Institutional Biosafety Committee, UC Davis Office of Environmental Health and Safety

MINUTES

January 28, 2013 (3-5p)

Hoagland Hall Rm 130

NOTE: Next IBC meeting: 2/25/2013

Start Time: 3:08pm

In attendance:

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

Gerhard Bauer Voting Member, Vice-Chair, IM Div of Hematology/Oncology

Nicole Corley Voting Member, Campus Veterinary Services
Bruce Draper Voting Member, Molecular & Cellular Biology

Angela Gelli Voting Member, Chair, Pharmacology

Diane Hoffmann Voting Member, School of Medicine Sponsored Programs

Fred Jacobsen Voting Member, Public Member
Dan Kliebenstein Voting Member, Plant Science
Elizabeth Maga Voting Member, Animal Science

Renee Tsolis Voting Member, Medical Microbiology & Immunology

Roger Belcourt Non-Voting Ex-Officio Member, Occupational Health Services

IBC support staff in attendance:

Niki Drazenovich Associate BioSafety Officer, Environmental Health and Safety Philip Barruel Associate BioSafety Officer, Environmental Health and Safety Malendia Maccree Associate BioSafety Officer, Environmental Health and Safety

Excused:

Jill Blackwelder-Parker Non-Voting Ex-Officio Member, Associate Vice Chancellor, Safety Services

Neil Speth Non-Voting Ex-Officio Member, UCDMC Employee Health Services

Victor Lukas Non-Voting Ex-Officio Member, Attending Veterinarian

Savithramma Dinesh-Kumar Voting Member, Plant Biology

Guests:

Bryce Falk, Plant Sciences

I. Review of past IBC meeting minutes: December 17, 2012

APPROVED (9-0-0)

II. Announcements: NONE

III. Old Business: NONE

N BUA No. 1026B BBP (primary and est human cells) BSL: 2, no agts Rev: mmm

Title: Mechanical characterization of cellular forces and processes

Project Summary:

This project involves the culturing of cells from both human and rat species, including primary cells. Cells will be cultured on PDMS micro-pillars developed from micro-machined silicon surfaces. Videomicroscopy, staining, and various other biological assays will be used to determine cell status and health. The experiments will serve to quantify cellular responses, primarily a cells ability to perform its principal function, to self-synthesized nanoparticles. Particles of interest include metal oxides and sodium yttrium fluorides doped with rare earth ions. Medical waste will be generated.

Tabled 12/17/2012 APPROVED (9-0-0)

IV. New Business:

1. **BSL3P**:

R BUA No. 0235-01

NIH: Inf agts (plants), IIID5a,
IIID5b, IIIF6 (App CII, CIII)

BSL: 3P, 1P, RG: 1

Rev: mmm

Title: <u>Biology, molecular biology and control of phloem-limited plant viruses</u> Project Summary:

The lab uses several plant viruses and host plants to assess virus:plant and virus:insect interactions. Most work is done in BSL1 - 2 conditions, but some in BSL3P, using recombinant plant viruses and plants, and wildtype insect vectors.

APPROVED (10-0-0) reviewed out of order

2. BSL2:

NIH: IIID3b(lenti), IIID3e(retro),

R BUA No. **0539-02**IIIE, BBP (primary and est human and NHP cells and tissues), IIIF6 (App CI,

CII)

Title: Flow effects on trophoblast/endothelial interaction

Project Summary:

The current project addresses the question: how does flow-derived shear stress induce trophoblast $\beta 1$ integrin expression and trophoblast migration on endothelium? The research will involve transfecting various mammalian cells (including human and non-human primate) with retroviral vectors and lentiviral vectors with potential oncogenes to analyze expression patterns. Sharps will be used to dissociate non-human primate tissues and medical waste will be generated.

APPROVED (9-0-0) RT arrived

R BUA No. 0615 NIH: Inf agts (humans and animals) BSL: 2, RG: 2 Rev: nld

Title: Pathogenesis of feline infectious diseases

Project Summary:

Projects done in this laboratory involve previously characterized animal infectious agents as well as identifying and characterizing potentially novel infectious agents of cats. Infectious agents handled by the lab could also include zoonotic agents as well. The research will involve experimentally infecting cats, analysis of tissues and blood and culturing of infectious agents. Sharps will be used and medical waste generated.

APPROVED (9-0-0) SB out

R BUA No. **0655-01** NIH: Inf agts (humans and animals) BSL: 2, RG: 2 Rev: nld

Title: Immune responses to mucosal pathogens

Project Summary:

The goal of the project is to determine the in vivo effects of innate cytokines and innate virus recognition on the ability of B lymphocytes to generate an immune response to influenza virus infection. The role and function of IgM in B cell response regulation to influenza infection using various gene-targeted mice will also be studied. Mice will be experimentally infected with different strains of influenza virus to identify the specific activation requirements of the antibody-producing B cells (acquired immunity). Virus will be propagated for these experiments in hen eggs and in vitro studies will be performed to measure the virus load in lungs of infected mice. None of the influenza virus strains used are classified as "highly pathogenic". Sharps will be used and medical waste generated.

APPROVED (10-0-0) SB returned

NIH: IIID3a(adeno), IIID3e(aav),

IIID4a, IIID4b, BBP (primary and R BUA No. 0748-02 BSL: 2, RG: 2 Rev: nld est human cells), IIIF6 (App CI)

The study of demyelinating diseases and disease treatment Title:

Project Summary:

The lab is will be studying demyelinating diseases and possible disease treatments. The different studies will involve use of viral vectors (adeno, AAV and lenti), transgenic mice as hosts for viral vectors and xenografting primary transduced MSCs onto mice. Vector will be produced in tissue culture and centrifuged for purification. Sharps will be used and medical waste generated.

APPROVED (10-0-0)

NIH: IIID4a, IIIE, BBP (primary R BUA No. 0767-05 BSL: 2, RG: 1 Rev: nld and est human cells), IIIF6 (App CI, CII)

Title: Gene therapy development using artificial transcription factors

Project Summary:

The lab is developing artificial transcription factors as an approach to gene therapy for several disorders. Human cell culture and animal models will be used. The factors will be delivered as plasmids to cells, as purified protein to mice or rats, and as genetically modified bacteria that will be injected into mice. Recombinant DNA will be made, sharps will be used, and medical waste will be generated.

APPROVED (10-0-0)

N BUA No. 0796-03 NIH: Inf agts (humans) BSL: 2, RG: 2 Rev: mmm

Characterization of *C. albicans* binding ligands for targeted drug delivery Title:

Project Summary:

The goal of this project is to identify ligands which bind specifically to C. albicans which can then be used as part of targeted drug delivery. C. albicans binding ligands will be identified using standard one bead-one compound (OBOC) methods. The identified ligands will be incorporated into a drug delivery system to determine if it can minimize the overall amount of antifungal drug used. A BSC will be used for all C. albicans work. Medical waste will be generated. Pipets will be disposed as sharps waste.

APPROVED (10-0-0)

NIH: IIID3a(retro, adeno).

IIID3b(lenti), IIIE, BBP (est human **R** BUA No. **0798** BSL: 2, RG: 2 Rev: mmm

cells), IIIF6 (App CII, VII, VIII)

Title: Role of Wnt signaling in neural development and neural stem cells

Project Summary:

The research goal is to knockout or knockdown Wnt signaling genes including *Wls*, *Lrp6*, and *beta-catenin*, the key molecules in the Wnt signaling pathway with a virus based *Cre-recombinase* and RNA interference and to test the rescue effects via viral transfections with the downstream Wnt signaling genes or potential target genes in mice and derived cells. The vectors to be used contain the genes of Cre-recombinase, GFP, Wnt/beta-catenin signaling genes.

APPROVED (10-0-0)

R BUA No. 0803

NIH: IIID3b(lenti), BBP (primary and est human cells), IIIF6 (App CI, CII)

BSL: 2, RG: 2

Rev: nld

Title: <u>Characterization of gene function *in vitro* through experimental gene titration</u> Project Summary:

The lab is focused on adipocyte and neuronal physiology/crosstalk, adipose tissue physiology and remodeling, and muscle metabolism. All projects leverage the use of the lentiviral mediated shRNA system to "knockdown" genes of interest and a lentiviral-mediated overexpression system (to rescue phenotype). Multiple different cell types will be used in established murine RAW264.7 monocytic, C2C12myoblast/tubes, 3T3-L1 preadipocyte/adipocyte cell lines and primary murine and human cell cultures. Sharps will be used to obtain primary cells from mice but they will not be used with recombinant materials. Medical waste will be generated.

APPROVED (10-0-0)

R BUA No. **0811**

NIH: IIID4a, BBP (est human cells), IIIF6 (App CI, CII)

BSL: 2, RG: 1

Rev: pb

Title: Role of the HER/PI3K/mTOR pathway in androgen-independent prostate cancer Project Summary:

This project utilizes human and mouse prostate cancer cells and athymic mouse models to study the effect of HER3 and related tyrosine kinase receptors as well as downstream targets including Akt and mTOR in the development and progression of prostate cancer. This study will utilize constructs expressing wild-type, truncated and mutated forms of Filamin A and wild-type ErbB3. In addition, promoter regions of various genes including ErbB3 and PSA will be cloned into vectors expressing luciferase to measure transcription factor binding. Sharps will be used during the project for the animal studies.

