SOURCE: IBC Archive | The Sunshine Project - FOI Fund | www.sunshine-project.org UNIVERSITY OF CALIFORNIA, DAVIS

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SANTA BARBARA · SANTA CRUZ

LARRY N. VANDERHOEF Chancellor at Davis OFFICE OF THE CHANCELLOR ONE SHIELDS AVENUE DAVIS, CALIFORNIA 95616-8558 TELEPHONE: (530) 752-2065 FAX: (530) 752-2400

OFFICE OF THE CAMPUS COUNSEL

Telephone: (530) 754-6295 Facsimile: (530) 752-4931

May 25, 2006

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

RE: California Public Records Act Request

Dear Mr. Hammond.

Enclosed is a receipt for your payment of \$6.20 for copies of the minutes of the campus' Institutional Biosafety Committee (IBC) since May 2003, which are also enclosed.

Names of investigators have been redacted from these minutes in order to protect their privacy and security interests. This information has been withheld in accordance with the National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, as well as pursuant to section 6255 of the California Public Records Act, which permits the University to not disclose records when the public interest served by not making the records public clearly outweighs the public interest served by disclosure of the record. In this case the public interest in withholding personally identifying information about these individuals due to actual harassment and threats of harassment that have occurred and continue to occur clearly outweighs the public interest in the disclosure of this information. See, e.g., Times Mirror Co. v. Superior Court, 53, Cal.3d 1325 (1991) (public interest in withholding the appointment calendars of the Governor of California due to "potential threat to the Governor's physical security" outweighed public interest in disclosure of the calendars); New York Times Co. v. Superior Court, 218 Cal.App.3d 1579 (1990) (names of persons who have violated water allocation limits may be withheld when there is evidence that release of such information may subject those persons to harassment or assault).

Also in accordance with the National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, a small amount of information considered to be proprietary has been redacted from these minutes.

SOURCE: IBC Archive | The Sunshine Project - FOI Fund | www.sunshine-project.org Hammond, Edward H.
May 25, 2006
Page 2

The UC Davis IBC reviews biohazardous activities. These biohazardous activities include all of the categories as listed in the Fink Committee Report. This review was started before the Fink Committee Report was published. The NSABB (National Science Advisory Board on Biosecurity) is currently reviewing the Fink Committee Report and if the NSABB issues recommendations concerning the review of the Fink Committee Report categories, we will reevaluate our practices at that time.

If you have any questions or additional requests please feel free to contact me.

Sincerely,

Lynette Temple

Information Practices Coordinator

Spette Jengle

(530) 752-3949

Enclosures

June 16, 2003 Minutes

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety

In attendance:

Jodi Casselman

Susan Cummings
Carl Foreman

Gilbert Garcia

Community Member, Sagres Discovery
Specialist, Environmental Health & Safety
Director, Environmental Health & Safety
Principal Technician, Environmental Health & Safety

Fred Jacobsen

Ex Officio Member, Environmental Health & Safety

William Jewell

Voting Member, Molecular Structure Facility

Voting Member, Molecular Structure Facility

Deborah Kimbrell Voting Member, Molecular & Cellular Biology
Nicholas Lerche Voting Member, Chair, California National Primate Research Center

Michael O'Malley Ex Officio Member, Employee Health Services

Maria Mudryj Voting Member, Med: Microbiology & Immunology

Sonia Rosenberger Voting Member, Biosafety Officer, Environmental Health & Safety

Phil Tillman Ex Officio Member, Campus Veterinarian

I. The April 21, 2003 minutes were reviewed

II. Report of Biosafety Level 1 project(s)

- A. Thea Wilkins' Biosafety Level 1 recombinant project, BUA 0452 renewal "Cotton genomics".
- B. Bo Liu's Biosafety Level 1 recombinant project, BUA 0106 renewal "Studies of cytoskeleton in higher plants and fungus Aspergillus". Dr. Liu is using Aspergillus nidulans, a species that is pathogenic only to humans with Chronic Granulomatous Disease. As part of BUA training, Dr. Liu has been instructed to provide this information to personnel on the project.
- C. Diane Beckles' Biosafety Level 1 recombinant project, new BUA 0711 "Screening transgenic tomato population expressing Arabidopsis transcription factors".

III. Review of Biological Use Authorizations (BUAs):

A. BUA No. 0693

Title: host responses

The Committee approved the protocol subject to the following condition:

1. Update the room number.

B. BUA No. 0672

Title: Genetic abnormalities underlying sudden cardiac death in humans

The Committee approved the protocol.

Minutes

C. BUA No. 0707

Title: Ion channels in the mammalian nervous system

The Committee approved the project subject to the following conditions:

- 1. Provide an updated signature page with the Department Chair's signature.
- 2. Provide source of cultured cell lines (general): vendor, species, tissue type.
- 3. Provide manufacturer information on the Ad-Easy vector system.

D. BUA No. 0708

Title: Cloning and expression of odorant-binding and pheromone-degrading enzymes

The Committee approved the project subject to the following conditions:

- 1. Complete the "Training of authorized users" table on page 2
- 2. Complete the "Lab locations of authorized users" table on page 2
- 3. Complete the "Select Agents and Toxins" section on page 3 either check all boxes "no" or check the single "I am not using any of the select agents or toxins listed below" box at the top of the page.
- 4. Provide rationale for listing BL21 cells as Biosafety Level 2.

E. BUA No. 0709

Title: A multicenter, randomized, double-blind, placebo controlled study to evaluate the efficacy and safety of in patients with stable angina

The Committee approved the project subject to the following conditions:

- Check the "yes" box and uncheck the "no" box for the question "This protocol will be submitted to NIH for Human Gene Transfer Proposal approval." We understand the protocol has already been submitted to NIH's RAC.
- 2. State in the BUA that the safety reporting requirements of Appendix M-1-C-4-b of the NIH Guidelines will be followed.
- 3. Consult with Infection Control before procedures are performed.
- 4. Invite Dr. Rosenberger to participate in Berlex's site initiation and training visit.
- 5. Have Berlex submit the answers to Appendix M that they submitted to the RAC (for our files).
- Have Berlex submit how they are meeting some of the recommendations in the NIH Report – Assessment of Adenoviral Vector Safety and Toxicity: Report of the National Institutes of Health Recombinant DNA Advisory Committee (Human Gene Therapy 13:3-13)
 - a. Determination of vector potency and strength should include analysis of transgene expression measure as levels of mRNA or protein
 - b. All research participants enrolled in gene transfer clinical trials should be monitored for several types of acute toxicities before and after vector administration. For better surveillance across all such studies, monitoring should routinely include a research participant's immune status (both humoral and cellular), cytokine profile, and predisposing or underlying conditions that might elevate an individual's sensitivity to a particular vector (research participant genotype, secondary and concurrent infections)....This monitoring should include measurements conducted both before and after vector administration.
 - c. Research participants in gene transfer clinical trials should be encouraged to agree to post-mortem examinations.

June 16, 2003 Minutes

- 7. Provide reference for the two human studies with the investigational product that were referenced in the informed consent document. We received a reference for only one from the Phase 1/2 trial Angiogenic Gene Therapy (AGENT) Trial in Patients with Stable Angina Pectoris (2002) Circulation 105:1291-1297.
- 8. Present the Institutional Review Board the following items for consideration in review of the informed consent document.
 - a. The NIH Report Assessment of Adenoviral Vector Safety and Toxicity: Report of the National Institutes of Health Recombinant DNA Advisory Committee recommended that "(I)nformed consent documents need to be improved to clarify risks and potential benefits faced by those who participate in gene transfer clinical trials." The Clinical Study Protocol (p58) instructs the investigator to "explain the nature of the study, its purpose and associated procedures, the expected duration and the potential benefits and risk of participation to each patient prior to his/her entry into the study...

The Benefits section of the informed consent document state that "the benefit you receive from this experimental treatment may be none, minimal, or significant". The results from the Phase 1/2 trial reported that "patients who received tended to have greater improvements in exercise tolerance at 4 weeks (1.3 versus 0.7 minutes...). A protocol-specified, subgroup analysis showed the greatest improvement in patients with baseline ETT <= 10 minutes (1.6 versus 0.6 minutes...)". We think that these results should be in the Benefits section of the informed consent document.

- b. The NIH Report Assessment of Adenoviral Vector Safety and Toxicity: Report of the National Institutes of Health Recombinant DNA Advisory Committee recommended that "(r)esearch participants in gene transfer clinical trials should be encouraged to agree to post-mortem examinations." We did not see post-mortems addressed in the informed consent document.
- c. The statement in Section 2 Study Procedure 2. "A series of tests over the next six weeks will....evaluate you for the presence of cancer." While Section 4 Risks and Discomforts 8. states that "it is possible that an undetected tumor could be stimulated to grow faster by the document does not tell you what body parts and types of cancers are evaluated in the screening process. Could the first statement be misinterpreted that the patient is being evaluated for all cancers?
- d. The Study Protocol specifies that cardiac medications should remain constant, unless absolutely necessary. Patients will probably wonder whether they can change their medications during the study period. Can this be addressed in the informed consent document?
- e. As we do not routinely review informed consent documents, we were wondering if some of the language was misleading.

Section 1 – Purpose and Background – "Humans have a gene that makes a protein, which governs the growth of blood vessels. This protein is called which stands for 'This statement appears to indicate we only know of one protein that governs the growth of blood vessels, and therefore, is the only one that can be used.

June 16, 2003 Minutes

Section 2 – Study Procedure – "If you decide to volunteer, we will make sure that it is safe for you to participate..." How is "safe" defined?

Section 6 – Additional Risks – "While animal tests suggest that this will be safe and effective..." How is effective defined?

Note: Additional conditions were specified at the July 21, 2003 meeting.

F. BUA No. unassigned

Title: Use of antimicrobial functions on Type N95 filter media

The Committee deferred protocol review until the Chemical Safety Administrative Advisory Committee has reviewed the protocol. The Committee had the following questions as well:

- 1. How is bacterial kill going to be evaluated?
- 2. What is the benefit of a treated N95 masked over a N99 respirator?

G. BUA No. 0642

Title: Pathogenic basis of hepatic fibrosis

The Committee approved the project subject to the following conditions:

- 1. Provide vector source and composition
- 2. Provide verification and method used to determine that the vector is replication-defective
- 3. Provide signed copy of amendment form.

H. BUA No. 0710

Title: Mechanisms and Regulation of Lymphokine Secretion by Single T Lymphocytes

The Committee approved the project subject to the following conditions:

- 1. Check yes box on top of page 9 "I am working with toxins known to affect humans and/or animals".
- 2. Replace all "should be" language with "must" or "shall".
- 3. Provide information on whether the pipettors used with toxin are dedicated and/or use aerosol tips.
- 4. Provide information on whether the Principal Investigator is autoclaving waste materials or whether the waste is being sent out as medical waste (medical waste collected from campus that is not sent to Stericycle is treated at UCDMC by an approved method, but not by autoclaving) see pages 8 and 13.

IV. DISCUSSION ITEMS:

A. Plant Transformation Facility BUA – The facility does need its own BUA with a high-level overview of how transgenic plants are generated and handled. Each Principal Investigator providing material to the facility shall have an approved BUA prior to submitting material.

SOURCE: IBC Archive | The Sunshine Project - FOI Fund | www.sunshine-project.org July 21, 2003 Minutes - draft

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety

In attendance:

Jodi Casselman Community Member, Sagres Discovery Susan Cummings Specialist, Environmental Health & Safety Carl Foreman Director, Environmental Health & Safety

Principal Technician, Environmental Health & Safety Gilbert Garcia Ex Officio Member, Environmental Health & Safety Fred Jacobsen William Jewell Voting Member, Molecular Structure Facility

Deborah Kimbrell Voting Member, Molecular & Cellular Biology

Judith Kjelstrom Voting Member, Microbiology (Biotechnology Program)

Nicholas Lerche Voting Member, Chair, California National Primate Research Center

Maria Mudryi Voting Member, Med: Microbiology & Immunology

Voting Member, Biosafety Officer, Environmental Health & Safety Sonia Rosenberger

Phil Tillman Ex Officio Member, Campus Veterinarian

Tim Wilson Community Member, Yolo County Health Department

- I. The April 21, 2003 revised minutes and June 16, 2003 minutes were approved.
- II. Review of Biological Use Authorizations (BUAs):

A. BUA No. 0709

Title: A multicenter, randomized, double-blind, placebo controlled study to evaluate the efficacy and safety of · in patients with stable angina

The Committee specified additional conditions for protocol approval:

- 1. Present the Institutional Review Board the following additional items for consideration in review of the informed consent document.
 - "Growth factor" is not defined, and known biological actions are limited to its action governing the growth of blood vessels. This appears to indicate that only acts on the body to stimulate the growth of blood vessels.
 - b. Consider whether and how to include status as an oncogene. Follows are selected references regarding status as an oncogene (not a comprehensive review).
 - 1) Infobiogen CancerGene database. CancerGene Card for http://caroll.vjf.cnrs.fr/cancergene/CG122.html
 - 2) R&D Systems. Fibroblast Growth Factors. 2001, Http://www.rndsystems.com/asp/g_sitebuilder.asp?bBodyOnly=1&bodyId=3
 - 3) Ornitz DM and Itoh N. Fibroblast growth factors. Genome Biology 2001, 2(3): reviews3005.1-3005.12 http://genomebiology.com/2001/2/3/reviews/3005
 - 4) Hajitou ., Baramova EN, Bajou K, Noe V, Bruyneel E, Mareel M, Collette J, Foidart HM and Calberg-Bacq CM. FGF-3 and FGF-4 elicit distinct oncogenic properties in mouse mammary myoepithelial cells. Oncogene 1998, 17: 2059-2071. http://www.nature.com/cgi-

SOURCE: IBC Archive | The Sunshine Project - FOI Fund | www.sunshine-project.org
July 21, 2003
Minutes - draft

taf/DynaPage.taf?file=/onc/journal/v17/n16/full/1202126a.html&filetype=pd f

- Kiuru-Kuhlefelt S, Sarlomo-Rikala M, Larramendy ML, Soderlund M, Hedman K, Miettinen M and Knuutila S. FGF4 and INT2 oncogenes are amplified and expressed in Kaposi's Sarcoma. *Modern Pathology* 2000, 13(4): 433-437
- 6) Talarico D, Ittmann M, Balsari A, Delli-Bovi P, Basch RS and Basilico C. Protection of mice against tumor growth by immunization with an oncogeneencoded growth factor. Proceedings of the National Academy of Sciences 1990, 87: 4222-4225
- 7) Delli-Bovi P, Curatoloa AM, Newman KM, Sato Y, Moscatelli D, Hewick RM, Rifkin DB and Basilico C. Processing, secretion, and biological properties of a novel growth factor of the fibroblast growth factor family with oncogenic potential. *Molecular and Cellular Biology* 1988, 8(7): 2933-2941.

B. BUA No. 0477

Title: SIV/SHIV in Macaques as a Model for AIDS Pathogenesis, Transmission, Vaccine Development and Antiviral Therapy

The Committee approved the protocol subject to the following conditions:

1. Clarify statement on page 7, Gene(s) to be cloned: "Portions of...SIV, HIV; entire SIV and SHIV genome". Are you cloning the entire genome or pieces of the entire genome? If the entire genome, what project does this refer to?

