Question #28)—All references to a laminar flow hood should be referenced as a particular class of Biosafety Cabinet.

Total: 12; vote for 12; opposed 0; abstained 0

Type of Research: rDNA, Biohazards

2005R0086 ONCOGENES AND TUMOR SUPPRESSOR GENES IN CANCER INITIATION AND PROGRESSION, Carlo Croce, Molecular Virology, Immunology, and Medical Genetics

Summary:
The investigator intends to study the process by which some genes contribute to the development and progression of certain human cancers. The development of cancer involves numerous steps which includes genetic changes that effect tumor suppressor genes, oncogenes, and modifiers in a manner that can initiate carcinogenesis. The investigators hope to identify and explore how overexpression or down regulation of oncogenes, tumor suppressor genes and miRNAs contribute to the development of tumor producing cells. The investigators also hope to clarify the molecular mechanisms by which the deregulation of the expression of certain genes contributes to carcinogenesis in humans. The study will use constructs carrying various human or mouse cDNAs and/or genomic sequences of interest, cloned under the control of a promoter, enabling expression of the encoded protein in bacteria, yeast, and mammalian (human, mouse, hamster) cell line. E.

coli K12 strains will be used along with retroviral/lentiviral vectors that are replication-competent and have little anticipated risks of pathogenicity.

The Committee **APPROVED WITH MODIFICATIONS** the biosafety plan

1. **General**—Provide Occupational Health Registry Questionnaires for all laboratory personnel.
2. **Protocol Summary** (Question #2)
   - Correct the typo in line 7 of the section to read "**deletion**" instead of "**delition**".
   - Provide a description of the transgenic animals to be used in this study; section 11 indicates that transgenic animals will be produced.
3. **Potential Risks** (Question #3)—Indicate whether the adenoviral vectors (referenced in question #3 and question #9) to be used lacks E1/E2 or E1/E3.
4. **Host System** (Question #7)—Specify the packaging cell lines for the adenoviral and lentiviral vectors.
5. **Host and/or DNA Source** (Question #8)—Indicate a Risk Group Classification of RG2.
6. **Biohazard** (Question #12)—Indicate the biohazard used in this study. If not applicable, state not applicable.
7. **Risk Group Assessment** (Question #13)—Indicate a Risk Group Classification of RG2.
8. **Training** (Question #25)
   - Indicate that all personnel will complete the annual online Biosafety Training. Biosafety training is available at www.ehs.ohio-state.edu at the biosafety link.
   - Indicate the personnel training will include review of *NIH Guidelines for Research Involving Recombinant DNA Molecules*.
9. **Medical Surveillance** (Question #26)—Indicate that employees will participate in a medical surveillance program as prescribed by Employee Health Services.
10. **Laboratory Space** (Question #29)
    - Please schedule a laboratory inspection; contact Nancy Vogue at 292-1284.
    - Revise this section to indicate where animals will be housed and the maximum animal-containment level for which the location is approved.

Total: 12; vote for 12; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2006R0002 NEWCASTLE DISEASE VIRUS BASED VECTORS FOR IMMUNIZATION AGAINST MEASLES AND RSV INFECTION, Stefan Niewiesk, Veterinary Biosciences

Summary:
The principle investigator proposes to test the Newcastle Disease Virus vectors expressing the measles virus and respiratory disease virus (RSV) proteins as a vaccine against infection with the measles virus and respiratory disease virus in cotton rats. The investigator hypothesizes that using the Newcastle Disease Virus to vector these proteins might overcome certain host mechanisms that interfere with producing a strong immune response to these antigens. The investigator will use proteins that are important for induction of both B cell and T Cell responses. For induction of the measles virus,

hemagglutinin (H) and fusion (F) protein will be used while fusion (F) and attachment (G) protein will be used for induction of the respiratory disease virus. Influenza A virus will be used as a control virus for the interferon induction. The investigator intends to achieve specific stimulation of B cells with interferon induction that could overcome the block of maternal antibodies in the measles vaccination. The investigator also intends to achieve strong T cell response through interferon induction to create a long-lasting immunization for respiratory disease virus (RSV).

The Committee **DEFERRED** the biosafety plan

1. **Protocol Summary** (Question #2)
   - Provide a detailed description of the experimental procedures and descriptive narrative to be done in the project including the route of inoculation, the dosage used, discussion of potential risks, and discussion of enhancing pathogenicity.
   - Provide a description of the use of necropsies as mentioned in section 33.
2. **Potential Risks** (Question #3)—
   - Discuss the potential risks of inserting the measles H and F protein genes into the Newcastle Disease Virus genome.
   - Discuss the risk, if any, or enhancing the infectivity of the Newcastle Disease Virus for humans.
   - Discuss how the modified vectors bearing proteins that induce cell fusion might behave.
   - Clarify whether or not the influenza A viruses used are known to infect other species.
3. **Consequences of Exposure** (Question #14)—Clarify the statement "NDV Hitchner B 1 causes more or less abortive infection in mammals..." and address what significance it has on the experiment.