APPROVED (10-0-0)

NIH: IIID3a(adeno), BBP (human

BSL: 2, RG: 2

Title: Transduction of skin tissue with adenoviral vector to create EPO secreting "EPODURE Biopumps"

Project Summary:

The facility will act as the manufacturing site for a biotech company sponsored human gene therapy clinical trial that has already received RAC and FDA approval. Skin biopsies from patients with chronic erythropoietin (EPO) deficiency will be received and transduced with adenoviral vector transferring the human erythropoietin gene. After transduction, these skin biopsies will be secreting human erythropoietin and are then called "Biopumps"; these will be shipped back to the clinical site where they will be implanted into the patient. Sharps will be avoided and medical waste will be generated.

APPROVED (9-0-0)

3. Bloodborne Pathogen Protocols:

N BUA No. 0533-02B

BBP (primary human blood and CSF)

BSL: 2, no agts

Rev: mmm

Rev: nld

Title: <u>Molecular and neuropathological abnormalities in neuropsychiatric and neurological disorders</u> Project Summary:

Fresh or frozen human blood, serum, or plasma is used to prepare total RNA/DNA/protein for molecular or immunological analyses. Aerosol generation is not expected, since extraction of DNA/RNA/protein is accomplished chemically, within a sealed tube. No grinders or sharps are used and medical waste is generated

APPROVED (10-0-0)

N BUA No. 1032B

BBP (primary human blood and cells)

BSL: 2, no agts

Rev: pb

Title: Vitamin B12 and folate blood levels in Alzheimer's patients

Project Summary:

The investigators will analyze vitamin B12 and folate blood levels in Alzheimer's disease patients. DNA will be isolated from blood and analyzed by ELISA and HPLC assays. Plasma and serum will be transported to clinical labs for further analysis; these labs are at

. Manipulations will occur on the open benchtop behind a plexiglass shield; a BSC is not available. Medical waste will be generated.

APPROVED (10-0-0)

N BUA No. 1034B

BBP (primary human cells)

BSL: 2, no agts

Rev: pb

Title: <u>Assessing inflammatory markers to predict events in nephrology trial; inflammation and diabetes</u> Project Summary:

In the first study the lab is receiving human blood to measure FGF-23 in serum samples. The second study will use various animal models of diabetes. Sharps will not be used with human samples. Medical waste will be generated

APPROVED (10-0-0)

N BUA No. 1036B BBP (est human cells) BSL: 2, no agts Rev: pb

Title: <u>Engineering articular cartilage using human dermis-derived stem cells and chondrocytes</u> Project Summary:

The goal of this proposal is to develop constructs to enable eventual resurfacing of articular cartilage of the knee joint. The chondral implant will consist of engineered cartilage formed with human dermis-derived stem cells or human chondrocytes. The primary success criterion will be the quality of the engineered osteochondral tissue, which will be determined by a battery of biomechanical, biochemical, and histological assessments to ensure tissue functionality. Constructs will eventually be implanted subcutaneously into mice, rabbits, or sheep, and, after 1-3 months, the inserted cartilages will be removed and assessed. Medical waste will be generated; sharps will be used.

APPROVED (10-0-0)

4. BSL1:

R BUA No. 0058 NIH: IIIE2a, IIIE, IIIF6 (App CII) BSL: 1, RG: 1 Rev: mmm

Title: The positive effect of introns on plant gene expression

Project Summary:

Intron-containing reporter gene fusions are made in standard *E. coli* cloning vectors and transferred to the binary vector pEND4K. These are then introduced into *Arabidopsis thaliana* by *Agrobacterium tumefaciens* -mediated transformation using a selection for resistance to kanamycin, a process that does not involve hazardous manipulations.

APPROVED (10-0-0)

5. IBC Notification Simultaneous with Initiation (NIH III-E):

R BUA No. **0023-01** NIH: IIIE2a, IIIE2B(1), IIIE, **BSL: 1, RG: 1** Rev: mmm

IIIF6 (App CI, CII)

Title: The regulation of gene expression in plants

Project Summary:

The focus of this project is centered on the mechanisms that govern plant growth and development and how these have evolved over time. To achieve this end a wide variety of plant species will be transformed with genes that are known or predicted to have an effect on vegetative and reproductive plant growth.

APPROVED (10-0-0)

6. Storage ONLY: NONE

7. Exempt Protocols Approved by BSO: NONE

R BUA No. 0898 IIIF6 (App CI) BSL: 1, no agts Rev: pb

Title: The role of the proteasome in troponin related cardiomyopathies

Project Summary:

For cell culture studies the a rat heart cell-line will be utilized to express mutant and wild-type troponins and proteasome subunits to determine the effect of these mutations on the signaling pathways involved in heart cell muscle contraction. H9C2 cells will be lysed and the lysate analyzed by western blotting. Mice, which have mutant forms of troponin (causes cardiomyopathies) and were obtained from another facility, are bred and tissues extracted for biochemical assays. Sharps will be used. No medical waste will be generated.

APPROVED(x-x-x)

B. Amendments:

Amend **0051-03(A) BSL: 1, RG: 1** Rev: mmm

Title: <u>Transient expression of heterologous proteins by Agroinfiltration of plant tissue</u>

Amendment to add: Large scale fermentation of (w/t)

Exp date: 06/18/2015 APPROVED (10-0-0)

Amend **0418-02(A)** NIH: IIID4a **BSL: 1, RG: 1** Rev: nld

Title: <u>Analysis of lens cytoskeleton</u>

Amendment to add: Injection of prepared AAV constructs into mice

Exp date: 12/20/2013 APPROVED (10-0-0)

Amend 0754-02(A) BBP (human brains and CSF) BSL: 2 (no agts) Rev: nld

Title: Rett syndrome and Alzheimer's Disease

Amendment to add: 1. ADC and IVD brain removal and cutting and collection of CSF (formalin fixing

and analysis)

2. Pediatric brain removal and cutting (formalin fixing and analysis)

Exp date: 12/17/2014 APPROVED (10-0-0)

Amend **0820(B)** NIH: IIIE3 **BSL:** 1 (no agts) Rev: nld Title: Cell lineage specific manupilation of gene expression in the mouse nervous system (new title)

Amendment to add: 1. Floxed MKK7 mice

2. B6.Cg-Tg(Syn1-cre)671Jxm/J mice

Exp date: 09/20/2013
APPROVED (10-0-0)

Amend **0979(A)** Inf agts (animals) **BSL: 2, RG: 2** Rev: nld

Title: CD4 T cell responses to Salmonella; Typhoid priority antigen identification and vaccine

development

Amendment to add: 1. Agents: *Plasmodium berghei* or *Plasmodium yoelii*

2. Procedure: Experimental infection of mice with *P. berghei* or *P. yoelii*

3. Procedure: Co-infection of mice with Salmonella typhimurium and P. yoelii or

P. berghei

Exp date: 07/18/2014 APPROVED (10-0-0)

Amend **0999(B)** Inf agts (sheep placental tissue) **BSL: 2 (no agts)** Rev: pb

Title: Biological examination and potential therapeutic applications of placental tissue

Amendment to add: Culture of primary sheep cells from placental tissue

Exp date: 01/23/2015 APPROVED (10-0-0)

C. SOPs for Courses and Core Facilities:

SOP No. 0009 NIH: IIID4a (aav in mice) BSL: 1, RG: 1 Rev: mmm

Title: <u>Imaging of optogenetically-labeled cells in eyes of live mice</u>

Abstract:

This SOP covers shared use of a unique optical device that will permit imaging of fluorescently-labeled cells in the retinas of live mice. In some cases, the gene of interest will be introduced by transgenic technology. In other cases, the gene of interest, conjugated to a fluorescent tag such as Green Fluorescent Protein (GFP), will have to be introduced by intraocular injection of that gene, packaged into AAV. The AAV injection is a service provided to investigators who wish to image their fluorescently tagged proteins in living mouse retinas.

APPROVED (10-0-0)

D. Conditional BUAs reviewed by ABSO, Final Approval by BSO:

R BUA No. 0712 NIH: Inf agts (animal) BSL: 2, RG: 2 Rev: nld

Title: <u>Immune response to intracellular pathogens in horses</u>

Review Date: 12/17/2012

R BUA No. 0799 NIH: IIID3b(lenti), IIIE3, IIIF6 BSL: 2, RG: 2 Rev: nld

(App CI, CII)

Title: Mechanism of the p53 family proteins-dependent tumor suppresssion

Review Date: 12/17/2012

N BUA No. 1029B

BBP (primary human blood and BSL: 2, no agts Rev: mmm

tissues)

Title: Targeting the PI3K/Akt/mTOR signaling system in inflammatory diseases

Review Date: 12/17/2012

E. Terminated BUAs:

BUA No. **0830-02B** Rev: nld

Title: SCN9A mutations in erythermalgia

BUA No. 0930B Rev: nld

Title: Epigenetics, inflammation and metabolic syndrome

V. Discussion Items:

1. Sean - Discuss what is considered a "sharp" and how they should be disposed. Micropipettes? Serological pipettes? Glass Pasteur pipettes? IBC decisions on all three types of pipettes will be clarified in SN#3 and become campus and UCDHS policy.

The following is the result of committee discussion and approval of the following methods to dispose of the various biohazardous pipette types: 1) Micropipettes and plastic serological pipettes: double bag, 2) Glass pasteur pipettes: sharps disposal

Revise Safety Net #3 - vote on final revision at IBC meeting

VI. Information Items:

1. Sean - After an IBC discussion via e-mail (1/16/13) BUA, which was Tabled during the Dec 2012 IBC meeting, was retroactively given Conditional Approval

VII. IBC Training: NONE

VIII. BSL3 Laboratory Information: NONE

IX. Notifications: NONE

X. Subcommittee Topics: NONE

End Time: 5:00p.m.