C. BUA No. 0620

Title: Extended Safety Evaluation in Subjects Who Have Participated in Chiron Technologies Center for Gene Therapy Retrovirus Protocols

The Committee approved the protocol.

D. BUA No. 0718

Title:

Ecological genetics of birds infected with West Nile Virus

The Committee approved the protocol.

Note: This BUA was originally designated 0711. As BUA number 0711 was already assigned to Diane Beckles, Dr. Ernest's BUA has been reassigned to number 0718.

E. BUA No. 0712

Title:

The role of innate immunity in Rhodococcus equi infection

The Committee approved the protocol.

The Committee requested the following when Dr. Watson renews her protocol in 3 years.

- 1. Use the current BUA form.
- 2. Include a reference list for those denoted in the project description text.

III. DISCUSSION ITEMS:

A. Biosafety Level of Vaccinia Ankara

Minutes - draft

We deferred this item until September when the RAC makes its recommendations.

B. Disposal of feces from FIV/FeLV-infected felines

The current practice of autoclaving feces from FIV/FeLV-infected felines in Niels Pederson's lab has been occurring for twenty years. Lon Kendall has asked the BSAAC for its opinion on whether this practice is necessary. As FIV and FeLV are not human pathogens, the waste does not meet the definition of regulated medical waste. FIV and FeLV are transmitted to other felines through close secretion or bite contact, but not incidental contact with feces. Unless the landfill has restrictions to accepting the feces, the BSAAC determined that autoclaving was unnecessary prior to disposal. Landfill personnel shall be informed of the change in a brief training.

C. Sacramento and Davis area members of Physicians for Social Responsibility July 18, 2003 letter to Virginia Hinshaw.

The letter recommends, in relation to the proposed National Biocontainment Laboratory: "2. That the Western National Center for Biodefense will maintain a fully transparent Biosafety Committee that will review and (dis)approve all projects to be conducted in the BL3 and BL4 facilities, and that all Biosafety Committee documentation will be made concurrently available to the entire public, and that any member of the public will have the right to attend all portions of all committee meetings:

The BSAAC will review and (dis)approve all projects covered by the NIH Guidelines for Research Involving Recombinant DNA Molecules and those at Biosafety Level 2 and above that would be conducted in the National Biocontainment Laboratory, in accordance with current UC Davis policy. As the BSAAC includes two public members, additional members of the public will not be invited to attend. BSAAC meeting minutes, once final, are currently public information. Minutes may be redacted for biosecurity purposes in cooperation with campus counsel.

D. Contained Research Facility

The facility is undergoing through the final commissioning process, and the facility's SOP is being written. The BSAAC would like to review the SOP before it's finalized.

E. Biological Safety Cabinets

The BSAAC would like to help select biological safety cabinet manufacturers and models on campus.

December 15, 2003 Minutes Approved 1/26/04

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety

In attendance:

Carl Foreman Director, Environmental Health & Safety

Fred Jacobsen Assistant Director, Environmental Health & Safety William Jewell Voting Member, Molecular Structure Facility

Judith Kjelstrom Voting Member, Microbiology (Biotechnology Program)
Nicholas Lerche Voting Member, Chair, California National Primate Research

Center

Michael O'Malley Occupational Health Physician

Jodi Casselman Voting Member, Sagres Discovery

Debbie Decker Environmental Health & Safety

Susan Cummings Environmental Health & Safety

I. Approval of November 17, 2003 Minutes

Approved with corrected spelling of Stacey Harmer's last name

II. Updates

- CSAAC Response re: Proposal from Dr. Kyoung Lee on N-95 Respirators Debbie Decker presented the Chemical Safety Committee perspective on the proposed use this respirator. The Chemical Committee concurs with the BSAAC that the N-95 is not suitable for the proposed experiment.
- 2. Review of Sonia Rosenberger's CCM BSL 3 Laboratory Certification report.

III. Review of Biological Use Authorizations (BUAs):

1. BSL 1 Projects

BUA No. 0654

Title: Development of markers for genotype analysis of animals

2. <u>NEW</u>

BUA No. 0722

Title: Estradiol induced neurogenesis in adult rodent brain following ischemic injury: Fate and roles of newborn neurons in brain recovery

Committee requested re-submission that would include:

- 1. Specify the level of heat required to terminally inactivate viral stocks
- 2. Explain how and where mice:
 - Will be exposed,
 - Will be housed/contained before and after exposed and
 - Cages and bedding will be decontaminated.
- 3. Provide specific details on decontamination procedures for potentially contaminated surfaces (BSC, countertops, etc).
- 4. Does this virus infect only mice?
- 5. Correct typographical error on page 6 (thymidine).
- 6. Provide training status for Shotaro Suzuki.

December 15, 2003

Minutes Approved 1/26/04

BUA No. 0723

Title: Novel Defensins of Human Epithelia & In vivo Models of Defensin Activity Committee approved with the following conditions:

- 1. Page 6 Please specify the host defense peptides and genes (class of genes).
- Page 9 Please include that mice will be exposed in a biosafety cabinet.
- 3. Page 8 Please correct spelling of inoculae

BUA No. 0724

Title: Bacterial Chemostaxis to the Herbicide Atrazine Committee requested resubmission that would include:

- Any BSL 2 organisms in the BUA and identify where and how they are stored and used.
- 2. The name of the PI in whose BSL 2 lab the organisms will be stored and that the PI, and her/his laboratory personnel will be trained in the risks associated with your BSL2 organism, including symptoms, disinfection, who to notify in the event of spill, etc.
- 3. That your laboratory personnel will be annually trained to dispose of the BSL 2 organism in accordance with the Medical Waste Management Plan currently in use in the laboratory where it is stored.

3. RENEWALS

BUA No. 0208

Title: Studies on Respiratory Syncytial Virus

The Committee granted approval of this BUA subject to the following:

- 1. Page 5 Please ensure Warren Kalina does not require BBP training.
- 2. Page 5 Please provide UCD IDs for all personnel.
- 3. Page 8 Please put an "X" in the Biosafety level 2 box after agent/toxin No. 2.
- 4. Page 8 Include that transportation of specimens will be in accordance with UCD Biosafety Manual section IV (f) Biological Safety Guidelines, Transportation and Shipping

BUA No. 0400

Title: SIV and HIV Pathogenesis

The Committee granted approval of this BUA subject to the following inclusion of the following condition:

1. Please clarify how organism will be transported outside the lab.

BUA No. 0575

Title: Comparison of tissue and species specific differences between recombinant steroidogenic cytochromes P450 and redox partner proteins with primary tissue counterparts

The Committee granted approved upon completion of the following condition:

1. Page 6 - Please change the biosafety level of "DNA/RNA source(s)" from Biosafety level 1 to Biosafety level 2

December 15, 2003 Minutes Approved 1/26/04

BUA No. 0606

Title Project 1: Vitamin Status Assessment in Human Blood

Title Project 2: Inhibition of Methyl-CpG-binding Protein Expression in a Human Hepatoma Cell Line

The Committee denied this BUA for a number of reasons including:

- 1. Application not complete
- Need to determine if equipment is a Biosafety cabinet or a laminar flow hood.
- 3. Need to provide vaccination opportunity
- 4. Need information on secondary containment

4. AMMENDMENTS

BUA No. 0687

Title: Effect of BMP-7 produced by ad gene transfer on mechanically adaptive bone model

The Committee approved with the following conditions:

- 1. Identify the adenovirus as replication defective.
- 2. Check if ARS picks up animal carcasses at the Medical Center.
- 3. Is the adenovirus used the same virus that you have been working on?
- 4. Please add if different genes are being cloned.
- 5. Please remove reference to disposal at the UCD Landfill or add the statement that the treated waste, now considered municipal garbage, is disposed of in the UCD Landfill.

5. FINAL APPROVAL of CONDITIONAL BUAS

BUA No. 0711

Title: Ecological genetics of birds with West Nile Virus Committee reviewed inactivation assay and approved as submitted.

BUA No. 0714

Title: Cell cycle regulation in peripheral blood and lymph node lymphocytes from HIV-infected subjects of long-acting interferon-alpha on innate and adaptive immunity in SIV-infected macaques

Committee discussed EH&S visit to lab and equipment specification information. Approval of BUA was granted if the equipment filter is capable of capturing cells. The recommendation that the cytometer user wear respiratory protection was forwarded.

BUA No. 0642

Title: "Pathological Basis of Hepatic Fibrosis Review of recent reference for self-inactivating retroviral vectors used in lab Committee approved this BUA as submitted.

IV. Discussion items

Deferred discussion items deferred due to lack of time. Item to include in the role of the BSAAC in recommending and/or requesting medical surveillance.

V. Next meeting

Minutes

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety

In attendance:

Carl Foreman Director, Environmental Health & Safety

Fred Jacobsen Assistant Director, Environmental Health & Safety William Jewell Voting Member, Molecular Structure Facility

Judy Kjelstrom Voting Member, Vice Chair, Microbiology (Biotechnology

Program)

Nicholas Lerche Voting Member, Chair, California National Primate Research

Center

Michael O'Malley Occupational Health Physician Jodi Casselman Voting Member, Sagres Discovery

John Mac Millan Chemistry Sarah Lievens Chemistry

Shotaro Suzuki Neurological and Physiological Behavior

Andrew Majewski Environmental Health & Safety Gilbert Garcia Environmental Health & Safety Jim Newman Environmental Health & Safety Susan Cummings **Environmental Health & Safety**

I. Approval of December 15, 2003 Minutes

Approved as written

II. **Old Business**

BUAs

1. Completed New

None

2. Completed Renewals

Notified of the completion of the following authorizations:

BUANo. 0575 BUA No. 0723 **BUA No. 0400**

BUA No. 0208 BUA No. 0714

BUA No. 0623

BUA No. 0655

3. Completed Amended

Notified of completion of following amendments:

BUA No. 0376 **BUA No. 0347**

SOURCE: IBC Archive | The Sunshine Project - FOI Fund | www.sunshine-project.org January 26, 2004 Minutes

III. New Business

BUAs

1. New

BUA No. 0722

Title: Estradiol induced neurogenesis in adult rodent brain following ischemic injury: Fate and roles of newborn neurons in brain recovery (resubmit)

Approved as submitted

2. Renewal

BUA No. 0458

Title: Anti-Microbial Human Cancer Cytotoxicity Screening of Natural Products Approved as submitted

BUA No. 0589

(under PI

Title: Characterization of proteins of M. bovis and hemolytic Neisseria Conditional approval pending provision of following:

- Ensure the transport cooler is dedicated for this purpose only and is properly labeled
- Identify the species of Neisseria being used
- Describe if Neisseria is being used as a control
- Provide more information on potential health hazards to lab personnel, symptoms for Neiserria

BUA No. 0235

Title: Biology and Molecular Biology of Plant Viruses Approved as submitted

3. Amended

BUA No. 0554

Title: Ecology, Vector Competence, Surveillance and Control of Arboviruses

Tabled pending provision of the following:

- Discuss medical surveillance with the UCD Occupational Health physician
- Provide details about the following
 - o The diseases, symptoms and potential for lab personnel exposure
 - o The procedures that will be used
 - What work is being done with the viruses

III. Discussion items

IV.

1. UCSD's Adenovirus practices and procedures

The committee members determined this guideline would be beneficial to campus and agreed to review a version modified by EH&S.

2. Designate a Vice Chair

The committee members nominated and voted Judith Kjelstrom as Vice Chair

SOURCE: IBC Archive | The Sunshine Project - FOI Fund | www.sunshine-project.org January 26, 2004 Minutes

- 3. Role of BSAAC in recommending and/or requiring medical surveillance It was decided that, on a case-by-case basis, the committee will request, or require, a PI to consult with the UC Davis Occupational Health Physician.
- 4. Classification Guide for Diagnostic Specimens and Infectious Substances It was decided this Guide was not needed
- 5. BUA Application information
 Committee reviewed the levels of BUA approval

V. Next meeting

February 23, 2004 106 Hoagland Hall

February 23, 2004 Minutes -

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety

In attendance:

Carl Foreman Director, Environmental Health & Safety

Fred Jacobsen Assistant Director, Environmental Health & Safety William Jewell Voting Member, Molecular Structure Facility Voting Member, Molecular & Cellular Biology

Judith Kjelstrom Voting Member, Microbiology (Biotechnology Program)

Jodi Casselman Voting Member, Public Member

Bryce Falk Guest Attendee

Susan Cummings Environmental Health and Safety

I. Approval of January, 2004 Minutes

Approved with minor revisions

II. Review of Biological Use Authorizations (BUAs):

A. NEW:

BUA No. 0725

Title: Mucosal Immunity and HIV-1/SIV Infection Conditional approved with completion of the following:

- 1. Follow-up to ensure the PI is included on the Animal Care Protocol
- Page 8 In accordance with the Biosafety Manual, ensure PI trains personnel to carry shipping documents when individually transporting off campus.
 http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?TITLE=49&PART=173&SECTION=134&YEAR=1999&TYPE=TEXT
- 3. Page 9 Document use of 70% ethanol as the disinfectant for both primary and secondary container.
- 4. Page 10 Recommend tips and pipettes be placed in a hard-walled Medical Waste (red) sharps container for treatment and disposal as Medical Waste in accordance with your Department Medical Waste Management Plan.

B. RENEWALS:

1. BUA No. 0664

Title: Epizootic Bovine Abortion (EBV) Agent: Organism Characterization and Development/Use of a mouse model

Conditional approved with completion of the following:

- Page 8 Identify source of bovine tissue and how it will be transported.
 - Specify when, and under what conditions, the Biosafety cabinet will be used.
 - Indicate contaminated materials that are autoclaved will be disposed of in Medical Waste in accordance with the Department Medical Waste Plan.

2. BUA No. 0589

Title: Characterization of proteins of M. Bovis and hemolytic Neisseria Approved as submitted

III. DISCUSSION ITEMS:

None

March 22, 2004 Minutes

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety

In attendance:

Deborah Kimbrell William Jewell Voting Member, Molecular & Cellular Biology Voting Member, Molecular Structure Facility

Bryce Falk Anthony Martinez Guest Attendee

Guest Attendee Voting Member, Chair

Nicholas Lerche Sandy Kelly Fred Jacobsen

Voting Member, Contained Research

Assistant Director, Environmental Health & Safety

Susan Cummings

Environmental Health and Safety

I. Approval of February 23, 2004 Minutes

Approved with minor revisions

II. Old Business

BUA No. 0713

III New Business

BUAs

1. NEW

BUA No. 0727

Title: Lymphocyte Trafficking in Rhesus Macaques

Approved as written

2. RENEWALS:

BUA No. 0636

Title: Hormones involved in Regulation of Obesity and Insulin Development/Use of a mouse model

Approved as written

3. BUA No. 0634

Lab Representative present)

Title: Recombinant DNA Studies in Human Cells

Granted conditional approved upon addition of the following items:

(

- 1. Page 6 Include the list of human cell lines in the list of vectors.
- 2. Page 12 referencing line "j" Indicate Wescodyne will be used
- 3. Page 10 Identify the transportation being referenced is internal to lab.