Total: 12; vote for 12; opposed 0; abstained 0

Type of Research: rDNA, Biohazards

2006R0003 GENE THERAPY OF BRAIN TUMORS, E. Antonio Chiocca, Neurological Surgery

Summary:
The principle investigator intends to study the effect of a drug that suppresses innate immunity on efficiency of oncolytic HSV to suppress brain tumors using a mouse model. The study will test the compound cyclophosp hamide (CPA) as a "viral oncolysis sensitizer". Mice and rats will be injected with human and mouse cell lines to create intracranial and subcutaneous tumors. The recombinant HSV viruses are replication competent and are propagated in Vero cells. The principal investigator hypothesizes that the host response in the initial phase of oncolytic virus infection, replication, and propagation (in tumors) will dictate its effectiveness with regard to oncolysis and side-effects.

The Committee **APPROVED WITH MODIFICATIONS** the biosafety plan

1. **Protocol Summary** (Question #2)—Provide a more detailed description of the experiments that will be conducted.

2. **IBC Review Requirements** (Question #5)—Indicate that work with RG2 agents requires IBC approval prior to the initiation of research.
3. **Vectors and Inserts** (Question #9)—Provide a list of the transgenes that will be inserted into the HSV vector in this study.
4. **Biohazards Transport** (Question #21)—Indicate that the primary container will be in a sealed, leak-proof secondary container for transport.
5. **Spill Management** (Question #28)—Revise the third sentence in the second paragraph to read "The Principal Investigator ***will*** be contacted..." rather than "The Principal Investigator ***should*** be contacted...".
6. **Laboratory Space** (Question #29)
   - Please schedule a laboratory inspection; contact Nancy Vogue at 292-1284.
   - Specify which procedures are being done in specific rooms of Wiseman Hall in respect to the approved containment level; some parts of Wiseman Hall are listed as BSL-1 and some parts are listed as BSL-2.

Total: 12; vote for 12; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2006R0004 BIOLOGY OF TAUOPATHIES STUDIED WITH HSV AMPLICONS-REVISED, E. Antonio Chiocca, Neurological Surgery

Summary:
The principle investigator intends to study an imbalance in the ratio of tau splice forms linked to neurodegeneration. The investigator will use HSV amplicons to efficiently deliver tau locus to primary neurons derived from mouse embryonic brain in cell culture. The HSV amplicons will then be used to determine the splicing of this gene and the functional consequences of its expression. The HSV amplicon vectors used in this study are replication incompetent and have been designed to eliminate the possibility of recovery of wild type HSV-1 from packaging reactions.

The Committee **APPROVED WITH MODIFICATIONS** the biosafety plan

1. **IBC Review Requirements** (Question #5)—Indicate that work with RG2 agents requires IBC approval prior to the initiation of research.
2. **Genes** (Question #6)—Specify here that the tau locus to be studied came from a human.
3. **Host System** (Question #7)—Specify whether or not the Vero cells are of human origin.
4. **Vectors and Inserts** (Question #9b)—Verify that the percentage of the vector is less than one percent; this seems like a small percentage for a 175 kb vector.
5. **Occupational Health Issues** (Question #17)—Provide information as to why immune conditions of workers may need to be checked.
6. **Bloodborne Pathogen Compliance** (Question #23)—Address the possibility of a needlestick.
7. **Animals** (Question #24)—Indicate the source of embryonic mouse brains referenced in section 2.
8. **Spill Management** (Question #28)—Revise the third sentence in the second paragraph to read "The Principal Investigator ***will*** be contacted..." rather than

"The Principal Investigator ***should*** be contacted...".

9. **Laboratory Space** (Question #29)
   - Please schedule a laboratory inspection; contact Nancy Vogue at 292-1284.
   - Specify which procedures are being done in specific rooms of Wiseman Hall in respect to the approved containment level; some parts of Wiseman Hall are listed as BSL-1 and some parts are listed as BSL-2.

Total: 12; vote for 12; opposed 0; abstained 0

Biosafety Level: Bsl-1 or bsl-2 depending on where they are doing the work
Type of Research: rDNA, Biohazards

PROTOCOLS APPROVED ADMINISTRATIVELY

2001R0045 ELF3 REGULATION OF TUMOR PROGRESSION AND METASTASIS IN HUMAN BREAST CANCER, Lisa Yee, Surgical Oncology

Date of Determination: January 20, 2006

Biosafety Level: BSL-2
Type of Research: Animal Gene Transfer

2005R0076 ROLE OF EUKARYOTIC TYPE SERINE/THREONINE KINASE (STK) AND SERINE/THREONINE PHOSPHATASE (STP OR PPPL) IN GROUP A STREPTOCOCCAL (GAS) PATHOGENESIS, Vijay Pancholi, Pathology

Date of Determination: January 5, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2005R0084 MYCOBACTERIA-MACROPHAGE INTERACTIONS IN IRON METABOLISM AND MACROPHAGE ACTIVATION, William P. Lafuse, Molecular, Virology, Immunology, and Medical Genetics

Date of Determination: February 8, 2006

Biosafety Level: BSL-3
Type of Research: rDNA, Biohazards

1997R0017 ROLE OF HTLV REX IN VIRAL REPLICATION AND TRANSFORMATION, Patrick L. Green, Veterinary Biosciences

Date of Determination: February 1, 2005

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

ANNUAL REVIEWS APPROVED ADMINSTRATIVELY

1989R0002 THE MOLECULAR CHARACTERIZATION OF LIGNIN-FORMING PEROZIDASE (DOE), James D. Metzger, Horticulture and Crop Science

Date of Determination: January 5, 2006

Biosafety Level: BSL-2
Type of Research: rDNA

1991R0015 THE ARABADOPSIS BIOLOGICAL RESOURCE CENTER AT THE OHIO STATE UNIVERSITY, Randall Scholl, Plant Biology