Institutional Biosafety Committee, UC Davis Office of Environmental Health and Safety

MINUTES

February 25, 2013 (3-5p)

Hoagland Hall Rm 130

NOTE: Next IBC meeting: 3/18/2013

Start Time: 3:10pm

In attendance:

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

Gerhard Bauer Voting Member, Vice-Chair, IM Div of Hematology/Oncology

Nicole Corley Voting Member, Campus Veterinary Services

Savithramma Dinesh-Kumar Voting Member, Plant Biology

Bruce Draper Voting Member, Molecular & Cellular Biology

Angela Gelli Voting Member, Chair, Pharmacology
Fred Jacobsen Voting Member, Public Member
Dan Kliebenstein Voting Member, Plant Science
Elizabeth Maga Voting Member, Animal Science

Victor Lukas Non-Voting Ex-Officio Member, Attending Veterinarian
Roger Belcourt Non-Voting Ex-Officio Member, Occupational Health Services

IBC support staff in attendance:

Niki Drazenovich Associate BioSafety Officer, Environmental Health and Safety Philip Barruel Associate BioSafety Officer, Environmental Health and Safety Malendia Maccree Associate BioSafety Officer, Environmental Health and Safety

Excused:

Jill Blackwelder-Parker Non-Voting Ex-Officio Member, Associate Vice Chancellor, Safety Services

Neil Speth Non-Voting Ex-Officio Member, UCDMC Employee Health Services

Renee Tsolis Voting Member, Medical Microbiology & Immunology
Diane Hoffmann Voting Member, School of Medicine Sponsored Programs

Guests:

Clifford Saron, Ctr for Mind & Brain, cdsaron@ucdavis.edu

I. Review of past IBC meeting minutes: January 28, 2013

APPROVED (8-0-0)

II. Announcements: NONE

III. Old Business: NONE

IV. New Business:

1. BSL2:

N BUA No. 0492-04

NIH: IID3b(lenti), BBP (human

BSL: 2, RG: 2

Rev: mmm

blood and tissues), IIIF6 (App CII)

Title: Sustained correction of hemophilia A

Project Summary:

The lab proposes to reprogram human fibroblast cells into IPSCs and subsequently differentiate them into endothelial cells. Minicircle plasmid constructs containing oncogenes will be transfected into human cell lines to induce pluripotency. To express Factor VIII we are will use recombinant DNA technology to generate constructs for Factor VII expression and will also have lentiviral viral vectors produced by the UCDMC vector core facility to transduce cells to express Factor VII. Medical waste will be generated and sharps will be used in manipulation of human tissues.

CONDITIONAL (8-0-0)

Sec 1, BSC information: Provide the most recent certification dates for the biological safety cabinets in lab which will be used for this work.

2. Sec 2D, #1 - Clarify why FACS will be used, which cells will be sorted, and identify the facility where the FACS sorting will take place.

NIH: IIID3a(adeno), IIID3b(lenti),

R BUA No. 0672 IIID4b, BBP (human blood and tissue), BSL: 2, RG: 2 Rev: pb

IIIF6 (App CII)

Title: Genetic abnormalities underlying sudden cardiac death in humans

Project Summary:

The research will involve transfecting cells isolated from both human and mouse cardiac tissue with genes associated with Mir1 and GFP. This will be performed by use of adenovirus and lentivirus, both of which are commercially available and replication deficient. The project also involves the use of human stem cells to repopulate the hearts of live mice that have been induced to have myocardial infarction. These human stem cells, which are commercially available, will be transduced with lentiviral vectors to express luciferase. Then they will be made to differentiate into mature cardiomyocytes by incubation with growth factors, and finally injected into live mice hearts. Medical waste will be generated. Sharps will be used for a variety of procedures.

CONDITIONAL (9-0-0) (DK arrived)

Sec 2D, #1, Sec 2E, #4 - The viral vector envelope as was described as "Intact FIV viral envelope," in Sec 2D, #1 but as VSV-G in Sec 2E, #4. Please update the BUA so that these sections are consistent.

NIH: IIID3a(adeno), IIID3b (lenti),

R BUA No. 0685 IIID4a, IIIE3, BBP (est human cells), BSL: 2, RG: 2 Rev: pb

IIIF6 (App CI)

Title: Role of focal adhesion molecules

Project Summary:

Experiments are designed to study the roles of focal adhesion molecules in some specific signaling pathways in cultured-cell and mouse model. cDNAs of focal adhesion molecules will be cloned into adenoviral vector to generate adenovirus for transducing cells, lentivirus-mediated short hairpin RNA (shRNA) will be used to knockdown gene expression and focal adhesion molecules/loxP mice will be generated for elucidating the roles of the focal adhesion molecules in mice development.

APPROVED (9-0-0)

NIH: Inf agts (humans), IIIE3,

R BUA No. 0723 IIIE, BBP (human blood and tissues), BSL: 2, RG: 2 Rev: nld

IIIF6 (App CII)

Title: Defensins and other mammalian-derived antimicrobial peptides of innate immunity

Project Summary:

The lab seeks to better understand the biology of mammalian antimicrobial peptides, key effector molecules of the innate immune system, in an effort to provide new therapeutic avenues to combat infectious disease. This project will entail antimicrobial peptide discovery using in vitro antibacterial bacterial screening assays, recombinantly expressing these peptides to define activity in vitro, and generating transgenic mice to test the role of these peptides in vivo by challenging the mice with infectious agents. Sharps will be used and medical waste generated.

CONDITIONAL (9-0-0)

- 1. Sec 3, #1 Clarify how you are using *Klebsiella pneumonia*.
- 2. Sec 3, #2 Clarify the source of *Klebsiella pneumonia*.

R BUA No. **0797**NIH: IIID2a, IIID4b, Inf agts(zoonotic), IIIF6 (App CII)

BSL: 2, RG: 2

Rev: nld

Title: <u>Cytoskeletal function in cell division, motility and attachment in *Giardia intestinalis* Project Summary:</u>

The project involves investigating the function of the ventral disc, a cytoskeletal organelle, in *Giardia intestinalis*, which is a common intestinal parasite. Wild-type and recombinant strains will be studied; primarily using live imaging and protein-tagging approaches to understand the function of this organelle in attachment to the intestinal villi. Mice and gerbils will be used as animal models to demonstrate the importance of identified cytoskeletal components to colonization in vivo. Sharps will be used and medical waste generated.

APPROVED (9-0-0)

N BUA No. **0854-06** $\frac{\text{NIH: IIID3a(retro), IIID6 (App KIV),}}{\text{BBP (est human cells), IIIF6 (App CI)}}$ BSL: 2, RG: 2Rev: nld

Title: <u>Large scale manufacturing of GMP grade retroviral vector</u> Project Summary:

The UC Davis GMP facility will manufacture GMP grade retroviral vector for a company (Epeius Biotechnologies Corp.) that would like to use it for preclinical, and later clinical, testing to develop a cancer therapeutic. 20 liters of retroviral vector supernatant will be manufactured. Regular laboratory equipment (10 layer, 1.35 liter volume cell stacks) will be used and sequential manufacturing will be applied. A closed system will be used for pooling of vector supernatant. No concentration and no spinning will be performed. No sharps will be used.

APPROVED (8-0-0) (GB abstained)

NIH: IIID3e(fiv), IIIE, BBP

(primary and est human cells), IIIF6 (App BSL: 2, RG: 1

CI, CII)

Title:

Project Summary:

R BUA No. 0905

The project is focused on studying signaling mechanisms in neurons and other cells and utilizes mammalian vectors for expression of signaling proteins (ion channels, kinases and their regulators such as G-protein coupled receptors) and their interacting proteins in primary neuronal cultures from rat and mice and in HEK293 cells; we also express these proteins and fragments of them in various *E. coli* strains mainly BL21 and DH5alpha for in vitro interaction studies. FIV-based lentiviral systems will be used to introduce shRNA and transgene expression cassettes for efficient knockdown or ectopic expression of signaling molecules in cultured neurons. We use mutant and transgenic animals in which target substrate binding of two key kinases (PKA, CaMKII) has been abrogated to evaluate the physiological importance of these interactions in vivo and ex vivo (like acute forebrain slices for electrophysiology). This work will show whether it is possible and desirable to target these interactions for drug treatment of various brain diseases including epilepsy and posttraumatic stress disorder. Sharps will not be used with recombinant DNA and medical waste will be generated.

APPROVED (9-0-0)

N BUA No. 1035

NIH: IIID3e(aav), IIID4a, BBP

(est human cells), IIIF6 (App CI)

BSL: 2, RG: 1

Rev: nld

Rev: nld

Title: Determining the role of MCH in the development of hyperphagia and obesity Project Summary:

The research project is aimed at identifying if removal of MCH in nodose ganglia prevents the onset of hyperphagia and subsequent obesity in rats fed a high fat diet. The lab will be infecting cultured mammalian cells and live rodents with shRNA using adeno-associated virus to determine the effect of knocking down melanin concentrating hormone. Sharps will be used to infect and necropsy animals and medical waste will be generated.

APPROVED (9-0-0)

N BUA No. 1037

NIH: IIID3b(lenti), BBP (primary human cells), IIIF6 (App CI)

BSL: 2, RG: 2

Rev: nld

Title: Extracellular matrix bioscaffold augmented with human stem cells for cardiovascular repair Project Summary:

This is an early translational study for evaluation of a xenogeneic extracellular matrix (ECM) biomaterial, recellularized with human mesenchymal stem cells (hMSC). The study is composed of an FDA approved small intestinal submucosa (SIS) derived ECM scaffold seeded with allogeneic human bone marrow-derived MSCs. Additional control groups will consist of ECM scaffolds generated in the laboratory, which will also undergo hMSC recellularization. For some experiments, hMSCs will be infected with eGFP VSV-G pseudotyped lentiviral vector (cloned and generated by the _______) to track the integration of hMSCs with the bioscaffolds. The ultimate aim of the current project is to develop an immunologically acceptable xenogeneic scaffold for cardiovascular tissue engineering. Sharps will be used and medical waste will be generated.