III. DISCUSSION ITEMS:

None

May 17, 2004 Minutes - Final

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety

In attendance:

Deborah Kimbrell Voting Member, Molecular & Cellular Biology William Jewell Voting Member, Molecular Structure Facility

Bryce Falk Plant Pathology

Nicholas Lerche Voting Member, Chair, California National Primate Research Center

Carl Foreman Director, Environmental Health & Safety

Michael O'Malley Occupational Health Physician
Jodi Casselman Voting Member, Sagres Discovery

Judy Kjelstrom Voting Member, Vice Chair, Microbiology Biotechnology Program

(via E-mail)

Tim Wilson Voting Member, Yolo County Health Department (via E-mail)

Lon Kendall Campus Veterinarian, VM:CLAS

Robin Matias Guest – School of Medicine: Neonatology Francis Poulain Guest – School of Medicine: Neonatology

Leslie Lyons Guest - VM: Population Health and Reproduction

Debbie Decker Environmental Health and Safety Susan Cummings Environmental Health and Safety

1. Approval March 22, 2004 Minutes

Approved as written

II. Old Business

Completed BUAs:

BUA No. 0727 BUA No. 0664

BUA No. 0634

III New Business

BUAs

1. New

BUA No. 0728

TITLE: Anti-infectious properties of pro-SPB processing products

Approved as written

BUA No. 0729

TITLE: Genetic Resources for Non-human Primates

Approved as written (NOTE: Policy Change)

2. RENEWALS:

BUA No. 0223

TITLE: Autoimmune reactions Within the Eye; Cancer-Associated retinopathy, RPE-hypersensitivity

Returned to PI for protocol development to include:

- 1. Human tissue is a BSL 2
- 2. Expand on Biosafety practices being sure to include discussion on decontamination and containment.
- 3. Identify the source of tissues. Provide a Human Use Protocol Number, or an exemption. (Page 4)

Minutes - Final

- 4. Explain procedures for getting the genes from the tissue.
- 5. Part B: Infectious Agents and Toxins: Bloodborne Pathogen section should be marked "yes".

BUA No. 0656

TITLE: Mutational Analysis of SIV and HIV-1 Nef and Envelope Characterization and Development/Use of a mouse model.

Approved with the following additions:

- 1. Include shared space signatures
- 2. Confirm centrifuge in Tupper Hall room 3316 is appropriate for viral DNA work.

BUA No. 0524

TITLE: Helicobacter pylori gastritis in rhesus macaques Approved upon documentation of Bloodborne Pathogen training for Linda

3. Amended

BUA No. 0519

TITLE: Human hepatitis B virus infection in cynomolgus macaques Approved with condition persons have adequate titer to work this project.

IV. DISCUSSION ITEMS:

- 1. Copy of information Pat Schlesinger provided, upon request, to the Sunshine Project.
- 2. Requirement for Animal Care staff inclusion on BUA discussed.

Minutes

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety September 20, 2004 145 Hoagland Hall

Start Time: 3:00 PM

In attendance:

Deborah Kimbrell Voting Member, Molecular & Cellular Biology William Jewell Voting Member, Molecular Structure Facility

Nicholas Lerche Voting Member, Chair, California National Primate Research

Center

Jodi Casselman Voting Member, Public Member

Judy Kjelstrom Voting Member, Vice Chair, Microbiology Biotechnology

Program (via e-mail)

Lon Kendall Campus Veterinarian, VM:CLAS (via e-mail)
Stephen Judd Voting Member, Gemini Bio-Products, Inc.

Bryce Falk Voting Member, Plant Pathology

Fred Jacobsen Voting Member, Assistant Director Environmental Health and

Safety

Gil Garcia Environmental Health and Safety
Dan Kermoyan Environmental Health and Safety, DSA

Susan Cummings Environmental Health and Safety

I. Member Introductions

Members voted that Committee Members e-mailed review comments will be entered into the minutes and counted towards quorum.

II Review May 17, 2004 Minutes

Approved as written

IV. Old Business

A.2 - Notification of Completed BUAs:

BUA No. 0505 BUA No. 0524 BUA No. 0725

A.4 - Notification of BSL 1 BUAs:

BUA No. 0730

IV. New Business

A.1 - New BUAs:

BUA No. 0731

TITLE: Translocations induced by abortive apoptosis

Authorization tabled pending resubmission of expanded BUA that incorporates:

- Page 1- Provide requested signatures.
- Page 4 Document that appropriate safety training has been provided.

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- Page 4 Include UCD ID numbers for all personnel.
- Page 4 Include contact information for all personnel.
- Page 7 Hosts, Vectors, Genes to be Cloned and DNA/RNA Sources are identified as Biosafety Level 2. The narrative does not support this. Please expand the narrative on procedures, including destruction and disposal methods.
- Page 7 Provide information supporting the narrative statement It is not considered that this fragment containing 1 exon is a high biological risk.
- Page 7 Define the MLL gene to be cloned.

A.2 – Renewal BUAs:

BUA No. 0223

TITLE: Autoimmune reactions Within the Eyes; Cancer-Associated retinopathy, RPE-hypersensitivity (Resubmission)

Approved as written pending submission of signatures.

BUA No. 0528

TITLE: Simian AIDS: Social Stress, Endocrine, and Immune Function Approved as written.

NOTE: Committee noted, with permission from PI, this BUA would be an excellent example/sample BUA. PI has agreed.

BUA No. 0534

TITLE: Investigation of human and animal zoonotic infections Withdrawn at request of PI

BUA No. 0547

TITLE: Congenital and acquired diseases and corrective gene-based therapies Approved pending:

- Include details on which genes are being transfected.
- Update the personnel list and corresponding training information.
- Fill in page 7 vector(s) and gene(s) sections.

BUA No. 0565

TITLE: Mouse models of Lyme Borreliosis, Helicobacter Enteritis, Bartonellosis, and Encephalitozoonosis (NOTE: consolidates BUA # 0571 and 0590) Approved pending completion of the following:

- Page 7 Clarify which E.coli strains are being used.
- Page 7 Clarify which genes will be cloned.
- Page 10 Properly label cooler used for transport.

BUA No. 0613

Molecular and Cellular Characterization of Sphingomyelinase, a Regulator of Ceramide Path and Apoptosis in the Lung.

Approved as Biosafety Level (BSL) 1 authorization.

Will submit a new authorization prior to working with organisms that are BSL 2 or greater.

BUA No. 0658

Murine Viral Antigens TITLE:

SOURCE: IBC Archive | The Sunshine Project - FOI Fund | www.sunshine-project.org September 20, 2004 Minutes

Authorization tabled pending resubmission of an expanded BUA that incorporates, at a minimum, the following information:

- Page 8 Identify viral strains.
- Offer immunization against rabies.
- The BSAAC will review regulations to determine if the cultivation of rabies virus raises the BSL to level three (3).
- Identify the cultivation work that will be done in a biosafety cabinet.
- Please clarify why respirators and a biosafety cabinet will be used.
- Please identify where virus cultivation work will be performed.
- Clarify what type of (respirator) fit testing will be required and if this will be required for all personnel working with the virus, including those listed on page 4.
- Page 5 shows no Select Agent work will be done. Page 9 states Select Agents will be used. Please clarify.
- Extend liquid disinfection time to one (1) hour.
- Clarify where necropsies will be performed (e.g., in Biosafety Cabinet).
- Detail how carcasses will be disposed.
- Detail the methods for packaging and transporting inoculated animals, propagated virus (etc.) and confirm that the method of containment is appropriate for transporting the animals and the agent.

BUA No. 0662

TITLE: Modulation of ErbB Receptors

Authorization tabled pending resubmission of an expanded BUA that incorporates, at a minimum, the following information:

- Submit protocol on new (February 24, 2004) BUA form available on the EH&S Website http://ehs.ucdavis.edu/biosfty/bio_forms.cfm.
- Identify the retroviral vector(s) used and include identification in the narrative.
- Page 1 Provide requested signatures.
- Designate the CO₂ incubator for this work only.

IV. Amended

None

V. Assurance Statements

None

VI. Discussion Items

- Types of Biosafety cabinets (BSC) used on campus, BSAAC to consider establishing criteria for EH&S to get into contract. EH&S will collect and prepare informational packets that will include durability data, manufacturer's warranty and warranty as tied to BSC longevity. At the request of the BSAAC, EH&S will schedule during regular BSAAC meeting times, Q & A sessions and/or product demonstrations.
- A request was made that the UCD Biosafety Manual and the campus Medical Waste Management Plan template be provided with the next meeting packet.

SOURCE: IBC Archive | The Sunshine Project - FOI Fund | www.sunshine-project.org September 20, 2004 Minutes

• Meeting dates that fall on Holidays – decision to move meeting to the second Monday of the month. EH&S to provide revised meeting schedule.

Adjourned: 4:00 PM

October 18, 2004 Minutes final

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety October 18, 2004 106 Hoagland Hall

Start Time: 3:00 PM

In attendance:

Deborah Kimbrell Voting Member, Molecular & Cellular Biology William Jewell Voting Member, Molecular Structure Facility

Nicholas Lerche Voting Member, Chair, California National Primate Research Center

Jodi Casselman Voting Member, Public Member

Judy Kjelstrom Voting Member, Vice Chair, Microbiology Biotechnology Program

(via e-mail)

Lon Kendall Voting Member Campus Veterinarian, VM:CLAS (via e-mail)

Stephen Judd Voting Member, Gemini Bio-Products, Inc.

Fred Jacobsen Voting Member, Assistant Director Environmental Health and Safety Carl Foreman Voting Member, Director Environmental Health and Safety, Acting

BSO

Mike O'Malley Ex-Officio Member, Employee Health Services

Susan Cummings Ex-Officio Member, Environmental Health and Safety

Debbie Decker Environmental Health and Safety

Brian Tarkington CNPRC; representing Hyde Lab BUA#0732

I. Approval September 20, 2004 Minutes

Approved as written

II. Old Business

A. BUAs

1. Completed New:

None

2. Completed Renewals:

None

3. Completed Amendments:

None

4. BSL 1 Renewal Notifications:

BUA No. 0321

III New Business

A. BUAs

1. New

BUA No. 0732

Title: Immunostimulatory DNA Priming of Lung Innate Immunity, Adenovirus Challenge (representing the Lab)

Authorization granted provisional approval pending inclusion of the following information:

- 1. Identify that this will not be a virus grown in the lab and that the replication defective virus will be obtained from the provider on an "as need" basis.
- 2. Page 5 Remove the list of non-select agents from this page
- 3. Page 7 Remove HEK-293A from the host list

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- 4. Page 9 Specify Page 9 the final concentration of bleach to be used will be 10%. To avoid exposure issues, a 2% so9lution of a gluteraldehyde product (e.g., Cidex) can be used.
- 5. Specify that personnel required to use an N-95 respirator are fit tested prior to use.

2. RENEWALS:

BUA No. 0499

Title: The Role of the Inflammatory Process in Etiology of Labyrinthitis Ossifcans Authorization granted provisional approval pending inclusion of the following information:

- 1. What animal(s) species is being used?
- 2. Page 8 Increase bleach contact time to 30 minutes (encapsulated bacteria)
- 3. Page 8 Clarify which P and P is being referenced
- 4. Please spell-check the document (biohazard, transfers, handling)
- 5. Page 8 Please replace the word "Pneumococcus" with streptococcus
- 6. The narrative indicates a biosafety cabinet (BSC) in Room 224 will be used. Room 224 is not included in the list of "Lab locations of authorized users".
- 7. Please expand on using a tissue culture hood for incubation
- 8. Please explain where and how animals will be housed during the experiment, how the assay will be performed and how carcasses will be disposed.

BUA No. 0663

Title: Defects in Pancreatic Function Type 2 Diabetes Mellitus

Authorization granted conditional approval pending inclusion of the following information:

- 1. Page 1 Provide clear signatures on cover sheet
- 2. Page 5 HEK293, used to propagate adenovirus, is a BSL 2 organism and needs to be included on page 9.
- 3. Page 5 In the "Vector(s)" section, identify the various plasmids.
- 4. Page 5 In the "Gene(s) to be cloned" section, identify the signaling molecules
- 5. Page 10 Identify the specific iodophor, concentration and contact time.

BUA No. 0666

Title: Studies with FHV-1 and other herpes viruses

Authorization granted conditional approval pending inclusion of the following information:

- Pages 3 There is no signature on the "Shared space principle investigator" line
 and shared space is identified in the narrative. Please obtain signature9s) from
 shared space PI(s) and provide them with necessary training information.
- 2. Page 8 Correct spelling of Herpes Simplex virus on "Agent/toxin No. 3 line.
- 3. Page 9 Increase sodium hypochlorite contact time to 30 minutes

BUA No. 0561

TITLE: Antibiotic selection for treatment of equine neonatal septicemia and equine biotype of C.pstb

Authorization tabled pending resubmission of an expanded BUA that incorporates, at a minimum, the following information:

- 1 .Put authorization on new Biological Use Authorization form available at (http://ehs.ucdavis.edu/ftpd/bua/bua prot may2004.doc)
- 2 Page 7 Correct spelling Campylobacter, Pasteurella, etc. and spell out genus (e.g., change strep to Streptococcus)
- 3 Page 7 Remove reference for using the bunsen burner to provide a sterile work area environment.
- 4 Page 7 Specify the appropriate protective clothing
- Page 7 Confirm work will be done using Biosafety Level 2 practices

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- 6 Confirm laboratory has a written Exposure Control Plan that includes emergency treatment. Dr. O'Malley, UC Davis's Occupational Health Physician, has agreed to evaluate the plan.
- 7 Page 7 Change bleach contact time to 30 minutes

3. Amended

None

4. Assurance Statements

None

IV. Discussion Items

NOTIFICATION of Change in Meeting Dates

Originally scheduled Date
12/20/04
01/17/05
02/21/05

NEW Scheduled Date
12/13/04
01/10/05
02/14/05

Adjourned: 5:00 PM

SOURCE: IBC Archive | The Sunshine Project - FOI Fund | www.sunshine-project.org BSAAC November, 15, 2004 Minutes -

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety November 15, 2004 106 Hoagland Hall

Start Time: 3:15 PM

In attendance:

Deborah Kimbrell Voting Member, Molecular & Cellular Biology

Jodi Casselman Voting Member, Public Member

Judith Kjelstrom Voting Member, Vice Chair, Microbiology

Biotechnology Program (via e-mail)

Lon Kendall Voting Member Campus Veterinarian, VM:CLAS Stephen Judd Voting Member, Gemini Bio-Products, Inc. (e-mail) Fred Jacobsen

Voting Member, Assistant Director Environmental

Health and Safety

Bryce Falk Voting Member, Plant Pathology

Ex-Officio Member, Environmental Health and Safety **Susan Cummings**

Gil Garcia **Environmental Health and Safety** Debbie Decker Environmental Health and Safety

Pat Wakenell VM: Population Health and Reproduction

Xi Chen Chemistry

Christian Leutenegger VM: Medicine and Epidemiology Samantha Mapes VM: Medicine and Epidemiology

I. **Approval October 18, 2004 Minutes**

Approved as written

NOTE: Following are changes made to November 15, 2004 Agenda

3UA number 0656 to 0658

: BUA number 0772 to 0725

change to review amended protocol "b"

BUA# 0733 from Initial (New) BSL 2 to BSL 1 New Notification

II. **Old Business**

A. BUAs

1. Completed New:

None

2. Completed Renewals:

BUA No. 0662 BUA No. 0658

3. Completed Amendments:

None

4. BSL 1 Renewal Notifications:

BUA No. 0733

Ш **New Business**

Minutes -

A. BUAs

1. New

BUA No. 0735

Title Chemoenzymatic Synthesis of Oligosaccharides and Glycoconjugates Conditional approval:

- 1. Verify required Biosafety training of all employees.
- 2. Provide documentation for using 70% isopropyl alcohol to wipe down surfaces
- 3. Page 6 - First line, correct spelling of the word "stored".