Date of Determination: January 20, 2006

Biosafety Level: BSL-1P
Type of Research: rDNA

2003R0004 REGULATION OF STOMATAL DEVELOPMENT IN ARABI, Fred D. Sack, Plant Biology

Date of Determination: January 11, 2006

Biosafety Level: BSL-1 & BSL-1P
Type of Research: rDNA

2004R0001 MEASLES VIRUS INDUCED IMMUNE SUPPRESSION, Stefan Niewiesk, Veterinary Biosciences

Date of Determination: January 11, 2006

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2004R0006 STRESS-RELATED EFFECTS ON VIRUS-INDUCED TUMORS, Eric Yang, Molecular Virology, Immunology, and Medical Genetics

Date of Determination: January 11, 2006

Biosafety Level: BSL-1
Type of Research: Biohazards

2004R0007 HISTONE ACETYLATION AND ENDOTHELIAL ACTIVATION, Dale Hoyt, Pharm CBO/Coll

Date of Determination: January 27, 2006

Biosafety Level: BSL-1

Type of Research: rDNA

2004R0008 EXAMINATION OF THE FUNCTION OF THE BARDET-BIEDL SYNDROME (BBS) PROTEINS, Kirk Mykytyn, Pharmacology

Date of Determination: January 17, 2006

Biosafety Level: BSL-1
Type of Research: rDNA

2004R0049 DEVELOPMENT OF A MODEL OF CARPAL TUNNEL SYNDROME-R24 SUPPORT, John A. Buford, Physical Therapy

Date of Determination: January 11, 2006

Biosafety Level: BSL-2
Type of Research: Biohazards

2004R0052 OSU CCC AND CALGB LEUKEMIA TISSUE BANKS AND CALIGIURI RESEARCH LABORATORY, Michael Caligiuri, Internal Medicine

Date of Determination: January 17, 2006

Biosafety Level: BSL-2
Type of Research: Biohazards

2005R0004 MITOCHONDRIAL TARGETING OF ATP-SENSITIVE K CHANNELS IN ISCHEMIC PRECONDITIONING, Keli Hu, Pharmacology

Date of Determination: January 20, 2006

Biosafety Level: BSL-1
Type of Research: rDNA

2005R0017 HYPERTENSION PHARMACOGENETICS, Wolfgang Sadee, Pharmacology

Date of Determination: January 20, 2006

Biosafety Level: BSL-1
Type of Research: rDNA

AMENDMENTS PPROVED ADMINSTRATIVELY

1991R0051 HUMAN ROTAVIRUSES, ENTERIC CALCIVIRUSES AND ENTERIC/RESPIRATORY CORONAVIRUSES: CHARACTERIZATION, STUDEIS OF DISEASE PATHOGENESIS AND IMMUNITY IN GNOTOBIOTIC PIGS AND CALVES AND DEVELOPMENT OF VACCINES, Linda J. Saif, OARDC Food Animal Health Research Program

Date of Determination: January 4, 2006

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

1999R0066 DETECTION, CHARACTERIZATION, PATHOGENESIS AND IMMUNITY TO ENTERIC VIRUSES OF SWINE AND CATTLE, Linda J. Saif, OARDC Food Animal Health Research Program

Date of Determination: January 4, 2006

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2001R0048 REGULATION OF IMMUNE RESPONSE DURING LEISHMANIASIS, Abhay Satoskar, Microbiology Admin

Date of Determination: January 11, 2006

Biosafety Level: BSL-2
Type of Research: Biohazards

2003R0057 RECOMBINANT DNA AND BIOHAZARDS SAFE PRACTICES FOR THE WEWERS LABORATORIES, Mark Wewers, Molecular Virology, Immunology, and Medical Genetics

Date of Determination: January 26, 2006

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2004R0001 MEASLES VIRUS INDUCED IMMUNE SUPPRESSION, Stefan Niewiesk, Veterinary Biosciences

Date of Determination: January 27, 2006

Biosafety Level: BSL-1
Type of Research: rDNA, Biohazards

2004R0049 DEVELOPMENT OF A MODEL OF CARPAL TUNNEL SYNDROME-R24 SUPPORT, John A. Buford, Physical Therapy

Date of Determination: January 11, 2006

Biosafety Level: BSL-2
Type of Research: Biohazards

2004R0052 OSU CCC AND CALGB LEUKEMIA TISSUE BANKS AND CALIGIURI RESEARCH LABORATORY, Michael Caligiuri, Internal Medicine

Date of Determination: January 17, 2006

Biosafety Level: BSL-1
Type of Research: Biohazards

2004R0053 INTERSPECIES TRANSMISSION OF INFLUENZA A VIRUS, Y. M. Saif, FAHRP/OARDC

Date of Determination: January 11, 2006

Biosafety Level: BSL-1
Type of Research: Biohazards

2004R0054 RESPIRATORY SYNCYTIAL VIRUS VECTOR, Stefan Niewiesk, Veterinary Biosciences

Date of Determination: January 27, 2006

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

EXEMPT PROTOCOLS

2006R0001 MOLECULAR GENETIC DISSECTION OF MITOCHONDRIAL COMPLEX I ASSEMBLY AND SITE-DIRECTED MUTAGENESIS OF MITOCHONDRIA-ENCODED SUBUNITS, Patrice Paul Hamel, Plant Cellular and Molecular Biology