APPROVED (9-0-0)

2. **Bloodborne Pathogen Protocols:**

R BUA No. 0796-02B

BBP (human blood and primary cells)

BSL: 2, no agts

Rev: mmm

Use of human blood/tissue/cell lines to identify cancer targeting ligands Title: **Project Summary:**

Human blood/tissue/cell lines can be used to identify high affinity cancer targeting peptides for cancer imaging and therapy. In addition, the cancer cells will be used to implant cancer in animal models to create xenografts that can be used for in vivo cancer imaging and therapeutic studies. We will use a BSC for all human blood/tissue and cell work. Medical waste will be generated. Sharps will be used with human cell lines and animals.

APPROVED (9-0-0)

BBP (primary and est human cells), R BUA No. 0913B

BSL: 2, no agts

Rev: pb

IIIF6 (App CI, CII, CIII) Chemical modifications of siRNA to control off-target effect and The bioorganic chemistry of RNA Title:

editing ADARs

Project Summary:

The lab is interested in developing new tools to study the ADAR proteins (adenosine deaminase acting on RNA). Since they are important to human disease human cell lines will be used. The lab is also interested in using chemical modifications as a tool to mitigate siRNA immune stimulation and poor target specificity, both of which are obstacles in the development of RNAi therapeutics. Human cell lines and peripheral blood mononuclear cells will be used in assessing the immunostimulatory effects and selectivity of our modified siRNAs. Sharps will not be used and medical waste will be generated.

TD work done in human cells- App CI (IIIF6) cells bought with siRNA already present. **APPROVED** (9-0-0)

N	BUA No.	1038B	BBP (human bloc	d)	BSL: 2, no agts	Rev: pb	
	Title:	Title: Psychological and biological effects of intensive meditation practice					
	Project Summary:						
	This project involves a field study collecting blood from up to 40 volunteers at the beginning and end of a 1						
	month meditation retreat to be held at . Up to 40 individual					40 individuals	
	from the community attending classes at will serve as a control group. Blood will be processed in						
	off-site field laboratory to prepare samples of serum, plasma, PBMC lysate, and nucleic acids as per protocols						
	established in collaborator laboratories at and Samples will be stored at -80C in a freezer at						
	and shipped to collaborators for assay. Blood will be collected by licensed						
	professional phlebotomists. No sharps will be used by laboratory personnel. Medical waste will be generated.						

APPROVED (9-0-0)

3. BSL1:

R BUA No. 0020

NIH: IIID4a, IIIE, IIIF6 (App CII)

BSL: 1, RG: 1

Rev: nld

Title: Mechanisms of asymmetric cell division during female meiosis

Project Summary:

This project studies the processes of cell division and early embryonic development in the non-pathogenic nematode *C. elegans*. A number of genes have been identified through forward genetic screens that are required for these processes and these genes and their interacting partners are now being studied at the molecular level. Plasmid DNA constructs engineered to express *C. elegans*, human, and cnidarian proteins will be introduced into *E. coli*, *Xenopus* cells (A6) and *C. elegans*. Scalpels will be used to dissect the worms and biotechnology waste will be generated.

APPROVED (9-0-0)

R BUA No. **0045**

NIH: Inf agts (animals), IIIF6 (App

BSL: 1, RG: 1

Rev: nld

Title: <u>Molecular genetic studies in chickens</u>

Project Summary:

This project investigates molecular genetic and cytogenetic characteristics of the chicken, its cells and tissues. The project will involve culture of cells for cytogenetic studies or for sequencing related to gene discovery. Cytogenetic studies will use cultured cells for fluorescence in situ hybridization (FISH). Fluorescent probes for FISH will be generated from DNA oligos, including MDV sequences cut from an MDV BAC or chicken gene sequences PCR'd from chicken cells. In addition, the project involves the culture of chicken cells which contain a recombinant form of the MDV for cytogenetic studies and for molecular characterization (DNA, RNA collection). *E. coli* K-12 will be utilized as a vector to store or amplify DNA for sequencing or probe creation.

APPROVED (9-0-0)

N BUA No. 1033

NIH: IIID3e(aav), IIIF6 (CI)

BSL: 1, RG: 1

Rev: pb

Title:

Imaging neural activity with genetically encoded calcium indicators following mechanical strain

<u>injury</u>

Project Summary:

The goal of this research is to utilize novel optical sensors and controllers for monitoring and manipulating neural circuitry following mechanical strain injury, a model of traumatic brain injury, in culture systems. Genetically-encoded calcium indicators (GECIs, GFP-based reporter constructs) have been expressed in rat primary neuronal cultures using a viral vector, Adeno-Associacted Virus (AAV), under the control of both neuron-specific and glial-specific promoters. Using the novel GECI/AAV technology, the investigators will first determine the relationship between calcium load in individual neurons and eventual cell death (loss of cells) and cell dysfunction (change in response to a stimulation) within individual cells. Sharps will be used and no medical waste generated.

CONDITIONAL (9-0-0)

Sec 2A, Table 1, vectors and Sec 2E #4 had different AAV serotypes indicated. Table 1 stated

1. serotype 2, but Sec 2E #4 indicated serotype 1. Please update the BUA so that these sections are consistent.

N BUA No. 1040 NIH: Inf agts (plants) BSL: 1, RG: 1 Rev: mmm

Title: <u>Effective disinfection of rough rice using UV radiation</u>

Project Summary:

The main purpose of this project is to investigate the disinfection of *Aspergillus flavus* spores on rough rice by using UV technology for food safety. These fungi are known as post-harvest pathogens of rice, but may also be a potential respiratory hazard to workers with allergies or compromised immune systems.

TABLED

- 1. Sec 1, work and equipment locations Please specify all room locations where fungi will be stored, grown, or manipulated (including all pure culture and infected rice samples).
- 2. Sec 3, 1 Please provide justification for use of the aflatoxin-producing strain of *A. flavus* rather than a nontoxigenic strain.
 - Sec 3, #5 If using toxigenic strains, provide references and information regarding aflatoxin (e.g.
- 3. route of exposure, LD50, inactivation procedures) and typical ranges of toxin production by the forms of fungi which may be present at each phase in the work. Wherever possible, cite scientific literature to support your risk assessment.
 - Sec 3, #6 Provide a description of overall workflow at each phase of the project which will involve
- 4. viable fungi with details on location of each activity and any special equipment or safety precautions which will be used.
- 5. Sec 3, #6 Specify all activities which will and will not be conducted in the biological safety cabinet.
 - Sec 3, #6 Include information regarding scale of work proposed, what amount and form of fungi
- 6. will be present at each phase of the work, and whether those fungi present inhalation hazard or aflatoxin hazard to humans.
 - Sec 3, #6 Include a description of all biological wastes generated in the work and how those wastes
- 7. will be inactivated for safe disposal. For toxin-producing strains, inactivation must include steps which will prevent exposure to and inactivate the toxin present in the sample.
 - Sec 3, #6 Provide a description of the spill clean-up procedure for the UV chamber and any
- 8. specialized or shared departmental equipment. For toxin-producing strains, clean-up procedures must include steps which will prevent exposure to and inactivate the toxin present in the sample.
 - Sec 3, #6 Alternative to answering questions 4-8 above, Standard Operating Procedures (SOPs) for
- 9. the various phases of work may be attached to the BUA to address reviewer questions and concerns regarding experiment procedures.
- 4. IBC Notification Simultaneous with Initiation (NIH III-E):

R BUA No. 0717 NIH: IIIE2a, IIIF6 (App CII) BSL: 1, RG: 1 Rev: pb

Title: <u>Evolution and variation in plant shade avoidance responses</u>

Project Summary:

We study how plant growth is altered in response to light in the Arabidopsis thaliana and tomato systems. Recombinant constructs will be used to express either allelic variants from one plant strain to another, overexpress genes of interest and tag proteins of interest with GFP or luciferase. Sharps will be used. No medical waste will be generated.

APPROVED (9-0-0)

- 5. Storage ONLY: NONE
- 6. Exempt Protocols Approved by BSO: NONE

B. Amendments:

Amend 0611(C) NIH: Inf agts (human) BSL: 2, RG: 2 Rev: nld

Title: <u>Management of pathogens in stormwater run off and bacterial diversity in wastewater reactors</u>
Amendment to add: Pathogenic *Escherichia coli*: EIEC, EHEC, EPEC, EAEC, ETEC (culture)

Exp date: 04/18/2014 APPROVED (9-0-0)

Amend 0776(B) NIH: Inf agts (zoonotic), BBP (est BSL: 2, RG: 2 Rev: nld

human cells)

Title: <u>Transmission and virulence of Mycobacterium tuberculosis</u>

Amendment to add: Host: U937 (human cell line)

Agent: Mycobacterium marinum

Procedure: Infection of U937 cells with M. marinum

Exp date: 04/16/2015 APPROVED (9-0-0)

Amend 0808-02B(A) NIH: IIID4a, BBP (est human cells) BSL: 2 (no agts) Rev: nld

Title: Studies in kidney cancer and polycystic kidney disease

Amendment to add:

1. Human cells: RENCA cells and luciferase transfected RCC cells

2. Xenograft human cells (RENCA and RCC (both luciferase transfected and non-

transfected) onto Balb/c mice or athymic nude mice (nu/nu)

Exp date: 11/21/2014 APPROVED (9-0-0)

Amend **0818(A)** NIH: Lentiviral particles, IIIF6 BSL: 2, RG: 2 Rev: nld

(App CI)

Title: Congenital myasthenic syndromes: Pathogenic mechanisms

Amendment to add:

1. Lentiviral particles expressing ColQ (produced by lab)

2. Transduction of mouse MSCs with lentiviral particles

Exp date: 12/20/2013 APPROVED (9-0-0)

Amend 0842(A) NIH: Inf agts (plants), IIIE2a,

BSL: 1, RG: 1 Rev: mmm

IIIE2b(3), IIIE2b(4), IIIE

Title: Plant pathogen etiology, transmission and resistance

Amendment to add: 1. Transgenic isolates *Fusarium subglutinans* (plant infections in greenhouse and

lab)

2. Wildtype Fusarium oxysporum add f.sp. (plant infections of cotton, rapini,

spinach and lettuce in

3. Wildtype Cibornina camelliae (plant infections of Camellia in greenhouse and

lab)

4. Change of disinfection procedure: Inactivate liquid waste with 10% bleach (f.c.)

for 30min before drain disposal (in lieu of autoclaving).