BUA No. 0734

Title Lucy Whittier Molecular and Diagnostic Core Facility

NOTE: Policy Change - Committee voted and approved issuing a second authorization number to this PI.

Conditional approval:

- 1. Resubmit on new form (May 2004)
- 2. Page 7 - Correct spelling errors
- 3. Page 9 - Correct time for disinfecting spills with 10% bleach (30 min.)
- 4. Obtain signatures from all Principle Investigators in shared spaces.

Deferred to December meeting due to lack of time

BUA No. 0725

Title: Protocol b - Generating Reagents for Cellular Immunology Assays

2. Renewals:

BUA No. 0525

Title Evaluation of the Efficiency of Various Vaccine Preparations Delivered in ovo or at Hatch

Conditional approval:

- 1. Page 9 - Include salmonella in list of organisms.
- 2. Verify the need for Medical Waste training (per BSO, Medical Waste and Bloodbourne Pathogen Trainings required).
- 3. Expand protocol detailing source of eggs and birds
- Reformat to correct pages. 4.
- 5. Page 6 - Identify (where] is being obtained).

3. Amended

None

4. Assurance Statements

None

IV. **Discussion Items**

None

V. **Information Items**

Stanford University "Recombinant DNA: Regulations and Guidelines" UC San Diego – (Appendix 10) "Adenovirus Fact Sheet"

Adjourned: 5:00 PM

BSAAC December 13, 2004

Minutes - DRAFT

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety December 13, 2004

December 13, 2004
106 Hoagland Hall

Start Time: 3:15 PM

In attendance:

Deborah Kimbrell Voting Member, Molecular & Cellular Biology

Jodi Casselman Voting Member, Public Member

Lon Kendall Voting Member Campus Veterinarian, VM:CLAS

Bryce Falk Voting Member, Plant Pathology

Judith Kjelstrom Voting Member, Vice Chair, Microbiology

Biotechnology Program

William Jewell Voting Member, Molecular Structure Facility

Carl Foreman Voting Member, Acting BSO, Environmental Health

and Safety Mike O'Malley Ex-Officio Member,

Employee Health Services

Mike O'Malley Ex-Officio Member, Employee Health Services

Susan Cummings Ex-Officio Member, Environmental Health and Safety

Art Perez Environmental Health and Safety

Bruno Chomel VM: Population Health and Reproduction Rick Kasten VM: Population Health and Reproduction

Christian Leutenegger VM: Medicine and Epidemiology

I. Approval November 15, 2004 Minutes

Approved with removal of double entry of Judith Kjelstrom's name in attendees

II. Old Business

- A. BUAs
 - 1. Completed New:

BUA No. 0732

2. Completed Renewals:

BUA No. 0499 BUA No. 0525

3. Completed Amendments:

None

4. BSL 1 Renewal Notifications:

None

III New Business

- A. BUAs
- 1. New

BUA No. 0736

Title Environmental Stress Signaling & Pathogenesis in Listeria

Monocytogenes:

Authorization tabled:

BSAAC December 13, 2004

Minutes - DRAFT

P. 5 - Narrative

- 1. Identify what you are cloning for.
- 2. Identify how and in what way the organism is altered by discussing the effects of the experiment e.g., will the manipulations alter the virulence of the organism?

P. 6 & 9 - Assessment of biohazard potential

- 1. Include information on the potential for reproductive harm in the annual training.
- 2. Correct spelling of "diagnosed".

P. 6 & 10 - Containment conditions

- 1. Change the term "sterile procedures" to "standard precautions and good laboratory practices".
- 2. For consistency, change the disinfectant for both spills and equipment/work surfaces to 10% bleach unless bleach cannot be used for both activities.

P. 6 & 10 – Transportation procedures

1. Identify the procedures that will be used for transportation. Review the campus policy for transport in University and privately owned vehicles.

BUA No. 0668

Title: Virulence and Immunity of granulocytic Ehrlichiae

Approved pending inclusion of:

Provide and updated letter from John Hopkins

- P. 4 Update number for animal use protocol
- P. 5
 - Clarify what is done with the collected blood samples sent for PCR and to
 - 2. Change spelling of vane to vein.
- P. 5&6 Check on foreign DNA that is inserted. Clarify what is being done at the John Hopkins Lab.
- P. 6 Change "that" to "than"

BUA No. 0534

Title: Investigation of human and animal zoonotic infections

Approved with following changes:

- P. 8 Remove reference for unnecessary respiratory protection.
- P. 9 Include blood as agent
- P. 11 Include comments offering medical surveillance

2. Renewals:

BUA No. 0522

Title Infections and Immunity to Measles and Influenza Viruses in Rhesus Macaque

Approved with inclusion of the following:

- P. 5 Update Animal Use Authorization protocol number
- P. 10 If it is necessary to wear a mask, employees will need, at a minimum, to be provided with and fit-tested for an N-95.
- P. 11

Influenza vaccine should be offered to employees – see the Occupational Health Physician

BSAAC December 13, 2004

Minutes - DRAFT

Employees should have a current measles vaccine or and up to date vaccination.

BUA No. 0662

Title Modulation of Erb Receptor

Approved with following changes:

NOTE: Protocol does not call for use of Select Agents

Clarify the use of hantan and hanta virus

Spell check document (e.g. p.10 - "following")

- P. 6 Change "rule of tissue culture" to "standard practices" Expand information to include description of containment for purification of isolation.
- P. 5 & 9 Correct inconsistency; Page 9 says using select agents and Page 5 says not using.
- P. 7 Remove reference to ethanol and include 30 minutes contact time for disinfection of hard surfaces with bleach.
- P. 8 Experimental Design

3. Amended

BUA No. 0725

Title: (Protocol b) Generating Reagents for Cellular Immunology Assays

NOTE:

ınd

hold the Animal Use protocols

Provide vaccinia information to Dr. Michael O'Malley, Occupational Health Physician.

P. 5 Add and authorized users. This should also be performed on their BUAs

P. 16

Specify bleach or ethanol use.

Change contact time for bleach to 30 minutes

4. Assurance Statements

None

IV. Discussion Items

None

V. Information Items

Update on BSO interviews

Dr. O'Malley requests time for discussion of medical treatment for human pathogens at next meeting.

Adjourned: 5:00 PM

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety February 14, 2005 106 Hoagland Hall

Start Time: 3:00 PM

In attendance:

Nick Lerche Voting Member, Chair, Primate Center

Jodi Casselman Voting Member, Public Member Stephen Judd Voting Member, Public Member

Judith Kjelstrom Voting Member, Vice Chair, Microbiology Biotechnology

Program

William Jewell Voting Member, Molecular Structure Facility

Carl Foreman Voting Member, Acting BSO, Environmental Health and

Safety

Mike O'Malley Ex-Officio Member, Employee Health Services

Excused:

Bryce Falk Voting Member, Plant Pathology

Lon Kendall Voting Member, Campus Veterinarian, VM: CLAS
Deborah Kimbrell Voting Member, Molecular & Cellular Biology
Tim Wilson Voting Member, Yolo County Health Department
Sandy Kelly Voting Member, Contained Research Facility

Guests:

Art Perez Environmental Health and Safety
Andrew Majewski Environmental Health and Safety

Dan Kermoyan
Liz Reay
Kathy Blaisdell
Environmental Health and Safety
Med: Microbiology and Immunology
Med: Microbiology and Immunology

Shirley Luckhart Med: Microbiology and Immunology

Jim Angelastro VM: Molecular Bioscience

Lisa Tell VM: Medicine and Epidemiology Bill Ferrier VM: CLAS Veterinary Services

I. Approval of December 23, 2004 Minutes

Approved as submitted

II. Old Business

A. BUAs

1. Completed New:

BUA No. 0736

Title: Environmental Stress Signaling & Pathogenesis in Listeria monocytogenes

- 2. Completed Renewals:
- 3. Completed Amendments:

None

4. BSL 1 Renewal Notifications:

None

III New Business

- 1. A. BUAs
 - 1. New:

BUA No. 0741

Title: Virulence Mechanisms of species

APPROVED pending inclusion of:

- o Page 10 Clarify growth media.
- Page 11 Under (3f) when using 70% ethanol, clarify the contact time when wiping vials.

BUA No. 0739

Title: Programs of Gene Expression During Synapse Formation APPROVED pending inclusion of:

o Page 5 – Specify the type of virus being used.

BUA No. 0738

Title: Molecular Mechanisms of Salmonella Pathogenesis APPROVED pending inclusion of:

- Page 5 Under Host information, specify cell lines, human or mouse.
- Page 5 Project summary, under experimental design, correct misspelling of studies (studes)
- o Page 5 Include "eye protection and surgical mask" usage when doing animal gavage feedings or inoculations (PPE).
- o Page 6 Correct misspellings of: Aerosol (aerosol), and formaldehyde reliably (formaldehyreliably)
- o Page 6 Specify host source.
- Page 7 Use 10% bleach to sanitize hard surfaces after a spill.
 Contact time of 30 minutes.

BUA No. 0740

Title: Destruction of Brain Tumor Through Loss-of-Function or Loss-of-Expression of ATF5

APPROVED pending inclusion of:

- o Insert page 4 in application submittal (lists authorized users, training and building location(s)).
- o Page 5 Correct misspelling of Qiagen (Quiagen) Kits.

BUA No. 0737

Title: Pathogenesis of

TABLED UNTIL NEXT MEETING -

- o Resubmit application on new form.
- o Page 9 Describe technique for controlling aerosols during culture collection.
- o Page 10 Clarify final concentration of bleach to be used.

- o Page 5 and 9 Description of potential illness and symptoms.
- Source of cultures from DHS.
- o Contact Dr. O'Malley at Occupational Health before rewrite.

BUA No. 0731

Title: Mosquito Immunity to Plasmodium Infection TABLED UNTIL NEXT MEETING -

- Contact Dr. O'Malley at Occupational Medicine before rewriting medical surveillance requirements (including Hepatitis B Vaccination for workers.)
- o Submit copy of USDA permit.
- o Page 12 Clarify bleach reference to either 10% bleach (final concentration) or 1% hypochlorite solution.
- o Note: Arthropod Containment Levels reference provided to committee during meeting. Will be included in BUA.

BUA No. 0742

Title: Identification and Characteristics of Lipid Components from Mycobacteria EMAIL REVIEW – Resubmit BUA addressing the following noted comments from the committee:

- O Page 8 Experimental Design: Please describe the sterile transfer of the stock culture in more detail. What instrument is being used with the sterile pipette tip? Are the tips plugged? How much volume is the aliquot? Disinfection with bleach should be for at least 30 minutes. What incubation temperature is being used? Are they incubated in the light or dark?
- O Page 9 First sentence: The four (4) species of Mycobacteria are all rapid growers (less that 7 days), but 24 hours my not be enough time for good growth. Have growth curves been done to assure that the cultures are truly in stationary phase (stated in item 2 under inoculating cultures)?
- O Page 9 Please describe in more detail as to how you will boil the cell suspensions? Will this be done in the biosafety cabinet or fume hood? How will you confirm 100% cell death?
- Page 9 Please describe the centrifugation procedure in more detail? What procedures are taken to prevent aerosols? What decontamination procedures will be used on the centrifuge?
- Page 10 Biohazard Potential: Contact Dr. O'Malley at
 Occupational Health since a medical treatment plan is needed for
 this research project. These mycobacteria species can be resistant
 to isoniazid, so a combination therapy must be used.
- Page 10 Mode of Transmission: Aerosols must be avoided.
 Pulmonary infections have been report with the M.fortuitum-chelone complex.
- o Page 10 Spills: Is there a better product than 5% phenol?
- o Page 10 Respiratory protection should be in place.
- Additionally, given the significant risks involved with your proposed research project, the committee recommends that you

contact Dr. Blaine Beaman of Med Microbiology & Immunology. He is a noted authority in working with Mycobacterium.

2. Renewal:

BUA No. 0670

Title: Fate and Transport of Waterborne Zoonoses TABLED UNTIL NEXT MEETING –

- o Page 9 Agent No. 2 misspelled Giardia (Gairdia)
- Page 9 Additional information needed concerning the use of ammonia for disinfection – concentration and contact time.
 Provide copy of reference for committee review.

3. Amended:

BUA No. 0400

Title: SIV and HIV Pathogenesis APPROVED pending inclusion of:

O Under item #7, specify concentration of bleach used to disinfect surfaces in amendment. (They use straight bleach.)

4. Assurance Statements

None

1. IV. Discussion Items

1. BUA No. 0577

Title: Comparison of Lab Tests for Monitoring Avian Aspergillosis In application, include –

- Add health restrictions to training section and in IACUC protocol
- Obtain respirator clearance and be fitted with respirator.
- Contact Dr. O'Malley at Occupational Health.

2. BUA No. 0554

Title: Identification and Characteristics of Lipid Components from Mycobacteria EMAIL REVIEW TO BE DONE PRIOR TO NEXT MEETING.

1. V. Information Items

1. Nick Lerche will be bringing to the committee information concerning the tie-in with IACUC Animal Use Authorization and Biological Use Authorizations.