Date of Determination: January 26, 2006

Biosafety Level: BSL-1
Type of Research: rDNA

PENDING PROTOCOLS

1994R0007 RECOMBINANT DNA AND BIOHAZARD SAFE PRACTICES FOR THE KNOELL LABORATORY, Daren L. Knoell, Pharmacy

Date of Last Communication: February 13, 2006

Type of Research: rDNA, Biohazards

2005R0080 USE MURINE RETROVIRAL-GENE TRANSFER/BONE MARROW TRANSPLANTATION TO STUDY THE BONE MARROW STEM CELL ORIGIN OF SOLID CANCER, Sanford H Barsky, Pathology

Date of Last Communication: February 7, 2006

Type of Research: rDNA

2005R0081 EPIGENETIC CHANGES IN LUNG CANCER, Gregory Otterson, Internal Medicine

Date of Last Communication: February 20, 2006

Type of Research: rDNA

2005R0087 PATHOGENESIS, INTERSPECIES TRANSMISSION, AND VACCINE STUDY OF INFLUENZA A VIRUSES, Chang Won Lee, Food Animal Health Research Program

Date of Last Communication: February 7, 2006

Type of Research: Biohazards

MINUTES
Institutional Biosafety Committee
09 March 2006

Attendees	Subcommittee rDNA	Bio	HGT	Members Present	Affiliation
X		X		Brian Ahmer	Biological Sciences
X	X	X		Angel Arroyo- Rodriguez	Ohio EPA
X	X			David Coplin (Co-Chair)	Plant Pathology
X		X	X	Lawrence A. Capitini	ULAR
X	X	X	X	Long-Sheng Chang	Pediatrics
X	X			Biao Ding	Plant Biology / Biotechnology
	X			Jyan-Chyun Jang	Horticulture & Crop Science
		X		Joseph J. Kowalski	Veterinary Clinical Science
X	X	X	X	Cecil Smith (IBO)	Environmental Health & Safety
	X	X		Jami St. Clair	Columbus Police Department
X		X		William Swoager	Microbiology
X	X	X		Kenneth Theil	OARDC
X	X	X	X	Marshall Williams (Co-Chair)	MVIMG
				Responsible Research Practices	
X				Kelli Cyrus	Biosafety Coordinator
X				Adam McClintock	Biomedical IRB Coordinator

The meeting was called to order at 10:01 in Room 422 Research Foundation Building, and was adjourned at 11:33. The Committee retained quorum for the entire meeting.

Late Arrivals:

1. Baio Ding 10:03
2. Long-Sheng Chang 10:05

Early Departures:

3. Baio Ding 10:50

1. **Approval of Minutes**
   The Committee approved the February 15, 2006 minutes unanimously.

2. **Institutional Biosafety Charter**
   The committee reviewed and discussed changes to the Institutional Biosafety Charter. Changes have been made and include the following:
   1. "Potential conflicts of interest of IBC members are identified and managed" has been added to part 3, section 8 to reflect conflict of interest procedures.
   2. Part 3, section 8, bullet g has been updated to remove the editorial comment that was mistakenly left in.

   The Committee voted unanimously to adopt the charter.

   Total: 10; vote for 10; opposed 0; abstained 0

3. **Review of Application Forms**

The Committee reviewed and discussed a revised draft of the general application form for rDNA, Biohazards, and Animal Gene Transfer protocols. The following revisions will be made to the form prior to initiation of use:

1. For the submission of an Animal Gene Transfer Application, appendices A, B, and C will be required.
2. The following language will be added to question #4 of the General Application form: "...plants, crops, and livestock poultry industry."
3. Question #13 of the General Application form will be modified to read "Animal Facilities" instead of "Animal Research" and "Plant Facilities" instead of "Plant Research". Co-chair David Coplin will revise this section to include questions regarding growth chambers and greenhouse facilities.
4. Question #17 of the General Application form will be modified to read "Controlled drainage and/or cement floors" instead of "Control cement floors". "Arthropod control program" will also be added to this section.
5. The language "inserts" will be removed from question # 5 of Appendix A and inserted into question #2.
6. The language "...host, vector and/or DNA source..." will be added to question #4 of Appendix A.
7. Question #2 of Appendix B will include a definition for 'agent(s)' and the language "consult the Institutional Biosafety Officer for assistance or" will be deleted to be consistent with question #4 in Appendix A.
8. Appendix C, question #5A will be modified to spell out 2/3 and will read "two-thirds".
9. Question #1 and question #6 will be deleted from Appendix C as they are repeats from appendices A and B.

The general application form for rDNA, Biohazards, and Animal Gene Transfer protocols will be revised and distributed to the committee prior to the April IBC meeting.

4. **Preliminary Review Form**

The Preliminary Review Form has been updated to a new format for consistency with the General IBC Application form. The committee reviewed and discussed a draft of the new version and the following changes will be made to the form prior to initiation of use:

1. The Section titled "Approvals" will be modified to reflect that the IIPC is no longer in existence. The checkbox indicating this approval will be deleted.
2. The link to the *NIH Guidelines* will be provided under Section C (http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html).

The Preliminary Review Form will be revised and distributed to the committee prior to the April IBC meeting.