Exp date: 12/19/2014 APPROVED (9-0-0) Amend **0845**(B) NIH: IIID4a BSL: 1 (no agts) Rev: pb

Title: Animal models of primary biliary cirrhosis and antigen-antibody interactions in cultured cells;

Animal model of seafood hypersensitivity (new title)

Amendment to add: plasmid DNA pCI-neo (injected into mice)

Exp date: 04/18/2014 APPROVED (9-0-0)

MC Amend 0900-03(A)

NIH: Inf agts (human), IIID2a,

BSL: 2, RG: 2

Rev: nld

BBP (human blood), IIIF6 (App CII)

Title: <u>Human pathogenic fungal research (new title)</u>

Amendment to add: 1. Cryptococcus neoformans and C. gattii (culture and susceptibility testing)

2. Generating C. neoformans and C. gatti knock-out mutants

3. Analysis of human blood (DNA extraction only)

4. Candida krusei, C. parapsilosis and C. glabrata (culture only)

Exp date: 05/21/2015 APPROVED (9-0-0)

Amend 0937B(A) BBP: NHP tissue BSL: 2 (no agts) Rev: pb

Title: <u>Immunological investigations into neurodevelopmental disorders</u>
Amendment to add: Non-human primate tissue (tissue culture)

Exp date: 10/18/2013 APPROVED (9-0-0)

Amend 1011(A) NIH: Inf agts (animal) BSL: 1, RG: 1 Rev: nld

Title: Aquatic animal health research

Amendment to add: Vibrio anguillarum (culture and infection of salmonids)

Exp date: 06/18/2015 APPROVED (9-0-0)

C. SOPs for Courses and Core Facilities: NONE

D. Conditional BUAs reviewed by ABSO, Final Approval by BSO: NONE

E. Terminated BUAs:

BUA No. **0900-01** Rev: nld

Title: Genotypic analysis of Cryptococcus sp.

BUA No. **0900-02** Rev: nld

Title: <u>Immunogenetic risk factors for coccidioidomycosis</u>

V. Discussion Items:

1. Sean - Should IBC policy be updated to reflect the OBA requirement for 2 public members instead of our current policy of three public members. WILL BE DISCUSSED 3/18/13 DUE TO TIME.

VI. Information Items:

1. EM will not be able to attend next 3 IBC meetings.

VII. IBC Training: NONE

VIII. BSL3 Laboratory Information: NONE

IX. Notifications: NONE

X. Subcommittee Topics: NONE

End Time: 5:30pm

Institutional Biosafety Committee, UC Davis Office of Environmental Health and Safety

MINUTES

March 18, 2013 (3-5p)

Hoagland Hall Rm 130

NOTE: Next IBC meeting: 4/15/2013

Start Time: 3:06 p.m.

In attendance:

Sean Barry Voting Member, Biosafety Officer, Environmental Health and Safety Gerhard Bauer Voting Member, Vice-Chair, IM Div of Hematology/Oncology

Savithramma Dinesh-Kumar Voting Member, Plant Biology

Bruce Draper Voting Member, Molecular & Cellular Biology

Angela Gelli Voting Member, Chair, Pharmacology

Diane Hoffmann Voting Member, School of Medicine Sponsored Programs

Fred Jacobsen Voting Member, Public Member Najita, Lyle Voting Member, Public Member

Renee Tsolis Voting Member, Medical Microbiology & Immunology Victor Lukas Non-Voting Ex-Officio Member, Attending Veterinarian Roger Belcourt Non-Voting Ex-Officio Member, Occupational Health Services

IBC support staff in attendance:

Niki Drazenovich Associate BioSafety Officer, Environmental Health and Safety Philip Barruel Associate BioSafety Officer, Environmental Health and Safety Malendia Maccree Associate BioSafety Officer, Environmental Health and Safety

Excused:

Jill Blackwelder-Parker Non-Voting Ex-Officio Member, Associate Vice Chancellor, Safety Services

Neil Speth Non-Voting Ex-Officio Member, UCDMC Employee Health Services

Elizabeth Maga Voting Member, Animal Science

Nicole Corley Voting Member, Campus Veterinary Services

Dan Kliebenstein Voting Member, Plant Science

Guests:

I. Review of past IBC meeting minutes: February 25, 2013

APPROVED (6-0-2) (Tsolis, Hoffman abstained; Najita didn't vote - not member yet)

II. Announcements:

1. Vote on accepting new IBC public member, Lyle Najita APPROVED (8-0-0)

III. Old Business:

BSL1:

N BUA No. 1040 NIH: Inf agts (plants) BSL: 1, RG: 1 Rev: mmm

Title: Effective disinfection of rough rice using UV radiation

Project Summary:

The main purpose of this project is to investigate the disinfection of *Aspergillus flavus* spores on rough rice by using UV technology for food safety. These fungi are known as post-harvest pathogens of rice. Not using sharps or generating medical waste.

Tabled 02/25/2013

APPROVED (9-0-0)

IV. New Business:

1. BSL2:

NIH: Inf Agts (zoonotic, human),

R BUA No. **0804** BBP (est human cells, NHP tissues, body BSL: 2, RG: 2 Rev: pb

fluids and blood)

Title: Therapeutic and prophylactic interventions against HIV/AIDS

Project Summary:

SIV infection of rhesus macaques is used as an animal model of HIV infection to test therapeutic and prophylactic interventions using a number of vaccine constructs (recombinant modified Vaccinia Ankara virus, BCG vaccine, delta-sec/delta-lys recombinant attenuated M. tb mc^2 5226, derivatives of rAMtb mc^2 5226). None of the recombinant constructs are developed in-house (all are received from outside sources). The projects generate sharps and medical waste.

APPROVED (9-0-0)

NIH: IIID3a(retro), IIID3b(lenti),

R BUA No. 0903

BBP (primary and est human cells and BSL: 2, RG: 2 Rev: nld

NHP semen and oocytes), IIIF8 (App CI,

CII

Title: <u>Production of induced pluripotent stem cells</u>

Project Summary:

The objective of this study is to develop more efficient technologies to produce induced pluripotent stem cells in different mammalian species, including humans, cattle, horses, dog and sheep. The role of histone modifying enzymes, like polycomb group complex 2 (PRC2) and others, during nuclear reprogramming following lentiviral transduction with defined factors will be investigated by means of overexpression of specific factors by retroviral vector transduction or downregulation using siRNA transfection. Sharps (glass slides and coverslips) will be used and medical waste will be generated.

APPROVED (9-0-0)

NIH: IIID3a(adeno), IIID3b(lenti),

IIID4a, IIIE, BBP (est human cells),

IIIF8 (App CI, CII)

Title: The role of the radiation generated cell adaptive response and tumorigenesis

Project Summary:

R BUA No. 0906

The proposed work is related to the low dose radiation induced adaptive protection in normal human skin cell lines HK18 and breast cell line MCF10A. After low dose exposure (similar doses as chest x-ray and CT), mitochondria activity will be analyzed including ATP production, ROS generation, and membrane potential, which will provide important information for understanding the molecular mechanism underlying normal cell response to environmental low dose radiation. Viral vectors will be used to express the coregulator genes in different cells and to assess their function and the mechanisms. The investigators also use mouse models to examine the role of the coregulators induced by low dose radiation in the physiological function of the animal such as radiation adaptive response and tumorigenesis. The mice used in these models are generated by either the

BSL: 2, RG: 2

Rev: mmm

or obtained from NIH institutes, commercial sources, or from collaborators in other universities. Medical waste will be generated.

APPROVED (9-0-0)

2. Bloodborne Pathogen Protocols:

N BUA No. 0670-02B BBP (NHP blood) BSL: 2, no agts Rev: nld

Title: Expanding the utility of social network analysis for multilevel health outcomes Project Summary:

The goal of this project is to determine, using a nonhuman primate, how internal (e.g., temperament; ancestry) and external factors (e.g., different environmental and social stressors) in multiple individuals interact to affect network structure and dynamics and how these, in turn, influence health outcomes in multiple social groups. NHP blood will be collected and analyzed for C-reactive protein, cytokines, and viral loads. No sharps will be used and medical waste will be generated.

APPROVED (9-0-0)

R BUA No. 0880-02B BBP (est human cells) BSL: 2, no agts Rev: mmm

Title: Migration and differentiation of human mesenchymal stem cells

Project Summary:

Human mesenchymal stem cells will be placed in various hypoxic conditions with and without differentiation media and the following laboratory tests will be used: isolation of RNA (quantitative PCR), protein (ELISA and Western blots), cell viability studies, and migration studies. Sharps will not be used and medical waste will be generated.