Adjourned: 4:40 PM

BSAAC March 28, 2005 Minutes

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety March 21, 2005 106 Hoagland Hall

Start Time: 3:00 PM

In attendance:

Nick Lerche Voting Member, Chair, Primate Center Jodi Casselman Voting Member, Public Member Stephen Judd Voting Member, Public member

Judith Kjelstrom Voting Member, Vice Chair, Microbiology Biotechnology Program

William Jewell Voting Member, Molecular Structure Facility

Carl Foreman Voting Member, Acting BSO, Environmental Health and Safety

Mike O'Malley Ex-Officio Member, Employee Health Services
Lon Kendall Voting Member, Campus Veterinarian, VM: CLAS
Deborah Kimbrell Voting member, Molecular & Cellular Biology
Susan Cummings Specialist 1, Environmental Health and Safety

Michelle Bell Administrative Assistant, Environmental Health and Safety

Excused:

Bryce Falk Voting Member, Plant Pathology

Tim Wilson Voting Member, Yolo County Health Department Sandy Kelley Voting Member, Contained Research Facility

lests:

Art Perez Environmental Health and Safety
Gilbert Garcia Environmental Health and Safety

Chris Petzold Genome Center Michael Leavell Genome Center

I. Approval of February 14, 2004 Minutes

Approved as submitted

II. Old Business

A. BUA's

1. Completed New:

BUA No. 0743

Title: Comparison of Lab Tests for Monitoring Avian Aspergillosis

Note: BUA# 0743 is a new number assigned to project. BUA# 0577 is a terminated project number With changes to:

- Page 5 requires UCD Training or evidence of training Check-in with Dr. O'Malley
- Page 10 IACUC coordination to verify animal use protocol #11353 requirements (PPE and medical surveillance
- Page 11 Experimental Procedures Item #3: add statement that after 24 hours, waste is not infectious
- Page 11 Experimental Procedures Item #3: change bonneted rat cages to "micro isolator cages".
- Page 12 Terminal inactivation of biological agent: Eliminate 70% isopropyl alcohol. Use only 10% bleach

2. Completed Renewals:

None

BSAAC March 28, 2005 Minutes

3. Completed Amendments:

None

4. BSL 1 Renewal Notifications:

None

5. Resubmitted:

BUA No. 0742

Title: Identification and Characteristics of Lipid Components from Mycobacteria APPROVED pending inclusion of:

• Page 4 – Add name to "trained" under authorized users

 Page 12 – Cell-surface lipid extraction: Add hexane to vials in a fumehood, not a BSC (potential fire hazard)

III. New Business

A. BUA's

1. New:

BUA No. 0735

Title: Chemoenzymatic Synthesis of Oligosaccharides and Glycoconjugates

TABLED UNTIL NEXT MEETING

*Page 4 - Training not documented. Also statement of experience using BSL2 organisms

2. Renewal:

BUA No. 0670

Title: Fate and Transport of Waterborne Zoonoses

TABLED UNTIL NEXT MEETING; Resubmit with changes to:

• Page 4 - Add 1 to training and authorized

Page 4 – Add PPE with animals with AUP (coordinate)

• Page 9 - Address aerosol precautions regarding mice inoculation procedure

BUA No. 0665

Title: Analysis of Biomarkers in Humans Exposed to Toxins and Viruses

BUA NOT REQUIRED

* Page 9 - Project 3 A, section 3 - suggests recombinant; remove from protocol

3. Amended:

None

IV. Assurance Statements:

None

V. Discussion Items

A. Authorizations

BUA No. 0383

Title: Molecular characterization and development of improved prophylactic and diagnostic reagents for control of viral infections of horses and ruminants

(Amendment to project including WNV VLPs and VEE)

- Cross reference clarification
- List procedures in detail and cross reference
- Clarify recombinant usage
- IACUC Animal Care Protocol review

BSAAC March 28, 2005 Minutes

2. BUA No. 0554

Title: Ecology, Vector Competence, Surveillance and Control of Arboviruses (Late submission)

- IACUC staff to review Animal Use Protocol and coordinate BSAAC requirements
- 3. Committee Members CVs/Biosketches submission for NIH
 - Committee Members to submit Biosketches electronically to Michelle Bell at EH&S
- 4. BSAAC's notification preference
 - Send out Minutes on Tuesday morning (1 week after previous meeting)
 - Receipt and Return E-mail preferences to verify receipt of received document
 - Meeting notice and attendance one week prior to next meeting, send out notice and verify meeting attendance.
- 5. BSO Update
 - Carl Foreman reviewed status for the BSO recruitment. HR is currently reviewing salary upgrade. Committee expressed support for salary upgrade.

VI. Information Items

1. DHHS 42 CFR Part 1003

Title: Possession, Use, and Transfer of Select Agents and Toxins; Final Rule – Copies handed out to committee members for their review.

2. Gerry Westcott updated the Biosafety committee on the AAALAC findings and the need to close the information loop when BUA's and AUP's are involved in a research project. The IACUC staff will take the coordination lead to ensure biosafety requirements are added to the animal use protocol (e.g. PPE requirements). Nick Lerche to send out to the Biosafety Committee items that need to be addressed.

Adjourned: 4:50 PM

Jinutes - DRAFT

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety April 18, 2005 106 Hoagland Hall

Start Time: 3:00 PM

In attendance:

Nick Lerche Voting Member, Chair, Primate Center

Judith Kjelstrom Voting Member, Vice Chair, Microbiology/Biotechnology Program

Jodi Casselman Voting Member, Public Member Stephen Judd Voting Member, Public Member

Lon Kendall Voting Member, Campus Veterinarian, VM: CLAS
Deborah Kimbrell Voting Member, Molecular & Cellular Biology

Bryce Falk Voting Member, Plant Pathology

Carl Foreman Voting Member, Acting BSO, Environmental Health and Safety

Susan Cummings Specialist 1, Environmental Health and Safety

Michelle Bell Administrative Assistant, Environmental Health and Safety

Excused:

William Jewell

Tim Wilson

Sandy Kelley

Mike O'Malley

Voting Member, Molecular Structure Facility

Voting Member, Yolo County Health Department

Voting Member, Contained Research Facility

Ex-Officio Member, Employee Health Services

Guests:

None

Approval of March 21, 2005 Minutes

Approved as submitted

II. Old Business

A. BUA's

1. Completed New:

BUA No. None

Title:

2. Completed Renewals:

BUA No. 0670

Title: Fate and Transport of Waterborne Zoonoses

APPROVED

BUA No. 0660

Title: Gating -permeation coupling of CLC-0 Chloride channel

APPROVED pending incluion of:

Page 9 - Safety: change the word 'displaced' to placed.

* Disposal: Add statement to 1:10 dilution "with a 30 minute contact time".

BUA No. 0665

Title: Analysis of Biomarkers in Humans Exposed to Toxins and Viruses APPROVED

BUA No. 0600

Title: Creation of a Mulluscan Cell Line

APPROVED pending inclusion of:

- Page 5 Need more detail in handling of vector
- Indicate the Biosafety level of Host
- Page 8 Again, need more detail in handling of vector

Minutes - DRAFT

3. Completed Amendments:

BUA No. 0554

Title: Ecology, Vector Competence, Surveillance and Control of Arboviruses

TABLED for Animal Care Protocol and provisions

- * Lon Kendall at VM: CLAS will contact regarding Animal Care Protocol
- Page 4 Request of respirator usage (Bakersfield location)
- Page 6 List Host, Vector, and Gene information with Biosafety levels indicated
- Risk Assessment: There is a conflict regarding "BLS-3" viral segments and RNA being transcribed in Haring Hall. Needs re-write.
- Page 7 Another mention of Haring Hall but referencing to BSL-2.

BUA No. 0653

Title: Cultivation, Characterization, and Immunopathogenesis of Protozoal Parasites Affecting Animals and Humans

APPROVED

BUA No. 0739

Title: Programs of Gene Expression During Synapse Formation

APPROVED

4. BSL 1 Renewal Notifications:

BUA No. None

Title:

5. Resubmitted

BUA No. None

Title:

III. New Business

A. BUA's

1. New:

BUA No. 0744

Title: Investigation of Respiratory Outbreaks in Horses

APPROVED with provisions to:

- Lon kendall at VM: CLAS will contact regarding Animal Care Protocol
- Page 10 Risk Assessment: Paragraph #3 Correct the spelling of "incoulum"
- * Risk Assessment: Paragraph #4 Change "10% bleach" to "1:10 dilution of household bleach"

BUA No. 0642

Title: Gene Therapy and Cell-Based Therapy for Liver Diseases

TABLED

- * Page 4 Add to list of authorized users and indicate appropriate training taken
- Page 5 Genes: Correct the spelling of "tolemerase"
- * Risk Assessment: Supply detail of precautions to be taken
- Specify what percentage of glutaraldehyde
- * Page 6 Paragraph 1: Correct the spelling of "colaborators"
- Paragraph 2: Specify the vector sources
- * Paragraph 3: Correct the spelling of "tarward"
- Paragraph 4: Eliminate the term "generally considered" and replace with "are"
- * Page 9 Risk Assessment: Specify that a fumehood will be used in regards to carbon tetrachloride
- * Risk Assessment: Specify what type of gloves (not latex)
- Page 13 Surveillance/immunization: Specify the percentage of glutaraldehyde

Minutes - DRAFT

2. Renewal

BUA No. 0561

Title: Antibiotic Selections for Treatment of Equine Neonatal Septicemia and Equine Biotype of

C. Pseudotuberculosis

APPROVED

BUA No. 0649

Title: Neural Development

APPROVED

BUA No. 0226

Title: The Dairy Food Safety Laboratory: Investigation of Technologies for Bacterial Detection, Sterilization, and Pasteurization of Various Sample Types Including Environmental, Food Products, and Waste Materials (Including Animal Feces)

TABLED

- * Page 4 Add to list of authorized users and indicate appropriate training taken
- * Page 6 paragraph #6 Change "10% bleach" to "1:10 dilution of household bleach"
- * Page 9 Risk Assessment: Paragraph #2: Specify source of agent (human)
- * Page 10 Paragraph #5 Change "10% bleach" to "1:10 dilution of household bleach"
- * Replace "gloves may be work" to "gloves will be worn"...
- Mention the practice of standard precautions
- Page 12 Standard procedures: Specify the wearing of gloves as standard precaution
- * Replace "antimicrobial soaps" with "soap and warm water"

3. Amended

BUA No. 0743

Title: Comparison of Laboratory Tests for Monitoring Avian Aspergillois APPROVED

IV. Assurance Statements:

None

V. Discussion Items

- A. Training needs for committee by creation of a manual
- B. BSAAC member possibly visiting Bakersfield

VI. Information Items

- A. Creation of Summary Sheet to include P.I., BUA, and comments. To be forwarded to BSAAC and DSAs
- B. Definitions:
 - 1. Provisional Approval = BSAAC chair has signed BUA prior to Committee meeting
 - 2. Consent Agenda = Pre-reviewed; changes made; requiring signature only
 - 3. Conditional Approval = Approved with corrections to be made

Adjourned: 5:00 PM

Minutes - FINAL

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety June 13, 2005 106 Hoagland Hall

Start Time: 3:00 PM

In attendance:

Nick Lerche Voting Member, Chair, Primate Center

Judith Kjelstrom Voting Member, Vice Chair, Microbiology Biotechnology Program

Jodi Casselman Voting Member, Public Member

William Jewell

Mike O'Malley

Lon Kendall

Deborah Kimbrell

Voting Member, Molecular Structure Facility

Ex-Officio Member, Employee Health Services

Voting Member, Campus Veterinarian, VM: CLAS

Voting Member, Molecular & Cellular Biology

Carl Foreman Voting Member, Acting BSO, Environmental Health and Safety

Michelle Bell Administrative Assistant, Environmental Health and Safety

Gil Garcia Prin. Technician, Environmental Health and Safety

Excused:

Bryce Falk Voting Member, Plant Pathology Stephen Judd Voting Member, Public Member

Sandy Kelley Voting Member, Contained Research Facility

Guests:

'ichi Brownlee Environmental Health and Safety

Liho Cho Med: Surgery
Jian Wu Internal Medicine

Dan Dana Environmental Health and Safety

Barbara Byrne VM: PMI

I. Approval of April 18, 2005 Minutes

Approved as submitted

II. Old Business

A. BUA's

1. Completed New:

BUA No. None

Title:

2. Completed Renewals:

BUA No. 0658

Title: Murine Viral Antigens

TABLED for corrections

- * Page 4 Lab Location CCM Room 1043: Clarification needed as to what is being done in that specific room
- * Page 8 Project Summary, Paragraph 2: Change the word "organism" to "infectious virus particle"
- * Page 9 Inactivation: 10% bleach, add "final concentration"
- * " Select Agent paragraph: 10% bleach, add "final concentration" and change contact time from 20 minutes to 30 minutes

3. Completed Amendments:

BUA No. None

Title:

Minutes - FINAL

4. BSL 1 Renewal Notifications:

BUA No. None

Title:

5. Resubmitted

BUA No. 0226

Title: The Dairy Food Safety Laboratory: Investigation of technologies for bacterial detection, sterilization and

Pasteurization of various sample types including environmental, food products and waste materials

(including animal feces).

APPROVED

BUA No. 0642

Title: Gene Therapy and Cell-Based Therapy for Liver Diseases

APPROVED with edits

- * Page 4 Animal protocol #10798, is not listed on this protocol
- Autoclaving not necessary for animal carcasses

III. New Business

A. BUA's

1. New:

BUA No. 0747

Title: Role of Murine Cytomegalovirus (MCMV) Infection in the Development and/or Exacerbation of Coronary Artery Disease (CAD)

APPROVED with edits

- * Page 10 Section 9, Item 'g': Change bleach time from '20' minutes to 30 minutes
- * " Section 11, Item 'c': Change bleach time from '20' minutes to 30 minutes

BUA No. 0748

***THIS IS A BLS1 as determined by BSAAC

Title: The use of a mouse model to study multiple sclerosis and glutamate excitotoxicity in neurons and oligodendroglia, and gliosis in these animals

**NOTE: is in the process of relocating to UCDavis. His lab contact, attended BSAAC meeting

APPROVED with edits

- * Page 3 must sign signature page indicating 'Principal Investigator' (upon his arrival to UCDavis)
- * " Department Chair and Shared space investigator must sign signature page
- * Page 4 Documentation needed for Appropriate Training taken and documented for both and
- * Page 8 Project Summary: Change "Petussis" to Pertussis; change "intraperoteneally" to intraperitoneally; change "deemded" to deemed.
- * Add statement (PPE) that lab coats and gloves are worn during mice inoculation

BUA No. 0745

Title: Studies of pathogenesis and host; bacterial interactions of Rhodococcus equi, microbial presence and Interactions in the environment and gastrointestinal tract, and characterization of bacteria isolated from clinical specimens.

APPROVED with edits and Pending Funding

- Page 4 Animal Protocol# 11038 Pending funding
- * Page 6 Section II: The committee requested that provide a list of collaborators. However, presence at the committee enabled her to verbally provide this information to the committee members. It was then decided that the list would not be necessary due to the extreme length as well as the fact that these collaborators were for diagnostic purposes only.
- * Page 8 Correct the spelling of "memenningiticum" to meningiticum
- * " Terminal activation paragraph: Delete the word "similar" and replace with "appropriate disinfectant known to kill isolates"

Minutes - FINAL

BUA No. 0528b

Title: Grown Factors to Reverse Cognitive Decline in Aging

TABLED

- Page 4 Authorized Users: Add Principal Investigator to list as well as indicate his Training
- Page 6 Project Summary: Provide more detail addressing decontamination, animal inoculation, and containment.
- * Page 11 Blood borne pathogens: Uncheck "N/A" box and check "Yes" box

2. Renewal

BUA No. 0635

· This is a BSL1

Title: Micronutrient absorption, metabolism and status in populations at risk of deficiency

APPROVED

BUA No. 0581

Title: Enteric pathogens associated with fruits, vegetables and nuts

APPROVED with edits

- * Page 10 Item 1: Change "70% alcohol" to "10% household bleach (final volume) for 30 minutes"
- * " Item 4: Change pipettes collection to "collected in Biohazard us container and then autoclaved after use."
- * " Item 5: Change "70% ethanol" to "10% household bleach (final volume) for 30 minutes"
- * Page 11 Procedure Deviation: Change "70% ethanol" to "10% household bleach (final volume) for 30 minutes

BUA No. 0669

Title: Gelatins in Allergic Inflammation, Cell Growth and Apoptosis

TABLED with changes

- * Page 4 Authorized Users: Add Principal Investigator to the list; include appropriate training
- * Page 4 " : Blood borne training for all users is recommended as indicated on Page 10 of this BUA
- Page 5 Change DNA/RNA sources from a BSL1 to 2
- Project Summary: Change BSL1 to 2
- * Page 8 Agent/Toxin No. 4: Check BSL2 box
- Project Summary: Change "1/10 volume bleach and 30 minute reaction" to "10% household bleach (final volume) for 30 minutes contact time"

BUA No. 0347

Title: Transcriptional activation of KSHV and RRV

TABLED with edits

- * Page 4 Authorized Users: Update the roster as some are no longer with UCDavis
- * " " : Add , to the list and indicate appropriate training
- Page 6 Specify which organisms are to be cloned
- * Word Document: Page 3: Update the SFV paragraph to reflect the primate to human contact (new emerging data)
- Word Document: Page 4: Terminal Inactivation paragraph: Change "70% ethanol" to "10% household bleach (final concentration) for 30 minutes contact time:
- * Overall, apply the information provided in

word document to the actual BUA.