5. **Annual Review Form**

Previously, investigators submitting annual reviews for exempt protocols were required to fill out the Preliminary Review Form. It was brought to the attention of the Committee that the Preliminary Review Form contains a number of questions that are tedious for the investigator to fill out on an annual basis. Therefore, the committee has decided to use the same Annual Review Form for both exempt and non-exempt studies. This review form contains all the necessary information for the committee to make a determination of changes in the proposal.

6. **Reviewer Sheets**

The committee reviewed and discussed changes to the Institutional Biosafety Committee Reviewer Sheets. The reviewer sheets have been modified to include containment level approvals. The committee also discussed a revision to the meeting packets. Previously, personalized reviewer sheets were made for each reviewer and included in the packets. The committee will now receive two blank reviewer sheets. The body of the first reviewer sheet will be left blank for those reviewers typing their responses. The body of the second reviewer sheet will include lines for those reviewers hand-writing their responses. Each reviewer will be required to print their full name in the required fields and sign at the bottom of the page.

RECOMBINANT DNA DEFERRED PROTOCOLS

1994R0007 RECOMBINANT DNA AND BIOHAZARD SAFE PRACTICES FOR THE KNOELL LABORATORY, Daren L. Knoell, Pharmacy

The protocol was **tabled** due to an earlier version of the application being distributed to the Committee. The revised application will be provided prior to the April meeting.

Type of Research: rDNA, Biohazards

2005R0080 USE MURINE RETROVIRAL-GENE TRANSFER/BONE MARROW TRANSPLANTATION TO STUDY THE BONE MARROW STEM CELL ORIGIN OF SOLID CANCER, Sanford H Barsky, Pathology

Discussion:
The principal investigator proposes to study and understand the bone marrow stem cell origin of solid cancers. The investigator intends to test whether breast cancer and lung cancer can be transferred by introducing "genetically marked" bone marrow derived from tumor-prone transgenic mice or wild-type healthy mice into either unmarked tumor-prone transgenic mice or normal healthy mice, respectively. By using an *ex vivo* method to label, a recombinant retrovirus carrying a GFP or luciferase expression unit will be used to genetically mark bone marrow cells. The labeled bone marrow cells will then be injected into lethally irradiated recipient mice by intravenous tail. The investigator hypothesizes that the cancer will develop in the recipient mice from the donor-derived bone marrow stem cells. The hypothesis will be tested by observing the recipient mice for 4-8 months.

The Committee discussed the revisions to the deferred protocol and feel that the principal investigator has adequately addressed the prior concerns.

The Committee **APPROVED** the biosafety plan

NOTE: Please revise the second sentence in Question #28 to read "Contaminated absorbent materials will be transferred to a lined red biohazard bag, autoclaved and placed in an infectious waste box for collection and disposal by Environmental Health & Safety."

NOTE: Please provide a copy of the revised application to the Institutional Biosafety Committee.

Total: 9; vote for 9; opposed 0; abstained 0

Biosafety Level: BSL-2

Type of Research: rDNA, Biohazards

2005R0081 EPIGENETIC CHANGES IN LUNG CANCER, Gregory Otterson, Internal Medicine

Discussion:
The principal investigator intends to study epigenetic events that alter the functional aspects of cancer, specifically thoracic malignancies. The investigator proposes to re-introduce "recombinant elements" into cell lines. These "recombinant elements" are microRNAs and are re-introduced using adenovirus vectors into the tumor cell lines. The investigator then intends to analyze the effect on downstream events, specifically cell viability, apoptosis, cell cycle, soft agar cloning, and sensitivity to chemotherapy and/or radiation.

The Committee discussed the revisions to the deferred protocol and feel that the principal investigator has not addressed all of the concerns.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Spill Management** (Question #15)—Indicate that the bleach being used for disinfection will be at a minimum concentration of 10%.
2. **Biosafety Cabinet** (Question #17)—Specify the type of biosafety cabinet that the laboratory contains.
3. **Personnel** (Question #22)—Please ensure that all laboratory personnel complete the Occupational Health Registry Questionnaire found online at https://rf.osu.edu/secure/ochre.

Total: 9; vote for 9; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: rDNA

RECOMBINANT DNA NEW PROTOCOL SUBMISSIONS

2006R0005 THE FHIT AND WWOX SIGNALING PATHWAYS IN CANCER, Kay Huebner, Molecular Virology, Immunology, and Medical Genetics

Summary:
The principal investigator intends to examine the mechanisms of FHIT and WWOX through both *in vivo* and *in vitro* studies. Mice that have developed inducible or spontaneous tumors will be injected with ~10^{10} viral particles. These particles will be injected either during the tumor development process or once the tumor is established for cure or reduction. In lower organisms, FHIT may be fused with Nit1 and some cells may be transfected and infected with Nit constructs to study the possible intersections of these pathways. Constructs in which FHIT and WWOX genomic sequences are cloned into vectors that allow expression of the gene will be used as well as constructs with antisense DNA or hairpin sequences allowing knockdown of expression of the gene. The *in vitro* experiments will study the upstream or downstream proteins affected by FHIT or WWOX. The goals of the study are to determine the function of the FHIT and WWOX tumor suppressor genes.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Protocol Summary** (Question #2)—Provide a description of the transgenic animals to be used in this study; section 11 indicates that transgenic animals will be produced.
2. **Potential Risks** (Question #3)—Indicate that there is a low potential for exposure to Adenovirus and mild respiratory symptoms.
3. **Vectors and Inserts** (Question #9b)—Provide information regarding the AAV system and lentiviral vectors to be used in this study.
4. **Occupational Health Issues** (Question #17)—Indicate that there is a low potential for exposure to Adenovirus and mild respiratory symptoms.
5. **Biohazards Transport** (Question #21)—Delete the first sentence in this section.
6. **Training** (Question #25)
   - Indicate that all personnel will complete the annual online Biosafety Training. Biosafety training is available at www.ehs.ohio-state.edu at the biosafety link.
   - Indicate the personnel training will include review of *NIH Guidelines for Research Involving Recombinant DNA Molecules*.
7. **Medical Surveillance** (Question #26)—Please ensure that all laboratory personnel complete the Occupational Health Registry Questionnaire found online at https://rf.osu.edu/secure/ochre; please be aware that the process for completing the Occupational Health Registry Questionnaire has changed to electronic submittal and all laboratory personnel will be required to submit the form online.
8. **Spill Management** (Question #28)—Revise step 4 of the section to read "The absorbent material used for clean up shall be disposed in a biohazard box" instead of "The absorbent material used for clean up should be disinfected before disposal in a biohazard box"; disinfecting the absorbent material prior to disposal increases risk exposure.
9. **Laboratory Space** (Question #29)—Indicate the laboratory space that will be used for BSL-2 practices.