APPROVED (9-0-0)

R BUA No. 0916B BBP (est human cell lines) BSL: 2, no agts Rev: mmm

Title: Antiestrogen Research

Project Summary:

The research involves the culturing of human cancer cell lines for the purpose of studying the effects of various antiestrogenic and chemotherapeutic agents on the growth of these cells. Human cancer cell lines are used to test growth inhibitory effects of compounds such as triphenylethlyenes, aromatase inhibitors and chemotherapeutic agents. As needed, cells will be cultured to replenish stocks held in cryogenic storage. Medical waste and sharps waste will be generated.

APPROVED (9-0-0)

N BUA No. 1041B

BBP (human blood and primary and est BSL: 2, no agts Rev: mmm

human cells)

Title: <u>Interaction of lipoprotein with the vascular wall</u>

Project Summary:

The project examines the interaction of lipoproteins with human cells under cultured conditions. All open work with cells is done in a biosafety cabinet and minimal opportunities for unintended exposures exist. No needles or scalpels are used. Glass pipets are used with cells and medical waste is generated.

APPROVED (9-0-0)

3. BSL1:

N BUA No. 1039 NIH: Inf agts (animal) BSL: 1, RG: 1 Rev: nld

Title: Experimental infection of boa constrictors with snake arenavirus

Project Summary:

The goal of this research is to definitively prove that snake arenavirus is the causative agent underlying Inclusion Body Disease (IBD) in boa constrictors. A reptile arenavirus will be cultured at UCSF, transported and given to 2 red-tailed boa constrictors by UCSF personnel. Dr. lab personnel will be monitoring the snakes, drawing 0.5-1ml of blood weekly for 2 months and then monthly thereafter, taking biopsies from liver and lung quarterly, and performing necropsies after 1 year. Sharps and medical waste will be generated during the blood draws, biopsies, and necropsy, as well as routine housing of the snakes.

APPROVED (9-0-0)

N BUA No. 1042 NIH: IIID4a BSL: 1, no agts Rev: pb

Title: Regulation of BDNF gene expression in zebrafish

Project Summary:

The study's goal is to understand what genes regulate Brain-derived Neurotrophic Factor (BDNF) production in the brain and how they do it. The strategy is to make transgenic zebrafish that carry a zebrafish BDNF gene fragment linked to the GFP reporter. The transgenic fish will be mutagenized using ethyl-nitrosourea (ENU) followed by mapping and cloning of the mutant genes. The transgenic fish will be generated by injecting zebrafish embryos with a plasmid carrying the BDNF/GFP constructs, raising the embryos, and collecting their sperm to check for transmission of the transgene. Transgenic lines will be produced by outcrossing transgenics with wild-type fish. Transgenic embryos will be observed live under a fluorescent microscope. Observations and analyses of processed embryos will be carried out in the lab. Sharps will be used and no medical waste will be generated.

APPROVED (9-0-0)

- 4. IBC Notification Simultaneous with Initiation (NIH III-E): NONE
- 5. Storage ONLY: NONE
- 6. Exempt Protocols Approved by BSO: NONE

B. Amendments:

Amend **0225-01(A)** NIH: IIIE2a **BSL: 1, RG: 1** Rev: mmm

Title: Functional analysis of quality and productivity traits in crop plants

Amendment to add:

2.

Exp date: 04/16/2015 APPROVED (9-0-0)

Amend 0524(B) NIH: Inf agts (animal) BSL: 2, RG: 1 Rev: nld

Title: Pathogenesis of *Helicobacter pylori*

Amendment to add: 1. Agent: Salmonella enterica serovar Typhymurium (BRD509, mouse-specific

attenuated strain)

2. Procedure: co-infect mice with *H. pylori* and *S. enterica* (BRD509, attenuated

strain)

Exp date: 07/19/2013 APPROVED (9-0-0)

Amend **0581**(**A**) NIH: **BSL:** 1, **RG:** 1 Rev: nld

Title: Enteric pathogens associated with foods and the environment

Amendment to add:

Exp date: 10/15/2015 APPROVED (9-0-0)

MC Amend 0730(A) BBP (est human cell lines) BSL: 2, no agts Rev: nld

Title: Reproduction and embryo development and growth of the fish

Amendment to add: Culture and analysis of established human cells expressing Estrogen responsive

element(ERE)-luciferase, ERE-GFP, estrogen receptor and morpholinos for TRL9

Exp date: 09/20/2013 APPROVED (9-0-0)

Amend **0897(A)** NIH: Inf agts (plants) **BSL: 1, RG: 1** Rev: nld

Title: The interaction between host organisms and microbes in health and disease

Amendment to add: Candidatus Liberibacter asiaticus infected leaves (analysis only)

Exp date: 10/15/2015 APPROVED (9-0-0)

NIH: IIIE2a Amend 0927(A) BSL: 1, RG: 1 Rev: mmm

Title: Walnut improvement program

Amendment to add:

1.

Exp date: 07/19/2013 **APPROVED** (9-0-0)

Amend 0965B(B) NIH: IIID4a BSL: 2, no agts Rev: mmm

Title: Radionuclides for imaging and therapy (new title)

Amendment to add: 1. Material: Human mesenchymal stem cells (transduced to express luciferase),

Daudi and J774A.1 cells

2. Project: Injecting radiolabeled transduced hMSCs into mice

Exp date: 03/21/2014 **APPROVED** (9-0-0)

MC Amend **0999(C)** NIH: IIID3b (lenti), IIID4b BSL: 2, RG: 2 Rev: pb

Biological examination and potential therapeutic applications of placental tissue Title:

1. Transduction of primary rat and sheep cells with lentiviral green fluorescent Amendment to add:

protein (GFP)

2. Transduced cells will be introduced into species of origin (rats or sheep)

Exp date: 01/23/2015 **APPROVED** (9-0-0)

C. SOPs for Courses and Core Facilities: NONE

D. Conditional BUAs reviewed by ABSO, Final Approval by BSO:

NIH: IIID3a(adeno), IIID3b(lenti),

R BUA No. **0672** BSL: 2, RG: 2 Rev: pb IIID4b, BBP (human blood and tissue),

IIIF6 (App CII)

Title: Genetic abnormalities underlying sudden cardiac death in humans

Review Date: 02/25/2013

NIH: Inf agts (humans), IIIE3,

R BUA No. 0723 IIIE, BBP (human blood and tissues), Rev: nld BSL: 2, RG: 2

IIIF6 (App CII)

Title: Defensins and other mammalian-derived antimicrobial peptides of innate immunity

Review Date: 02/25/2013

N BUA No. 1033 NIH: IIID3e(aav), IIIF6 (CI) BSL: 1, RG: 1 Rev: pb

Imaging neural activity with genetically encoded calcium indicators following mechanical strain Title:

injury

Review Date: 02/25/2013

E. Terminated BUAs:

Rev: nld BUA No. 0732-02

Title: Development of a rhesus monkey model of COPD

V. **Discussion Items: NONE**

1. Sean-Should IBC policy be updated to reflect the OBA requirement for 2 public members instead of our current policy of three public members? (Committee consented, no vote was taken)

VI. Information Items:

1. Sean - Update on Select Agent PI and new Tier 1 regulations.

VII. IBC Training:

1. Sean - Training on BSL3 HVAC systems, will put training on SmartSite

VIII. BSL3 Laboratory Information:

1. Sean - J1 reverification **APPROVED** (9-0-0)

IX. Notifications: NONE

X. Subcommittee Topics: NONE

End Time: 5:11 p.m.

Institutional Biosafety Committee, UC Davis Office of Environmental Health and Safety

MINUTES April 15, 2013 (3-5p)

Hoagland Hall Rm 130

NOTE: Next IBC meeting: 5/20/2013

Start Time: 3:05 p.m.

In attendance:

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

Nicole Corley Voting Member, Campus Veterinary Services

Savithramma Dinesh-Kumar Voting Member, Plant Biology

Bruce Draper Voting Member, Molecular & Cellular Biology

Angela Gelli Voting Member, Chair, Pharmacology
Fred Jacobsen Voting Member, Public Member
Lyle Najita Voting Member, Public Member

Renee Tsolis Voting Member, Medical Microbiology & Immunology
Victor Lukas Non-Voting Ex-Officio Member, Attending Veterinarian
Roger Belcourt Non-Voting Ex-Officio Member, Occupational Health Services

IBC support staff in attendance:

Philip Barruel Associate BioSafety Officer, Environmental Health and Safety Malendia Maccree Associate BioSafety Officer, Environmental Health and Safety

Excused:

Jill Blackwelder-Parker Non-Voting Ex-Officio Member, Associate Vice Chancellor, Safety Services

Neil Speth Non-Voting Ex-Officio Member, UCDMC Employee Health Services

Elizabeth Maga Voting Member, Animal Science
Dan Kliebenstein Voting Member, Plant Science

Diane Hoffmann

Gerhard Bauer

Voting Member, School of Medicine Sponsored Programs

Voting Member, Vice-Chair, IM Div of Hematology/Oncology

Niki Drazenovich

Associate BioSafety Officer, Environmental Health and Safety

Guests: NONE

I. Review of past IBC meeting minutes: March 18, 2013

APPROVED (7-0-1)

II. Announcements:

1. List announcements

III. Old Business: NONE

IV. New Business:

1. BSL2:

NIH: IIID3b(lenti), IIID4b,

R BUA No. 0295-01 BBP(primary and est human cells), BSL: 2, RG: 2

IIIF8 (App CI, CII)

Title: Growth and differentiation of airway epithelial cells in response to cytokines and injury Project Summary:

The project uses expression clones or siRNA clones for transfection studies to modulate the gene expression level of cytokines and signaling molecules in cells. These studies are on a small scale in cell culture dishesroutine exercises in most molecular biology labs. Some of the cell lines which will be analyzed and used as a host for recombinant constructs have been established in the lab from human trachial tissue. Medical waste and will be generated. Sharps will be used.