BUA No. 0288-01

- BSL1 (Grant Review every 3 years)

Title: Gene mapping and cloning in the cruciferous crops

APPROVED

BUA No. 0641

Title: Microbial study of food borne pathogens on produce

APPROVED with edits

- * Page 9 Section 3: All lab benches... Change: "70% Ethanol" to "10% household bleach (final volume) for 30 minute contact time"
- * " Section 3: Major cleaning... Change: "70% Ethanol" to "10% household bleach (final volume) for 30 minute contact time"
- * " Section 5: 10% bleach... add "(final volume) for 30 minute contact time"

BSAAC

Minutes - FINAL

3. Amended

BUA No. 0687

Title: Role of anabolic and Catabolic Cytokines in Cartilage Homeostasis and Prostate Cancer TABLED with edits

- * Page 6 Address the points of the project summary in the discussion area and provide more detail
- * Page 8 Address the points of the project summary in the discussion area and provide more detail

BUA No. 0322

Title: Increased safety and efficacy of recombinant vaccines and diagnostic kits Unable to discuss due to elapsed time

- * DSA to provide electronic submission (including any attachments) to Michelle Bell
- * Michelle to send electronically to BSAAC chair to review during hiatus

IV. Assurance Statements:

Principal Investigator	<u>Title</u>
1.	Elucidating the NNR/N11-mediated resistance gisnaling network
2.	Control of Cellular Processes During Embryogenesis in Higher Plants
3.	Analysis of Virulence Genes in Plant Pathogenic Bacteria
4.	Use of Wild Lycopersicon Species in Breeding for Improvement of Cultivated Tomato
5.	Molecular Genetic Analyses of Nectary Development and Establishment of Carpel
	Polarity in Arabidopsis
6.	Tolerance to Below-Ground Environmental Stress Vegetables

V. Discussion Items

- A. BSAAC on hiatus for July and August 2005. DSAs to electronically submit BUAs, amendments, audits, etc to Michelle Bell who will forward to Committee Chair for Provisional Approval. Meetings to resume September 19, 2005.
- B. Summary Sheet to be sent to BSAAC with minutes

VI. Information Items

A. None

Adjourned: 5:10 PM

Minutes - FINAL

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety September 19, 2005 106 Hoagland Hall

Start Time: 3:00 PM

In attendance:

Judith Kjelstrom Voting Member, Vice Chair, Microbiology/Biotechnology Program

Jodi Casselman Voting Member, Public Member Stephen Judd Voting Member, Public Member

Deborah Kimbrell Voting Member, Molecular & Cellular Biology

Bryce Falk Voting Member, Plant Pathology

William Jewell
Sandy Kelley
Voting Member, Molecular Structure Facility
Voting Member, Contained Research Facility
Mike O'Malley
Ex-Officio Member, Employee Health Services

Carl Foreman Ex-Officio, Director, Environmental Health and Safety

Sean Barry Voting Member, BioSafety Officer, Environmental Health and Safety

Michelle Bell Ex-Officio, BioSafety Program Coordinator, Environmental Health and Safety

Excused:

Nick Lerche Voting Member, Chair, Primate Center

Lon Kendall Voting Member, Campus Veterinarian, VM: CLAS

Guests:

Gil Garcia Prin. Technician, Environmental Health and Safety

Jeff Ching Department Safety Advisor (BUA 0751 & 0752), Environmental Health and Safety

'yunseok Hong Med Pathology (Lab Contact for BUA 0754)

Jan Dana Department Safety Advisor (BUA 0753 & 0754), Environmental Health and Safety Art Perez Department Safety Advisor (BUA 0546 & 0614), Environmental Health and Safety

Judith Kjelstrom (Vice Chair of the committee) chaired this meeting in Nick Lerche's absence.

I. Approval of June 13, 2005 Minutes

Approved as submitted

II. Old Business

A. BUA's

1. Completed New:

BUA No. None

Title:

2. Completed Renewals:

BUA No. None

Title:

3. Completed Amendments:

BUA No. None

Title:

4. BSL 1 Renewal Notifications:

BUA No. None

Title:

Minutes - FINAL

5. Resubmitted

BUA No. None

Title:

III. New Business

A. BUA's

1. New:

BUA No. 0751

Title: Duox2 Regulation of Viral Infection TABLED - Resubmit with following changes:

Page 5: Specify transport method of infectious viral particles obtained from Dr. McManus at UCSF

" : Each virus shipment from UCSF to be checked for replication deficiency upon arrival at UCD, prior to first use

" ": Detail PPE and terminal inactivation

Page 9: Project Summary: Detail project

BUA No. 0752

Title: Role of Tubulin Tyrosine Ligase in the Regulation of Cell Growth

TABLED - Resubmit with following changes:

Page 5: Specify transport method of infectious viral particles obtained from Dr. McManus at UCSF

": Each virus shipment from UCSF to be checked for replication deficiency upon arrival at UCD, prior to first use

" ": Detail PPE and terminal inactivation Page 9: Project Summary: Detail project

BUA No. 0753

Title: Development of cancer-specific adenovirus

CONDITIONAL APPROVAL WITH CHANGES

General: Specify transport method of nude mice - are microisolators being used?

General: Sean Barry will send an informational letter to regarding the work being done in the space he

is providing to. a is mentioned on the BUA but is not a user on this project.

Page 5: Second paragraph: change spelling of "epithilial" to epithelial

": Second paragraph: change (culture) "hood" to "cabinet"

": Second paragraph: UV light not recommended

Page 13: State "will not deviate"

Note: The committee has agreed that, due to special circumstance, Dr. Pan is allowed to submit his changes

electronically for approval prior to the October 17, 2005 committee meeting.

BUA No. 0754

Title: Inhibition of the Alzheimer's Beta-Amyloi Oligomer Formation

CONDITIONAL APPROVAL WITH CHANGES

Page 5: Gene(s) to be cloned: Change spelling of "isulin" to "insulin"

General: Specify medical treatment for accidental exposure to lentivirus vector; add to laboratory SOP

Note: Disinfecting the interior package is probably not necessary

2. Renewal

BUA No. 0544

Title: Parasites of Animal and Man

CONDITIONAL APPROVAL WITH CHANGES

Page 10: Specify number of adenovirus virion particles per ml

" : Clarify whether adenovirus is being produced in the lab

Minutes - FINAL

BUA No. 0546

Title: Foodborne and Waterborne Pathogens

CONDITIONAL APPROVAL WITH CHANGES

Project Summary: Methodology: Clarify: Terminal inactivation, 75% ethanol; should use 70% ethanol

3. Amended

BUA No. 0614

Title: Adenovirus That Cause Hemorrhagic Disease In Deer

APPROVED

IV. Assurance Statements:

None

V. Discussion Items

Due to the absence of the committee chair, it was decided to postpone the discussion of the July and August 2005 Provisional Approvals until the October 17, 2005 meeting. (see attached)

VI. Information Items

None

Adjourned: 4:50 PM

Minutes - FINAL

To be discussed as time permits

** July Provisionals

BUA No. 0322

Title: Increased safety and efficacy of recombinant vaccines and diagnostic kits

Approved by BSAAC Chair 07/21/05

BUA No. 0347

Title: Animal Model Studies with Infectious Agents

Approved by BSAAC Chair 07/21/05

BUA No. 0383-01

Title: Molecular characterization and development of improved prophylactic and diagnostic reagents for

control of viral infections of horses and ruminants

Approved by BSAAC Chair 07/21/05

BUA No. 0528-B

Title: Growth Factors to Reverse Cognitive Decline in Aging

Approved by BSAAC Chair 07/21/05

BUA No. 0554

Title: Ecology, Vector Competence, Surveillance and Control of Arborviruses

Approved by BSAAC Chair 07/21/05

BUA No. 0682

Title: Viral Transfection to Treat Epileptic Activity

Approved by BSAAC Chair 07/21/05

BUA No. 0683

Title: Infectious Diseases of Dogs and Cats

Approved by BSAAC Chair 07/21/05

BUA No. 0684

Title: Biochemical adaptation of mammals and fish to environmental stress

Approved by BSAAC Chair 07/21/05

** August Provisionals

BUA No. 0606

Title: Vitamin Status Assessment in Human Blood

Project Termination & acknowleged by BSAAC Chair 08/16/05

BUA No. 0642

Title: Gene Therapy and Cell-Based Therapy for Liver Diseases

Edits (per BSAAC 06/13/05) made & acknowledged by BSAAC Chair 08/16/05

BUA No. 0749

Title: Biosynthesis of 14C-Vitamin B12 by Salmonella enterica serova Typhimurium

Approved w/Edits per BSAAC Chair 08/16/05

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety October 17, 2005 106 Hoagland Hall

Start Time: 3:00 PM

In attendance:

Nick Lerche Voting Member, Chair, Primate Center Stephen Judd Voting Member, Public Member

William Jewell

Mike O'Malley

Lon Kendall

Deborah Kimbrell

Voting Member, Molecular Structure Facility

Ex-Officio Member, Employee Health Services

Voting Member, Campus Veterinarian, VM: CLAS

Voting Member, Molecular & Cellular Biology

Bryce Falk Voting Member, Plant Pathology

Michelle Bell
Carl Foreman

Biosafety Program Coordinator, Environmental Health and Safety
Voting Member, Acting BSO, Environmental Health and Safety

Excused:

Judith Kjelstrom Voting Member, Vice Chair, Microbiology Biotechnology Program

Jodi Casselman Voting Member, Public Member

Absent:

Sandy Kelley Voting Member, Contained Research Facility

uests:

I. Approval of September 19, 2005 Minutes

Approved as submitted

II. Old Business

A. BUA's

1. Completed New:

BUA No. 0738

Title: Molecular mechanisms of Salmonella Pathogenesis

CONDITIONAL with changes to:

- Provide more information on infected animal handling and waste handling
- * Document that 70% ethanol is an effective decontaminant for Salmonella
- * Are you following surface bleach treatment with 70% ethanol spray, or is the ethanol spray an alternative to surface bleach treatment? The ethanol spray by itself is not considered an effective surface decontaminant--please clarify its use or remove it from the project summary (OK to use after bleach)

✓BUA No. 0658

Title: Murine Viral Antigens

APPROVED

2. Completed Renewals:

BUA No. None

Title:

Minutes - FINAL

3. Completed Amendments:

BUA No. None

Title:

4. BSL 1 Renewal Notifications:

BUA No. None

Title:

5. Resubmitted

✓ BUA No. 0751

Title: Duox2 regulation of viral infection

APPROVED, but PI should add a statement about terminal inactivation

III. New Business

A. BUA's

1. New:

/ BUA No. 0755

Title: Friedreich's ataxia, mitochondria and cell death

CONDITIONAL with changes to:

 Delete 70% ethanol for terminal inactivation or provide documentation that it is effective for HeLa cells

Alternatively, substitute 30 minute exposure to 10% final concentration household bleach for 70% ethanol

 \mathcal{L}

BUA No. 0756

Title: Cell Signaling in Meiosis CONDITIONAL with changes to:

Page 5: Check "NO" box stating "This protocol will be submitted to NIH for Human Gene Transfer Proposal

approval"

' Spell out "PLD" and "PA"

BUA No. 0757

Title: Role of sand fly salivary protein maxadilan in pathogenesis of Leishmania chagasi

TABLED

Page 8: Rewrite project summary and address all of the the bulleted points in the instructions

- Add discussion of vector containment and worker protection for infected sandflies
- Detail PPE for research staff working with infected hamsters
- * Add discussion of lab hygeine -- surface decontamination, waste collection and treatment, etc.
- * Add discussion of lab exposure potential (at least twelve lab infections by Leishmania have been reported)
- Contact Employee Health Services to formulate a staff health surveillance program and include in the revised BUA

2. Renewal

BUA No. 0322

Title: Increased safety and efficacy of recombinant vaccines and diagnostic kits

CONDITIONAL with changes to:

- Change "10% sodium hypochlorite solution" to 10% household bleach
- * Document effectiveness of Lysol for surface decontamination against these agents
- * Specify consistently which genes are being cloned and which cloning system is being used (genes specified in the project summary were different from genes specified in the agents table, and there was no discussion of the cloning system)

Minutes - FINAL

3. Amended

BUA No. 0565

Title: Immunopathogenesis of anaplasma phagocytophila

TABLED with changes:

- * Clarify experimental program with the agent. Detail the background, the source of the agent, personal protection, decontamination, terminal inactivation, etc.
- * Resubmit on regular BUA form as a new BUA, with a complete project summary

BUA No. 0554

Title: Ecology, Vector Competence, Surveillance and Control of Arbovirus

**Removed from agenda pending completion

IV. Assurance Statements:

1. X-ray Structure Determination of Biologically Important Protein

2. <u>Identification of Genes Causing Obesity or Diabetes In Response to Variations In The Amount and</u>

Type of Fat.

3. <u>Molecular Mechanisms of Mitochondrial Fission</u>

4. <u>Mechanism of Plant Perception of Oligosaccharide Signals</u>

5. <u>Human Alu Repeats: Germ-Line Methylation and Heat Shock Response</u>

6. Experimental Manipulation of Ecdysteroid Levels During Insect Development

The reason for the Assurance Statements was explained to the committee.