Total: 9; vote for 9; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2006R0006 QUANTITATING BACTERIAL COUNTS AND BACTERIAL GENE EXPRESSION IN ANIMALS, Brian Ahmer, Microbiology

Summary:
The principal investigator intends to study the host range determinants and basic pathogenesis. The principal investigator proposes to perform genetic studies including gene cloning and mutagenesis on the signal-detecting organisms including *Escherichia*, *Salmonella*, *Enterobacter*, and *Klebsiella*. Work with signal generators including *Aeromonas*, *Pseudomonas*, *Vibrio*, *Yersinia* (excluding *pestis*) and *Hafnia* will also be performed. Standard cloning of genes from these bacteria using *E. coli* K12 or placing the cloned genes back into their host origin will be completed. A variety of vectors will be used for routine cloning, allelic exchange, and expression studies.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Protocol Summary** (Question #2)—Revise the last sentence in the first paragraph to reference the category of bacterial species as RG1 or RG2 rather than BSL1 or BSL2.
2. **Vectors and Inserts** (Question #9)—Provide and overview of the vectors to be used in this study.
3. **Personal Protective Equipment** (Question #19)
   - Revise the section to read "...lab coats and **gloves** are used" instead of "...only lab coats are used."
   - Revise the first sentence to read "...safety **goggles**..." instead of "...safety **glasses**..."
4. **Waste Disposal** (Question #22)
   - Indicate that the solid waste will be autoclaved before disposed of in a Biohazard burn box and picked up by Environmental Health & Safety.
   - Indicate that the liquid waste containing human pathogens will be absorbed onto inert material after treatment and then disposed of in a Biohazard burn box and picked up by Environmental Health & Safety.
5. **Animals** (Question #24)
   - Indicate the source and species of turtles to be used.
   - Under the section marked 'other', clarify whether or not the water in the turtle is a source of potential infection.
   - Indicate whether or not ULAR is involved in the care of the animals used in this study and if so, provide their procedures.
   - Provide detail regarding the large animal arrangements made with North Carolina State University and Texas A&M University; clarify whether or not OSU personnel will visit these campuses and conduct research there.
6. **Training** (Question #25)—Spell out the abbreviations 'PPE' and 'MSDS'.
7. **Medical Surveillance** (Question #26)—Please ensure that all laboratory personnel complete the Occupational Health Registry Questionnaire found online at https://rf.osu.edu/secure/ochre; please be aware that the process for completing the Occupational Health Registry Questionnaire has changed to electronic submittal and all laboratory personnel will be required to submit the form online.
8. **Disinfection** (Question #27)
   - Describe the procedures to be used for handling fecal material and specimens.
   - Revise the section to reflect a longer contact time; 10% bleach for 20 minutes.

Total: 9; vote for 8; opposed 0; abstained 1

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2006R0010 GENE SILENCING IN PETUNIA X HYBRIDA USING TOBACCO RATTLE VIRUS (TRV), Michelle Jones, Horticulture and Crop Science

Summary:
The investigator intends to study the molecular regulation of flower senescence. The study will use virus-induced gene silencing (VIGS) to determine which genes have a functional role in the petal senescence program. Using the tobacco rattle virus (TRV) containing fragments of senescence-related genes from petunias, the investigator will induce VIGS in

petunias. A chalcone synthetase reporter gene that will silence anthocyanin synthesis in transformed flower petals will be used. The investigator intends to evaluate and identify the plants with accelerated or delayed petal senescence.

The Committee **APPROVED** the biosafety plan

NOTE: Please provide containment levels for Williams Hall and the indoor growth Chamber in Question #16.

NOTE: Please provide the contact time for Question #14 and Question #15.

NOTE: Please provide a copy of the revised application to the Institutional Biosafety Committee.

Total: 10; vote for 10; opposed 0; abstained 0

Biosafety Level: BSL-2P
Type of Research: rDNA

BIOHAZARDS DEFERRED PROTOCOLS

2005R0087 PATHOGENESIS, INTERSPECIES TRANSMISSION, AND VACCINE STUDY OF INFLUENZA A VIRUSES, Chang Won Lee, Food Animal Health Research Program

Discussion:
The principal investigator intends characterize low pathogenicity avian influenza virus isolates. The investigators will laboratory work which will involve creating infectious clones of full-length DNA using reverse genetics. Using new methods in biotechnology, the investigators hope to attenuate the virus and create a more effective vaccine. The research will also include animal studies involving chickens and turkeys to assess interspecies transmission. Other aims of the study include the development of advanced vaccine or preventive treatment (including companion diagnostic testing) and assessing the effect of vaccines on antigenic drift of the avian influenza virus.