APPROVED (8-0-0)

NIH: Inf agts (humans), IIID2a,

 $IIID3a(mva),\,IIID4a,\,BBP\,(primary$

R BUA No. 0609 human blood, est human and NHP cells, BSL: 2, RG: 2 Rev: nld

primary NHP blood and tissues), IIIF8

(Ann CL CII)

Title: Evaluation of protective CMV vaccines in Rhesus macaques

Project Summary:

The lab is focused on evaluating the efficacy of human cytomegalovirus (HCMV) vaccines. The primary objective measure for evaluating the efficiency of any vaccine is whether protective levels of immunity are generated and sustained in the vaccinees. Using the RhCMV/rhesus macaque model, seronegative macaques will be immunized with RhCMV or HCMV, viral immunogens individual genes from SIV, flagellin gene (Salmonella) or replication defective recombinant modified vaccinia Ankara (rMVA) expressing the same proteins. Animals will be challenged with wild-type virus, or primary isolates, and immune responses followed. This work will entail the use of and/or generation of the aforementioned recombinant constructs, culture and propagation of RhCMV and HCMV, handling and processing of RhCMV and/or SIV-inoculated NHP body fluids and tissues in an effort to determine whether changing the kinetics of gene expression during the RhCMV infection cycle can broaden protective immune responses. Sharps will be used and medical waste generated.

APPROVED (8-0-0)

R BUA No. **0801**NIH: IIID3b(lenti), IIID4b(lenti),
BBP (est human cells), IIIF8 (App CII)

BSL: 2, RG: 2

Rev: pb

Title: <u>Development of olfactory circuitry</u>

Project Summary:

This study is focused on the molecular mechanisms of olfactory system development. Transcription regulation and genetic functions of odorant receptor and other neuronal plasticity genes will be investigated by lentiviral gene transfer in vivo (into olfactory bulbs of mice) and in vitro. Medical waste will be generated. Sharps will be used.

APPROVED (8-0-0)

Rev: pb

NIH: IIID3b(lenti), IIID4a (lenti-

R BUA No. 0807-01 transduced human cells), BBP (est. BSL: 2, RG: 2 Rev: pb

human cells), IIIF8 (App CII)

Title: <u>Inducible regulation of Src, GRP, AR and KDM protein expression in human prostate cancer cells</u>

Project Summary:

The investigators will use pre-cloned doxycycline-inducible Src, gastrin-releasing peptide (GRP) and shRNA against androgen receptor (AR) and DNA methylase (KDM) to study the functions of these molecules in human prostate cancer. Stable transduction (with lentivirus) with these constructs into various prostate cancer cells will be performed and the stable clones will be selected. Laboratory mice will be implanted with the stable clones subcutaneously or orthotopically. The roles of Src, GRP and respective shRNA on tumor progression will be studied through induction of their expression via doxycycline in the animals' drinking water. Medical wastes will be generated and sharps will be used.

APPROVED (8-0-0)

R BUA No. 0907-01 NIH: IIID3b(lenti), IIIE, IIIF8 (App BSL: 2, RG: 2 Rev: mmm

Title: <u>Non-linear microscopy of pluripotent stem cells and their derivatives</u> Project Summary:

Mouse and human pluripotent stem cells will be differentiated into cardiomyocytes. The cardiomyocyte yield and function will be assessed using non-linear microscopy, confocal imaging of Ca2+ and membrane potential, patch-clamp techniques, quantitative PCR, immunostaining and flow cytometry. Cell lines will be transduced with lentiviral vectors containing the GFP reporter gene to facilitate identification of the cell type during the differentiation process. Sharps will be used and medical waste generated

APPROVED(x-x-x)

NIH: IIID3b(lenti), IIID4a, BBP

N BUA No. 1045 (human primary cells and tissues), IIIF8 BSL: 2, RG: 2 Rev: pb

(App CI)

Title: <u>Biological examination and potential therapeutic applications of discarded human surgical waste</u>;

biological examination of animal model tissue

Project Summary:

One aim of this study is to determine potential therapeutic applications of tissues, with regards to the treatment of diseases. The hypothesis is that transplanting stem cells into defective neural tissue will aid in regeneration of the damaged tissue. The effects of using an allogeneic tissue source in the treatment of SCI and PNI will be studied in rat models. Rat and mouse tissue will be obtained then transduced with a lentiviral vector with green fluorescent protein (GFP) in order to assess cellular viability post transplantation. Another aim of this study is to better understand biomarkers of disease processes. The tissue types used will be human surgical waste. Sharps will be used; medical waste will be generated.

APPROVED (8-0-0)

NIH: Inf Agts (human, animal), IIID3b (lenti), IIID3e (baculo), BBP

N BUA No. 1046

IIID3b (lenti), IIID3e (baculo), BBP *BSL: 2, RG: 2* (est. human cells), IIIF8 (App CII)

Title: <u>Viral replication and oncogenesis</u>

Project Summary:

Kaposi's sarcoma (KS) emerges as the major malignancy in AIDS patients. KSHV gene regulation will be studied by defining K-Rta binding sites on the viral genome and analyzing the effects of K-Rta on KSHV chromatin. Tools adapted for the proposed research are the KSHV promoter-library, KSHV promoter-chip, and a lentivirus vector to deliver inhibitory RNA (shRNA), the chromatin immunoprecipitation (ChIP) method has been refined for detailed analysis of viral and cellular transcription factors assembled on the whole range of KSHV promoters. Cellular and viral proteins will be knocked-down from KSHV latently-infected BCBL-1 to evaluate the effect of KSHV reactivation, and protein interaction will be analysed by GST-pull down after purifying proteins with baculovirus expression system, to test interaction between tagged protein and another proteins. Additionally, MDV oncogene and its associated protein will be knocked-down in naturally infected chicken T-cells, and effects of down-regulation of target gene will be evaluated. Medical waste will be generated; no sharps will be used with these biological materials.

APPROVED (8-0-0)

N BUA No. 1047 NIH: IIID3b(lenti), BBP (prim human cells), IIIF8 (App CI) BSL: 2, RG: 2 Rev: pb

Title: Stem and progenitor cell isolation, culturing and application in extracellular matrix (ECM)

bioscaffold augmentation

Project Summary:

Human and porcine MSCs will be isolated from bone marrow and these MSCs will be cultured for phenotype, differentiation potential and immunomodulation comparison. If it is proven that human and porcine MSCs share similar characteristics, porcine MSCs will be seeded onto a FDA approved biodegradable small intestinal submucosa derived ECM bioscaffold. The augmented scaffold will then be grafted onto the ventricle of a porcine model of chronic left ventricular dysfunction. The goal of this study is to provide an EMC bioscaffold augmented with human MSCs for cardiovascular repair. The porcine model and transplantation will be done

. The MSCs isolation, culturing, characterization and seeding onto ECM bioscaffold will be done at the will also test the efficacy of the augmented bioscaffold in a chick embryo chorioallantoic membrane model by quantifying angiogenesis. In this experiment, fertilized chicken eggs will be used as an in vitro model. A lentiviral vector carrying luciferase and GFP will be used to label cells in select experiments. Sharps will be used and medical waste generated.

APPROVED (8-0-0)

2. Bloodborne Pathogen Protocols:

R BUA No. 0033-01

BBP (est human cells), IIIE,
IIIF1, IIIF8 (App CII)

BSL: 2, RG: 1

Rev: nld

Title: K-Cl cotransporters in neurons and epithelia

Project Summary

This project focuses on the study of the structure, function, and regulation of chloride transport proteins. DNA encoding these transporters will be inserted into both prokaryotic and eukaryotic expression vectors and cultured in eukaryotic cells. Sharps will not be used and medical waste will be generated.

APPROVED (8-0-0)

Rev: pb

R BUA No. **0787B**BBP (human tissue, human blood, est

human cells)

BSL: 2, no agts

Title: <u>Pre-clinical and correlative studies in non-small cell lung cancer (NSCLC) and other cancers</u> Project Summary:

Pre-clinical research is conducted on human cell lines to test molecular pathways involved in cancer therapeutics. Research protocols will include cell proliferation assays, DNA/RNA/protein extractions, DNA/RNA-based assays, and protein-based assays. Correlative studies are conducted to identify key biomarkers (using PCR-based assays) to be used for clinical trials. Medical waste will be generated. Sharps will be used.

APPROVED (8-0-0)

R BUA No. **0807-02B** BBP (est human cells) **BSL: 2, no agts** Rev: pb

Title: Molecular and cellular study of kidney cancer

Project Summary:

The growth and spread of human renal cell carcinoma (RCC) will be studied in tissue culture and in SCID mice. The animals will be injected with RCC cell lines both subcutaneously and orthotopically. Drug treatments at the time of implantation and weeks after will be administrated to study prevention of primary and metastatic tumor growth and intervention of tumor progression. Sharps will be used and medical waste will be generated.

APPROVED (8-0-0)

R BUA No. **0907-02B**BBP (human blood and est human cells)

BSL: 2, no agts

Rev: mmm

Title: <u>Analysis of single prokaryotic and eukaryotic cells using laser tweezers Raman spectroscopy</u> Project Summary:

This project involves the application of Raman spectroscopy, an optical laser-based technique, for analyzing the biochemistry of single living cells (prokaryotic and eukaryotic). All culture work takes place in a biological safety cabinet; cells will be sealed in glass-bottom cell culture dishes for Raman analysis. Glass Pasteur pipettes will be used to suction medium/liquid to wash the cell pellets. Sharps waste (Pasteur pipets) and medical waste will be generated.