V. Discussion Items

1. BSAAC clarification: are investigators who work with exempt quantities of Select Agent toxins required to have a BUA?

Policy clarification: No, a BUA is not required but we will develop a notification system, possibly through DaFIS

2. Do we require a BUA for work with primary human and primate cell lines? *Policy clarification:* No, we do not.

VI. Information Items

1. Michele Igo <u>The Role of the Bacterial Cell Surface in the Virulence of Xylella fastidiosa</u> - Exempt from NIH Acknowledged

To be discussed as time permits

** July Provisionals

BUA No. 0322

Title: Increased safety and efficacy of recombinant vaccines and diagnostic kits

Approved by BSAAC Chair 07/21/05

✓ BUA No. 0347

Title: Animal Model Studies with Infectious Agents

Approved by BSAAC Chair 07/21/05

BUA No. 0383-01

Title: Molecular characterization and development of improved prophylactic and diagnostic reagents for

control of viral infections of horses and ruminants

Approved by BSAAC Chair 07/21/05

BUA No. 0528-B

Fitle: Growth Factors to Reverse Cognitive Decline in Aging

Approved by BSAAC Chair 07/21/05

BUA No. 0554

Title: Ecology, Vector Competence, Surveillance and Control of Arborviruses

Approved by BSAAC Chair 07/21/05

BSAAC

Minutes - FINAL

BUA No. 0682

Title: Viral Transfection to Treat Epileptic Activity

Approved by BSAAC Chair 07/21/05

BUA No. 0683

Title: Infectious Diseases of Dogs and Cats

Approved by BSAAC Chair 07/21/05

BUA No. 0684

Title: Biochemical adaptation of mammals and fish to environmental stress

Approved by BSAAC Chair 07/21/05

** August Provisionals

BUA No. 0606

Title: Vitamin Status Assessment in Human Blood

Project Termination & acknowleged by BSAAC Chair 08/16/05

BUA No. 0642

Title: Gene Therapy and Cell-Based Therapy for Liver Diseases

Edits (per BSAAC 06/13/05) made & acknowledged by BSAAC Chair 08/16/05

BUA No. 0749

Title: Biosynthesis of 14C-Vitamin B12 by Salmonella enterica serova Typhimurium

Approved w/Edits per BSAAC Chair 08/16/05

It was decided that all above Provisionally Approved BUAs would be considered Conditionally approved pending comments from campus veterinarian.

Adjourned: 4:30 PM

Minutes - FINAL

Biological Safety Administrative Advisory Committee
University of California, Davis
Office of Environmental Health and Safety
November 21, 2005
106 Hoagland Hall
CORRECTED VERSION 3 December 2005

Start Time: 3:00 P.M.

In attendance:

Nick Lerche Voting Member, Chair, Primate Center

Judith Kjelstrom Voting Member, Vice Chair, Microbiology/Biotechnology Program

Jodi Casselman Voting Member, Office of the Vice Chancellor for Research

Lon Kendall Voting Member, Center for Lab Animal Science

Bryce Falk Voting Member, Plant Pathology

Sandy Kelley Voting Member, Contained Research Facility
Lisa Strelow Voting Member, Center for Comparative Medicine

Carl Foreman Voting Member, Director, Environmental Health and Safety

Sean Barry Voting Member, BioSafety Officer, Environmental Health and Safety

Gil Garcia Prin. Technician, Environmental Health and Safety

Excused:

Stephen Judd Voting Member, Public Member

Deborah Kimbrell Voting Member, Molecular & Cellular Biology
William Jewell Voting Member, Molecular Structure Facility
Mike O'Malley Ex-Officio Member, Employee Health Services

Michelle Bell BioSafety Program Coordinator, Environmental Health and Safety

Guests:

Int Perez Department Safety Advisor, Environmental Health and Safety

Jeff Ching Department Safety Advisor, Environmental Health and Safety

Karen Villanueva Dr. Borowsky's lab

Shirley Luckhart Medical Microbiology and Immunology Kathy Blaisdell Medical Microbiology and Immunology

I. Introduction of Dr. Lisa Strelow as a member of the BSAAC

II. Approval of October 17, 2005 Minutes

Approved as submitted

III. Old Business

A. BUA's

1. Completed New:

BUA No. 0751

Title: Duox2 Regulation of Viral Infection

FINAL APPROVAL

BUA No. 0753

Title: Development of Cancer-Specific Adenovirus

FINAL APPROVAL

BUA No. 0754

Title: Inhibition of the Alzheimer's Beta-Amyloid Oligomer Formation

FINAL APPROVAL

BSAAC

Minutes - FINAL

2. Completed Renewals:

BUA No. 0546

Title: Foodborne and Waterborne Pathogens

FINAL APPROVAL

BUA No. 0641

Title: Microbial Study of Foodborne Pathogens on Produce

FINAL APPROVAL

3. Completed Amendments:

BUA No. None

Title:

4. BSL 1 Notifications:

BUA No. None

Title:

5. Resubmitted

BUA No. 0565

Title: Mouse Model and Immunopathogenesis of Anaplasma Phagocytophilum

FINAL APPROVAL

IV. New Business

A. BUA's

1. New:

BUA No. 0711

Title: Transformation of Arabidopsis with a wheat starch synthase gene

APPROVED

BUA No. 0758

Title: Effects of Rhinovirus on Airway Epithelium

TABLED for changes:

- 1. The protocol should include more detail about specific processes, e.g...:
 - a. How is the virus denatured ("...done under conditions where the virus is denatured") does this mean that the virus is denatured by the assay or prior to it?
 - b. Either omit or elaborate on phrases and qualifiers such as "set periods of time: and "are also sometimes determined by"
- 2. What is the source of the human mucosal cells (primary culture, commercial source, stock, etc)?
- 3. The human cells should be included in the list of potentially infectious agents as a BSL-2 agent
- 4. What is the nexus between the BUA and Human Subjects (IRB)?

BUA No. 0759

Title: RNA Interference

CONDITIONAL APPROVAL with edits to:

- 1. Specify the source and the primary reference for the lentivirus vectors
- 2. Specify the source(s) of the various cells used in your work
- 3. Clarify the "BSL3 practices" that you will be using
- 4. Specify 30 minute contact time for 10% bleach decontamination
- 5. Indicate where the mouse treatments (inoculations) will occur (CLAS facilities or the lab?)
- 6. Specify the type of package that you will use to contain the viral vectors outside of the containment cabinet
- 7. Review the project summaries carefully to detect and fix typographical/spelling errors

Minutes - FINAL

2. Renewal

BUA No. 0236

Title: Developmental Regulation of Plant Genes

APPROVED

BUA No. 0376

Title: Recombinant DNA Protocols: Phytochrome Analyses

APPROVED

BUA No. 0393

Title: Leptospira Vaccine Development

TABLED for changes:

- Clarify the type of training PI and Polli Ward are scheduled to receive or have already received (on 12/20/2005 and 11/17/2005)
- 2. Clarify the meaning of the sentence in your project summary: "Any bacteria, recombinant viruses, other viruses and animal carcasses used in the above projects are transported in rigid, tightly sealed, ..."ctc. No agents other than Leptospira interrogans were listed in your protocol, so this sentence caused the Committee some concern. Please discuss only the agents to be used in your work, and please be very specific about them.
- 3. The health surveillance checklist on page 10 was checked ambiguously some were checked "no," and some "N/A". The proposed work suggests that all should be checked "N/A".
- 4. The Committee noted one or two typographical or spelling errors and a mis-checked box (p. 5, "DNA/RNA sources")

BUA No. 0639

Title: Bacterial Pathogens: Interactions with the Host and Environmental Survival

TABLED with query:

- I Clarify "exempt status" of strain (PGM-) *
- 2 Identify UCD locations where animals are treated (inoculated)
- 3 Confirm that personnel will be wearing gloves and PPE during all phases of the work including animal handling and animal care
- * CDC website confirmed exempt status of strain. Therefore, BSO reclassified protocol to Conditional Approval pending response to items 2 & 3 above.

CONDITIONAL APPROVAL

BUA No. 0676

Title: Therapeutic Agents for Mannheimia Haemolytica Infections of Ruminants

APPROVED

BUA No. 0686

Title: Adeno-associated Viral Angiostatin Vector in a Murine Glioma Model

APPROVED

BUA No. 0691

Title: Phaff Yeast Culture Collection

TABLED for changes:

- 1. Submit a complete inventory of the live collection
- 2. Include information on the methods used to maintain living cultures; specifically, are you passaging the cultures, and if so, how are they being handled from a Biosafety standpoint?
- 3. Identify the BSL2 species and strains
- 4. Identify other individuals who maintain the collection, and include them in the roster of authorized users
- 5. Specify methods of transportation for cultures sent and received
- 6. Identify the faculty member responsible for the collection, and include that person in the roster of authorized users 3

BSAAC

Minutes - FINAL

BUA No. 0692

Title:

protocol was submitted for provisional approval to the BSAAC Chair PROVISIONAL APPROVAL

BUA No. 0694

Title: Use of recombinant DNA in the Animal Biotechnology and Genomics Laboratory

APPROVED

BUA No. 0690

Title: The Virulence Plasmids of

TABLED for changes:

- 1 Detail information on agent origins, transportation, lab and animal care employee health surveillance
- 2 Specify methods to determine that total toxin in possession does not exceed exempt limits.
- 3 Attach CAHFS Health and Safety Protocol to revised BUA

3. Amended

BUA No. 0731

Title: Mosquito immunity to Plasmodium infection

APPROVED

4. Termed

BUA No. 0703

Title: Inactivation of HIV in Breastmilk by Heat Treatment

APPROVED

V. Assurance Statements:

- 1 Prescribed Herbivory in Vegetation Management
- 2. <u>Effects of Introduced Fish on Native Biodiversity and Ecosystem Subsidy</u>
- 3. Wheat Applied Genomics
- 4. <u>Insolation of Pathogen Associate Molecules that Trigger Rice XA21-Mediated Defense Response</u>
- 5. PElucidating the NRR/NH1 Mediated Resistance Signaling Network
- 6. Control of Cellular Processes During Embryogenesis in Higher Plants

VI. Discussion Items

 Reschedule January and February 2006 BSAAC meetings due to holidays BSO's office will communicate new dates by e-mail

VII. Information Items

SOP of ABSL2 & ABSL3

Tabled until December meeting

2. Policy Statement: Retaining / destroying BUA hardcopies

BSO advised that BUAs are to be left with the Biosafety Program Coordinator for shredding.

Meeting was adjourned at 4:40 PM

Minutes - FINAL 12/19/05

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety December 19, 2005 106 Hoagland Hall

Start Time: 3:00 PM

In attendance:

Nick Lerche Voting Member, Chair, Primate Center

Judith Kjelstrom Voting Member, Vice Chair, Microbiology/Biotechnology Program

Jodi Casselman Voting Member, Office of the Vice Chancellor for Research

Lisa Strelow Voting Member, Center for Comparative Medicine
Deborah Kimbrell Voting Member, Molecular & Cellular Biology
William Jewell Voting Member, Molecular Structure Facility
Mike O'Malley Ex-Officio Member, Employee Health Services

Carl Foreman Voting Member, Director, Environmental Health and Safety

Sean Barry Voting Member, BioSafety Officer, Environmental Health and Safety

Gil Garcia Prin. Technician, Environmental Health and Safety

Michelle Bell BioSafety Program Coordinator, Environmental Health and Safety

Excused:

Lon Kendall Voting Member, Center for Lab Animal Science
Sandy Kelley Voting Member, Contained Research Facility

Stephen Judd Voting Member, Public Member Bryce Falk Voting Member, Plant Pathology

Guests:

Indistine JudalDepartment Safety Advisor, Environmental Health and SafetyJeff ChingDepartment Safety Advisor, Environmental Health and SafetyDan DanaDepartment Safety Advisor, Environmental Health and Safety

Tian Xue Cell Biology and Human Anatomy
Suk Ying Tsang Cell Biology and Human Anatomy

I. Approval of November 21, 2005 Minutes

II. Introduction of Dr. Bette Hinton of Yolo County Public Health as upcoming public member (will start in January 2006)

III. Old Business

A. BUA's

1. Completed New:

BUA No. None

Title:

2. Completed Renewals:

BUA No. None

Title:

3. Completed Amendments:

BUA No. None

Title:

4. BSL 1 Notifications:

BUA No. None

Title:

BSAAC Minutes - FINAL 12/19/05

5. Resubmitted

BUA No. 0393

Title: Leptospira vaccine development TABLED with following requested changes:

- * Clarify whether animals are used in the project. If animals are being uses, reference the IACUC protocol
- Correct spelling error

BUA No. 0690

Title: The virulence plasmids of CONDITIONAL for following edits:

* Specify how the

is inactivated

BUA No. 0757

Title: Role of sand fly salivary protein maxadilan in pathogenesis of Leishmania chagasi APPROVED

BUA No. 0758

Title: Effects of rhinovirus on airway epithelium

CONDITIONAL for following edits:

- What is SDS and paraformaldehyde concentration and exposure time for viral inactivation
- * Note: Remain current on Bloodborne pathogen training (Tissue source is high risk for Hepatitis B and HIV)

1V. New Business

A. BUA's

1. New:

BUA No. 0760

Title: Somatic gene transfer of ion channels

CONDITIONAL for following edits:

- * Identify lentiviral and adenoviral vectors
- * Delete references to exposure time for cabinet surface decontamination ("for at least one hour")
- * Delete "do not carry or express any viral genes" (this is incorrect)
- Identify cDNA as mouse origin
- Provide literature reference for lentivirus

2. Renewal

BUA No. 0553

Title: Molecular pathogenesis studies and DNA vaccine development for FIV and SIV infection CONDITIONAL for following edits:

- What is being used to disinfect centrifuge vessels
- Specify PPE to be used while working with Vaccinia
- Specify disinfectant being used to decontaminate biosafety cabinet interior
- Paraformaldehyde concentrations were inconsistent
- * Clarify the source of herpes cytomegalovirus plasmids (human, cat, primate?)

BUA No. 0555

Title: iextile CONDITIONAL for following edits:

- * Specify bleach contact time and final concentration
 - Correct typographical error
 - Clarify "UCD Microbiology Lab" source of S.aureus (clinical isolates not allowed)
- * Per Dr. O'Malley, change "advised" to not use bacterium to "required"

BSAAC Minutes - FINAL 12/19/05

BUA No. 0692

Title: Suppressed cell proliferation and differential gene expression by n-3 fatty acids

Committee review postponed until January

BUA No. 0744

Title: Investigation of respiratory outbreaks in horses

PI temporarily withdrew BUA

3. Amended

BUA No. 0347

Title: Animal model studies with infectious agents

APPROVED

V. Notifications:

A. BSL-1 Exempts

1. BUA No. 0210

Title: Creation of novel antibody derived fusion proteins for cancer treatments

APPROVED

2. BUA No. 0761

Title: Perception of environmental toxicants

APPROVED

B. Termed or Expired

. BUA No. 0217

Title: Structure and function of mammalian RNA polymerase II

APPROVED

BUA No. 0489

Title: Biology of rodent borne zoonoses in northern California; reservoir host competence of rodents for the

lyme disease spirochete

APPROVED

C. Reviewed by BSO for final approval

BUA No. 0322

Title: Increased safety and efficacy of recombinant vaccines and diagnostic kits

APPROVED

2. BUA No. 0759

Title: RNA interference

APPROVED

VI. Assurance Statements:

1. <u>Isolation of the wheat Ph1 locus suppressor Sul-Ph1</u>

2. <u>Characterization of the gene network that regulates vernalization in wheat</u>

3. Regulatory networks controlling the transcription of rice start ciosynthesis genes

4. Protein components of cross-linked structures of the integument

VII. Discussion Items

1. Biosafety Program Coordinator to send out consensus to members for rescheduling February 2006 BSAAC meeting

BSAAC Minutes - FINAL 12/19/05

VII. Information Items

- 1. SOP of ABSL2 & ABSL3 discussed
- 2. Members to leave BUA copies with Biosafety Program Coordinator to be shredded
- 3. Possibility of increasing Public Membership to three also discussed

Meeting was adjourned at 4:50 PM

September 22, 2003 Minutes - draft

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety

In attendance:

Jodi Casselman

Susan Cummings
Carl Foreman

William Jewell
Deborah Kimbrell

Deborah Kimbrell

Voting Member, Molecular & Cellular Biology

Voting Member, Missakialary (Biotachuallar B

Judith Kjelstrom Voting Member, Microbiology (Biotechnology Program)

Nicholas Lerche Voting Member, Chair, California National Primate Research Center

Maria Mudryj Voting Member, Med: Microbiology & Immunology

Sonia Rosenberger Voting Member, Biosafety Officer, Environmental Health & Safety

I. Approval of the July 21, 2003 meeting minutes was deferred.

II. Report Biosafety Level 1 projects

- A. Biosafety Level 1 recombinant project, new BUA 0715 "Manipulation of genes controlling quantitatively inherited traits for plant improvement".
- B. Biosafety Level 1 recombinant project, new BUA 0717 "Evolution and variation in plant shade avoidance responses".