The Committee discussed the revisions to the deferred protocol and feel that the principal investigator has not addressed all of the concerns.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **General**
   - As required for work with avian influenza virus, provide documentation that an APHIS permit has been obtained.
   - Specify whether or not the APHIS permit allows the transportation of the avian influenza virus from the laboratory to other locations (such as Athens and Georgia as noted in Questions #3 and #7).
2. **Protocol Summary** (Question #2)
   - Provide a more detailed description of the experiments that will be conducted.
   - Specify where the incinerator is located and whether or not it is approved for the terminal disposal of infected animal carcasses.

- Specify the Ag Guide being used (give the title, source, and version).
- Indicate that the carcasses will be placed in burn boxes for pick-up by the Office of Environmental Health and Safety.

3. **Potential Risks** (Question #3)—Indicate the criteria for recognizing an increase in virulence of the virus *in vitro*.
4. **Agent Acquisition** (Question #7)—Indicate that the viruses not being used for animal experiments be destroyed by autoclaving followed by incineration.
5. **Biohazards Transport** (Question #12)
   - Indicate how the infected animals will be transported from the isolation rooms to the necropsy rooms in another building.
   - Provide more detail describing the procedures for the handling of embyonated eggs inoculated with avian influenza virus in the laboratory setting.

NOTE: The Committee suggested that the principal investigator work with Dr. Ken Theil to address the above modifications.

Total: 9; vote for 9; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Biohazards

BIOHAZARDS NEW PROTOCOLS

2006R0008 PARAINFLUENZA VIRUS INFECTION IN COTTON RATS, Stefan Niewiesk, Veterinary Biosciences

Summary:
The human parainfluenza virus type 3 (HPV-3) contains two glycoproteins, the hemagglutinin-neuraminidase (HN) protein and the fusion (F) protein. Dr. Anne Moscona, a collaborator in this project from Cornell University has selected naturally occurring mutants that either have a high binding affinity to the receptor or a lower receptor cleavage activity. The investigator intends to study the effect of these mutants in terms of viral replication *in vivo* and immunopathology by testing them in the cotton rat model. The investigator also proposes to evaluate the effect of humagglutinin-neuraminidase inhibitors on wildtype HPV-3 in the animal model.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Protocol Summary** (Question #2)—Provide a more detailed description of the experiments that will be conducted.
2. **Laboratory Space** (Question #20)—Indicate that the date of last inspection for Sisson Hall (animal room) was January 15, 2006.

Total: 9; vote for 8; opposed 0; abstained 1

Biosafety Level: BSL-2
Type of Research: Biohazards

2006R0009 EFFECTS OF HIV INFECTION ON HOST CELL PROTEINS, Richard Fishel, Molecular

Virology, Immunology, and Medical Genetics

Summary:
The principal investigator proposes to evaluate the effect of HIV infection on the phosphorylation status of host DNA repair proteins. The investigator hypothesizes that the phosphorylation will aid in reducing HIV infection efficiency. The study will encompass producing HIV-1 virus and releasing it into the media. The media is then added to a T cell line and the T cells would be lysed in the presence of SDS and analyzed.

The Committee **REQUIRES MODIFICATIONS** to the biosafety plan

1. **Potential Risks** (Question #3)—Describe the risks and types of exposure that could present potential risks.
2. **Spill Management** (Question #19)
   - Indicate that Environmental Health & Safety will be notified of a spill.
   - Clarify the statement "there is no risk of aerosol formation" in the last sentence of the first paragraph.
3. **Training** (Question #25)—Indicate that the training will include BSL-3 standard practices.

Total: 9; vote for 9; opposed 0; abstained 0

Biosafety Level: BSL-2
Type of Research: Biohazards

PROTOCOLS APPROVED ADMINISTRATIVELY

1997R0017 ROLE OF HTLV REX IN VIRAL REPLICATION AND TRANSFORMATION, Patrick L. Green, Veterinary Biosciences

Date of Determination: February 1, 2006

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2005R0084 MYCOBACTERIA-MACROPHAGE INTERACTIONS IN IRON METABOLISM AND MACROPHAGE ACTIVATION, William Lafuse, Molecular Virology, Immunology, and Medical Genetics

Date of Determination: February 8, 2006

Biosafety Level: BSL-3
Type of Research: rDNA, Biohazards

ANNUAL REVIEWS APPROVED ADMINSTRATIVELY

2002R0066 BONE MORPHOGEN THERAPY FOR EQUINE FRACTURE HEALING, Alicia

Bertone, Veterinary Clinical Sciences

Date of Determination: February 20, 2006

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2002R0074 HUMAN BLOOD AND TISSUE PROCESSING, Michael Para, Infectious Diseases

Date of Determination: February 23, 2006

Biosafety Level: BSL-2
Type of Research: Biohazards

2003R0008 TYPE IV SECRETION AND SIGNAL TRANSDUCTION IN EHRLICHIOSES, Yasuko Rikihisa, Veterinary Biosciences