III. Review of Biological Use Authorizations (BUAs):

A. BUA No. 0713

Title: Lymphocyte trafficking in rhesus macaques

The Committee approved the protocol subject to the following conditions:

- 1. Page 3: submit revised BUA complete with signatures
- 2. Page 5: check "yes" box for Staphylococcal enterotoxin
- 3. Page 6: complete host, vector information
- 4. Page 7: please clarify "rhesus papio virus" are you referring to *Herpesvirus papio*, B virus?
- 5. In the project summary, please substitute the abbreviation HBV-2 with Herpes B virus as HBV refers to Hepatitis B virus.
- 6. In the project summary, please give more detail on the procedures to be used for how lymphocyte trafficking will be assessed, security of freezers, and how syringes will be transported to animal cages. Please also confirm that syringes used for injections will be disposed of as medical waste, and detail how samples will be transported from one facility to another (containers used, university vehicle).

September 22, 2003 Minutes - draft

B. BUA No. 0714

Title: Cell cycle regulation in peripheral blood and lymph node lymphocytes from HIV-infected subjects and effects of long-acting interferon-alpha on innate and adaptive immunity in SIV-infected macaques

The Committee deferred review of the protocol and requested the following information:

- 1. Dr. Rosenberger will review the supplied Exposure Control Plan and Medical Waste Management Plan.
- 2. Add "No deviations" where appropriate on the bottom of pages 10-12.
- 3. Please provide additional information on the transport containers used for transferring infectious samples, whether biohazard labels are used, and whether the handler wears protective clothing.
- 4. Please provide an assessment of biohazard potential.
- 5. Please provide information on how the technician is protected from exposure to live virus when performing flow cytometry.

C. BUA No. 0716

Title: Cigarette smoke, Chlamydia pneumoniae and Atherosclerosis

The Committee approved the protocol subject to the following conditions:

- 1. Include and his appropriate staff on the BUA or have submit his own BUA.
- 2. Surgical masks will be worn by animal care staff throughout the duration of the experiment.
- 3. Ensure transportation of infected animals is by university vehicle in isolator cages.

D. BUA No. 0642

Title: Pathogenic basis of hepatic fibrosis

The Committee approved the amendment subject to the following conditions:

- 1. Add stem cells to the Exposure Control Plan and Medical Waste Management Plan.
- 2. Provide source and designation of stem cells.
- 3. If available, provide a more recent reference for the self-inactivating retroviral vector

III. DISCUSSION ITEMS:

A. HR postings and security concerns

The Committee determined that the inclusion of select agent species/genera in HR job postings was not a security concern.

B. Progress on action items from prior meeting

- 1. Checklist for cell line surveillance Lerche and Rosenberger
- 2. Containment guidelines for transgenics Rosenberger
- 3. Review serum banking for rodent handlers BSAAC

September 22, 2003 Minutes - draft

C. Determination of NIH Guidelines applicability to project In response to a request from Dr. Rosenberger, the Committee reviewed whether project is covered by the NIH Guidelines for Research Involving Recombinant DNA Molecules and requires a BUA. The Committee requested that complete a BUA.

- D. Communication regarding July's conditional approval of The BUA's conditions have been met for final approval.

 BUA 0477
- E. Communication regarding July's conditional approval of BUA 0709
- F. CSAAC review of BUA

 The Committee requested formal correspondence from the CSAAC on its review before reviewing the BUA further.
- G. Greenhouse for BUA
 Additional containment for the foodborne pathogens of interest is required.
- H. Determine containment for BUA procedure

 If the CDC procedure for WNV lysis has been validated by CVEC, the materials receives from CVEC can be worked with on the bench rather than a biological safety cabinet. Please have provide documentation of the validation.

November 17, 2003 Minutes

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety

In attendance:

Jodi Casselman

Community Member, Sagres Discovery

Fred Jacobsen

Assistant Director, Environmental Health & Safety

Michael O'Malley

Voting Member, Employee Health

Phil Tillman

Campus Veterinarian, Environmental Health and Safety

William Jewell

Voting Member, Molecular Structure Facility

Judith Kjelstrom

Voting Member, Microbiology (Biotechnology Program)

Nicholas Lerche

Voting Member, Chair, California National Primate Research Center

Gil Garcia Sonia Rosenberger Environmental Health & Safety Biosafety Officer, UC Berkeley

Susan Cummings

Specialist, Environmental Health & Safety

L Approval of the July 21, 2003 and September 22, 2003 meeting minutes.

II. Review of Updates

Biosafety Officer Position - Position has been opened as a Specialist 2. Final filing 11/24/03

Certification of

BSL3 lab - from September Updates

Sonia Rosenberger, former UCD-BSO, reviewed the items needed to complete certification of as a BSL3 lab. She has determined they have been completed and that the lab meets all requirements necessary for certification. The BSAAC concurred with Dr. Rosenberger's determination. Dr. Rosenberger will write a letter acting BSO, Carl Foreman, and cc: the committee chair, Nick Lerche, for the December meeting stating this lab meets the certification requirements for operation.

III. Review of Biological Use Authorizations (BUAs):

REVIEW OF BIOSAFETY LEVEL 1 PROJECTS

BUA No. 0719

Title:

Molecular mechanism of circadian regulation in Arabidopsis

NEW

BUA No. 0720

Title: Noninvasive imaging of cell trafficking

The Committee granted conditional approval subject to the following:

- 1. Specify how animals will be transported to lab.
- 2. Specify how animals will be maintained in the lab
- 3. Animal carcasses to be treated as medical waste (put in red bag for ARS pickup)
- 4. Sharps, cell containers, etc that have been contaminated with cell line are to be considered medical waste.

November 17, 2003 Minutes

BUA No. 0721

Title: Stable expression of siRNA

The Committee approved the application with the following changes:

- 1. Change the 1:100 dilution (Clorox) to 1:10 dilution (page 7)
- 2. Obtain documentation for vector purity from Clontech
- 3. Find out if a permit or license is needed to get the vector from Clontech

RENEWALS

BUA 0655

Title: Immune response of mucosal pathogens (3 projects)

The Committee approved this renewal with the following changes:

1. Spell check document (e.g., page 6 - material, opiates)

PROJECTS 1 and 2

1. Specify that transportation (of organisms) in a university vehicle will be done in accordance requirements for transportation of infectious agents. Check with to determine if items are autoclaved prior to being sent to the med center for disposal. (Pages 8 and 9)

BUA 0623

Title: Newborn Gut/Lung Associated Infection: Use of Lactoferrin for Host Protection

The Committee approved this renewal with the following changes:

- 1. Provide UCD identification numbers for all laboratory personnel. (Page 4)
- 2. Supply more detail on the endotoxin(s) that will be used. (Page 8)

BUA 0609

Title: Infection of Rhesus Macaques with Rhesus Cytomegalovirus The Committee approved this renewal without change.

BUA 0505

Title: Survival of Food-borne Pathogens

The Committee approved this renewal with the following changes:

- 1. Change "5% bleach" to 1:10 final dilution (Page 9)
- 2. Spell check document e.g. "straying" instead of spraying. (Page 11)
- 3. For consistency, please use the term "Biosafety cabinet" throughout document.
- 4. If transportation of organism is needed, specify how and the location organisms will be transferred to and from.

AMMENDMENTS

BUA No. 0347

Title: Analysis of AIDS retrovirus envelope gene, molecular analyses of human and animal immunodeficiency virus and regulation of HIV expression

The Committee approved the protocol pending completion of the following:

- 1. Provide clarifying detail on how, and conditions under which, mice will be inoculated.
- 2. Describe how infected mice will be contained.
- 3. Please include where researcher is getting the virus.

November 17, 2003 Minutes

BUA No. 0519

Title:

Influenze dose-finding study in rhesus macaques

The Committee approved ammendment without change.

BUA No. 0642

Title: Pathogenic basis of hepatic fibrosis

The Committee approved authorization as submitted.

CONTINUED AMMENDMENT

BUA 0714

Title: Cell cycle regulation in peripheral blood and lymph node lymphocytes from HIV-infected subjects of long-acting interferon-alpha on innate and adaptive immunity in SIV-infected macaques

The BSAAC approved this protocol pending confirmation by. EH&S that the MoFlow cytometer operates in BSL2 containment when sorting of cells to ensure protection for users and those passing by.

IV. Discussion Items

Deferred

December 15, 2003 Minutes Approved 1/26/04

Biological Safety Administrative Advisory Committee University of California, Davis Office of Environmental Health and Safety

In attendance:

Carl Foreman Director, Environmental Health & Safety

Fred Jacobsen Assistant Director, Environmental Health & Safety William Jewell Voting Member, Molecular Structure Facility

Judith Kjelstrom Voting Member, Microbiology (Biotechnology Program)
Nicholas Lerche Voting Member, Chair, California National Primate Research

Center

Michael O'Malley Occupational Health Physician
Jodi Casselman Voting Member, Sagres Discovery
Debbie Decker Environmental Health & Safety

Susan Cummings Environmental Health & Safety

I. Approval of November 17, 2003 Minutes

Approved with corrected spelling of

last name

BSL 3 Laboratory Certification report.

II. Updates

- CSAAC Response re: Proposal from
 Decker presented the Chemical Safety Committee perspective on the proposed use
 this respirator. The Chemical Committee concurs with the BSAAC that the N-95 is
 not suitable for the proposed experiment.
- 2. Review of Sonia Rosenberger's BSL 3 La

III. Review of Biological Use Authorizations (BUAs):

1. BSL 1 Projects

BUA No. 0654

Title: Development of markers for genotype analysis of animals

2. <u>NEW</u>

BUA No. 0722

Title: Estradiol induced neurogenesis in adult rodent brain following ischemic injury: Fate and roles of newborn neurons in brain recovery

Committee requested re-submission that would include:

- 1. Specify the level of heat required to terminally inactivate viral stocks
- 2. Explain how and where mice:
 - Will be exposed,
 - Will be housed/contained before and after exposed and
 - Cages and bedding will be decontaminated.
- 3. Provide specific details on decontamination procedures for potentially contaminated surfaces (BSC, countertops, etc).
- 4. Does this virus infect only mice?
- 5. Correct typographical error on page 6 (thymidine).
- 6. Provide training status for

December 15, 2003 Minutes Approved 1/26/04

BUA No. 0723

Title: Novel Defensins of Human Epithelia & In vivo Models of Defensin Activity Committee approved with the following conditions:

- 1. Page 6 Please specify the host defense peptides and genes (class of genes).
- 2. Page 9 Please include that mice will be exposed in a biosafety cabinet.
- 3. Page 8 Please correct spelling of inoculae

BUA No. 0724

Title: Bacterial Chemostaxis to the Herbicide Atrazine Committee requested resubmission that would include:

- 1. Any BSL 2 organisms in the BUA and identify where and how they are stored and used.
- 2. The name of the PI in whose BSL 2 lab the organisms will be stored and that the PI, and her/his laboratory personnel will be trained in the risks associated with your BSL2 organism, including symptoms, disinfection, who to notify in the event of spill, etc.
- 3. That your laboratory personnel will be annually trained to dispose of the BSL 2 organism in accordance with the Medical Waste Management Plan currently in use in the laboratory where it is stored.

3. RENEWALS

BUA No. 0208

Title: Studies on Respiratory Syncytial Virus

The Committee granted approval of this BUA subject to the following:

- 1. Page 5 Please ensure does not require BBP training.
- 2. Page 5 Please provide UCD IDs for all personnel.
- 3. Page 8 Please put an "X" in the Biosafety level 2 box after agent/toxin No. 2.
- 4. Page 8 Include that transportation of specimens will be in accordance with UCD Biosafety Manual section IV (f) Biological Safety Guidelines, Transportation and Shipping

BUA No. 0400

Title: SIV and HIV Pathogenesis

The Committee granted approval of this BUA subject to the following inclusion of the following condition:

1. Please clarify how organism will be transported outside the lab.

BUA No. 0575

Title: Comparison of tissue and species specific differences between recombinant steroidogenic cytochromes P450 and redox partner proteins with primary tissue counterparts

The Committee granted approved upon completion of the following condition:

1. Page 6 - Please change the biosafety level of "DNA/RNA source(s)" from Biosafety level 1 to Biosafety level 2

December 15, 2003 Minutes Approved 1/26/04

BUA No. 0606

Title Project 1: Vitamin Status Assessment in Human Blood

Title Project 2: Inhibition of Methyl-CpG-binding Protein Expression in a Human Hepatoma Cell Line

The Committee denied this BUA for a number of reasons including:

1. Application not complete

- 2. Need to determine if equipment is a Biosafety cabinet or a laminar flow hood.
- 3. Need to provide vaccination opportunity
- 4. Need information on secondary containment

4. AMMENDMENTS

BUA No. 0687

Title: Effect of BMP-7 produced by ad gene transfer on mechanically adaptive bone model

The Committee approved with the following conditions:

- 1. Identify the adenovirus as replication defective.
- 2. Check if ARS picks up animal carcasses at the Medical Center.
- 3. Is the adenovirus used the same virus that you have been working on?
- 4. Please add if different genes are being cloned.
- 5. Please remove reference to disposal at the UCD Landfill or add the statement that the treated waste, now considered municipal garbage, is disposed of in the UCD Landfill.

5. FINAL APPROVAL of CONDITIONAL BUAS

BUA No. 0711

Title: Ecological genetics of birds with West Nile Virus

Committee reviewed inactivation assay and approved as submitted.

BUA No. 0714

Title: Cell cycle regulation in peripheral blood and lymph node lymphocytes from HIV-infected subjects of long-acting interferon-alpha on innate and adaptive immunity in SIV-infected macaques

Committee discussed EH&S visit to lab and equipment specification information. Approval of BUA was granted if the equipment filter is capable of capturing cells. The recommendation that the cytometer user wear respiratory protection was forwarded.

BUA No. 0642

Title: "Pathological Basis of Hepatic Fibrosis Review of recent reference for self-inactivating retroviral vectors used in lab Committee approved this BUA as submitted.

IV. Discussion items

Deferred discussion items deferred due to lack of time. Item to include in the role of the BSAAC in recommending and/or requesting medical surveillance.

V. Next meeting