Date of Determination: February 8, 2006

Biosafety Level: BSL-2
Type of Research: Biohazards

2003R0060 EFFECTS OF PHOTOPERIDO ON CELLULAR AND ORGANISMAL ENERGETIC DEMANDS, Randy Nelson, Psychology

Date of Determination: February 23, 2006

Biosafety Level: BSL-3
Type of Research: Biohazards

2004R0004 THE EFFECT OF EXTRACELLULAR MATRIX-CELL SIGNALING MECHANISMS ON SKELETAL MUSCLE GROWTH, Sandra Velleman, Animal Sciences

Date of Determination: February 1, 2006

Biosafety Level: BSL-1
Type of Research: rDNA

2004R0012 TREATMENT OF CHRONIC WOODCHUCK HEPATITIS VIRAL INFECTIONS, Daral Jackwood, Food Animal Health Program

Date of Determination: February 20, 2006

Biosafety Level: BSL-2
Type of Research: Biohazards

2004R0015 GENOME SCANNING FOR ABERRANT METHYLATION IN CANINE LYMPHOMA, Laura Rush, Veterinary Biosciences

Date of Determination: February 14, 2006

Biosafety Level: BSL-1
Type of Research: rDNA

2004R0019 BEHAVIORAL STUDIES OF ECHO-PROCESSING AND COMMUNICATION BY BATS, William Masters, Evolution, Ecology, and Organismal Biology

Date of Determination: February 14, 2006

Biosafety Level: BSL-2
Type of Research: rDNA

2004R0042 TARGETING THE MITOCHONDRIAL CALCIUM UNIPORTER, Douglas Pfeiffer, Molecular & Cellular Biochemistry

Date of Determination: February 1, 2006

Biosafety Level: BSL-1
Type of Research: rDNA

2004R0054 RESPIRATORY SYNCYTIAL VIRUS VECTOR, Stefan Niewiesk, Veterinary Biosciences

Date of Determination: February 20, 2006

Biosafety Level: BSL-1
Type of Research: rDNA, Biohazards

2004R0055 CANINE DISTEMPER VIRUS INFECTION IN VIVO AND IN VITRO, Stefan Niewiesk, Veterinary Biosciences

Date of Determination: February 20, 2006

Biosafety Level: BSL-2
Type of Research: Biohazards

2005R0019 INFECTIOUS BURSAL DISEASE VIRUS INFECTION STUDIES, Daral Jackwood, Food Animal Health Program

Date of Determination: February 20, 2006

Biosafety Level: BSL-2
Type of Research: Biohazards

2005R0021 FC RECEPTOR BIOLOGY, Clark Anderson, Internal Medicine

Date of Determination: February 1, 2006

Biosafety Level: BSL-1
Type of Research: rDNA

2005R0024 MOLECULAR ANALYSIS OF ACCURATE RIBOSOMAL TRANSLOCATION, Kurt Fredrick, Microbiology Administration

Date of Determination: February 8, 2006

Biosafety Level: BSL-1
Type of Research: rDNA

AMENDMENTS PPROVED ADMINSTRATIVELY

1999R0066 DETECTION, CHARACTERIZATION, PATHOGENESIS, AND IMMUNITY TO ENTERIC VIRUSES OF SWINE AND CATTLE, Linda J Saif, FAHRP/OARDC

Date of Determination: February 14, 2006

Biosafety Level: BSL-2
Type of Research: rDNA, Biohazards

2003R0040 RECOMBINANT DNA AND BIOHAZARD SAFE PRACTICE FOR THE GUNN LABORATORIES, John S. Gunn, Molecular Virology, Immunology, and Medical Genetics

Date of Determination: February 8, 2006

Biosafety Level: BSL-3
Type of Research: rDNA, Biohazards

2005R0043 ONCOLYTIC HSV TARGETING TO THE P16 TUMOR SUPPRESSOR PATHWAY, E. Antonio Chiocca, Neurosurgery

Date of Determination: February 1, 2006

Biosafety Level: BSL-2
Type of Research: Biohazards

EXEMPT PROTOCOLS

2006R0007 MOLECULAR STUDIES OF ION CHANNELS IN PRIMARY NEURON/GLIA CULTURES, Chen Gu, Neuroscience

Date of Determination: February 14, 2006

Biosafety Level: BSL-7
Type of Research: rDNA

PENDING PROTOCOLS

2005R0086 ONCOGENES AND TUMOR SUPPRESSOR GENES IN CANCER INITIATION AND PROGRESSION, Carlo Croce, Molecular Virology, Immunology, and Medical Genetics

Date of Last Communication: February 24, 2006

Type of Research: rDNA, Biohazards

2006R0002 NEWCASTLE DISEASE VIRUS BASED VECTORS FOR IMMUNIZATION AGAINST MEASLES AND RSV INFECTION, Stefan Niewiesk, Veterinary Biosciences

Date of Last Communication: February 24, 2006

Type of Research: rDNA, Biohazards

2006R0003 GENE THERAPY OF BRAIN TUMORS, E. Antonio Chiocca, Neurological Surgery

Date of Last Communication: February 24, 2006

Type of Research: rDNA, Biohazards

2006R0004 BIOLOGY OF TAUOPATHIES STUDIED WITH HSV AMPLICONS-REVISED, E. Antonio Chiocca, Neurological Surgery

Date of Last Communication: February 24, 2006

Type of Research: rDNA, Biohazards