APPROVED (8-0-0)

N BUA No. 1043B BBP (est human cells) BSL: 2, no agts Rev: pb

Title: Nano-engineering approach towards regulation of cellular signaling cascades Project Summary:

Current research indicates that nanoengineering of surfaces play an important role in regulating cellular behavior in diverse physiological and pathological processes including immune and inflammatory responses. Appling Atomic Force Microscopy enables: 1) sub-nanometer resolution in membrane structural features visualization of some systems, 2) new insights via cellular signaling processes as enabled by AFM imaging in conjunction with laser scanning confocal microscopy, and 3) single cell mechanics enabled by using modified AFM probes. Jurkat T cell, human aortic endothelial cells and other mouse cell lines will be studied in vitro to learn how the nanoengineered surface impacts cellular behaviors. No sharps will be used. Medical waste will be generated.

TABLED

Rev: pb

N BUA No. 1048B BBP (est human cells) BSL: 2, no agts Rev: nld

Title: Sodium channel structure-function

Project Summary:

The main goal of this research is to understand the structure and function of human voltage-gated sodium channels. The human cell line, tsA-201, will be used to express recombinant channels from plasmids. Sharps will not be used and medical waste will be generated.

APPROVED (8-0-0)

3. BSL1:

NIH: Inf agts (plants), IIID5a,

R BUA No. **0235-03** IIIE2a, IIIE2b(2), IIIE2b(5), **BSL:** 1P/2P/3P RG: 1 Rev: mmm

IIIF8 (App CII)

Title: RNA-interference to control insect vectors of plant pathogens

Project Summary:

The lab is inducing RNA interference (RNAi) activity in insects and plants to identify and use deleterious RNA sequences for inducing negative phenotypes in plant feeding insects. Four types of hemipterans and various mealybug species are primary targets. The research will involve use of transgenic plants and cells, recombinant plant viruses, and endemic bacterial plant pathogens. All work with quarantined live insect vectors (H. vitripennis and D. citri) is conducted at BL3P (UCD

APPROVED (8-0-0)

R BUA No. 0812 NIH: Inf agts (plants), IIIE2a,

BSL: 1, RG: 1 Rev: mmm

Title: Biochemistry, molecular biology and control of bacterial plant pathogens

Project Summary:

The laboratory studies the interaction between bacteria and plants. Tomato and *Arabidopsis* plants will be used; along with the bacterial pathogens *Pseudomonas, Xanthomonas, Agrobacterium,* and *Clavibacter.* Sharps waste is generated during plant inoculations. Medical waste will not be generated.

APPROVED (8-0-0)

R BUA No. **0912** NIH: Inf agts (plants), IIIE2a, IIIE,

IIIF8 (App CI, CII, CIII)

BSL: 1P/2P, RG: 1 Rev: mmm

BSL: 1, RG: 1

Title: Molecular basis of plant-pathogen interactions

Project Summary:

The long-term goal of the research program is to understand the molecular mechanisms by which plant immune receptors recognize pathogens and initiate immune signaling. This research includes gene discovery. The program also includes expression of recombinant proteins in insect cells using baculovirus expression system. In addition, in vitro translation and plant transient expression systems will be used to produce plant proteins and pathogen effector proteins to generate protein microarrays. This work will generate sharps and microbiological waste (e.g. used petri dishes; razor blades).

APPROVED (7-0-0) (DK stepped out)

R BUA No. **0914** NIH: Inf agts (plants), IIIF2

Title: Diseases of forest trees in California

Project Summary:

This research uses cultures of various fungal plant pathogens to study forest tree diseases though inoculation studies, DNA sequencing, and other lab experiments. Scalpels are used to remove tissues from diseased plants to obtain cultures.

APPROVED (8-0-0)

N BUA No. 1044 NIH: Inf agts (plants) BSL: 1, RG: 1 Rev: mmm

Title: <u>Ecology</u>, epidemiology, and control of fungal disease and post-harvest contaminants of fruit and nut

crops

Rev: mmm

Project Summary:

The lab is located at the with additional work occurring on the UC Davis campus. Fungal plant pathogens are isolated and identified in a variety of nut and fruit tree and vine plants. Contaminated almonds are sent to Davis for non-destructive analyses. Culture-based and culture-independent methods are used to detect and identify plant pathogens from samples of plant roots, shoots, bark, and soil collected within California. Also, are conducted to test pathogenicity of fungi, to evaluate plant resistance to pathogens; and to test efficacy of e.g., soil amendments, chemical treatments). Fungal isolates are identified using PCR analysis and sequence analysis of ITS regions or other identifying gene loci.

APPROVED (8-0-0)

4. IBC Notification Simultaneous with Initiation (NIH III-E):

R BUA No. 0689 NIH: IIIE2a BSL: 1, RG: 1 Rev: mmm

Title: Salt and drought tolerance in plants

Project Summary:

The proposed project aims at the development of transgenic crop plants able to adapt and grow under limiting environmental conditions in general, and under salinity and water deficit in particular. The project is applying a multidisciplinary approach that combines physiology, molecular biology and biotechnology to identify key molecular determinants that enable the plants to tolerate abiotic stress(es). Transgenic plants will be produced and tested in laboratory greenhouse

APPROVED (8-0-0)

R BUA No. 0800

NIH: IIIE2a, IIIE, IIIF8 (App CII)

BSL: 1, RG: 1

Rev: mmm

Title: Molecular and biochemical analysis of symbiotic plant receptor kinase complexes

Project Summary:

The lab conducts biochemical and cell biological studies of receptor complexes in plant roots. A portion of the work is conducted in transgenic plants, where chimeric receptors have been constructed to provide epitopes for affinity purification. Transient assays (i.e., transformation is somatic, not germinal) are also employed using hairy root transformation to deduce gene function via over expression and RNAi methods. Razor blades and scalpels are used to manipulate plant tissue. Medical waste is not generated.

APPROVED (8-0-0)

5. Storage ONLY: NONE

6. Exempt Protocols Approved by BSO: NONE

B. Amendments:

Amend 0670(B) NIH: Inf agts (zoonotic) BSL: 2, RG: 2 Rev: nld

Title: water and foodborne disease laboratory

Amendment to add: 1. Culture of *Staphylococcus aureus* (MRSA)

2. Analysis of dairy cow milk spiked with MRSA (culture and analysis)

Exp date: 06/20/2014 APPROVED (8-0-0)

Amend 0748-02(A) NIH: IIID3b(lenti) BSL: 2, RG: 2 Rev: nld

Title: The study of demyelinating diseases and disease treatment

Amendment to add: 1. Lentiviral transfection in HEK293 cells

2. Lentiviral transduction in primary mouse cells

Exp date: 02/28/2016 APPROVED (8-0-0)

C. SOPs for Courses and Core Facilities: NONE

D. Conditional BUAs reviewed by ABSO, Final Approval by BSO: NONE

E. Terminated BUAs:

BUA No. **0875-02** Rev: nld

Title: Ex vivo model of exposure to Yersinia pestis

V. Discussion Items:

Sean -

- 2. Sean BSL3: HVAC testing looks good, IBC Approval for another year continued use (7-0-1) (RT abstained)
- 3. Sean IBC conference training opportunities funding may start next year
- 4. Sean BIO UCD roll-out: a special meeting will be scheduled soon for demo of BIO

VI. Information Items:

1. Sean - UCD is no longer registered with CDC for Tier 1 Select Agents.

VII. IBC Training: NONE

VIII. BSL3 Laboratory Information: NONE

IX. Notifications: NONE

X. Subcommittee Topics: NONE

End Time: 5:32p.m.

Institutional Biosafety Committee, UC Davis Office of Environmental Health and Safety

MINUTES

May 20, 2013 (3-5p) Hoagland Hall Rm 130

NOTE: Next IBC meeting: 06/17/2013

Start Time: 3:08p.m.

In attendance:

Sean Barry Voting Member, Biosafety Officer, Environmental Health and Safety Gerhard Bauer Voting Member, Vice-Chair, IM Div of Hematology/Oncology

Nicole Corley Voting Member, Campus Veterinary Services

Savithramma Dinesh-Kumar Voting Member, Plant Biology

Bruce Draper Voting Member, Molecular & Cellular Biology

Angela Gelli Voting Member, Chair, Pharmacology

Diane Hoffmann Voting Member, School of Medicine Sponsored Programs

Fred Jacobsen Voting Member, Public Member
Dan Kliebenstein Voting Member, Plant Science

Renee Tsolis Voting Member, Medical Microbiology & Immunology
Victor Lukas Non-Voting Ex-Officio Member, Attending Veterinarian
Roger Belcourt Non-Voting Ex-Officio Member, Occupational Health Services

IBC support staff in attendance:

Niki Drazenovich Associate BioSafety Officer, Environmental Health and Safety Malendia Maccree Associate BioSafety Officer, Environmental Health and Safety

Excused:

Jill Blackwelder-Parker Non-Voting Ex-Officio Member, Associate Vice Chancellor, Safety Services

Neil Speth Non-Voting Ex-Officio Member, UCDMC Employee Health Services

Elizabeth Maga Voting Member, Animal Science

Philip Barruel Associate BioSafety Officer, Environmental Health and Safety

Guests: NONE

I. Review of past IBC meeting minutes: April 15, 2013

APPROVED (9-0-1) DH abstained

II. Announcements:

1. Sean's last IBC meeting before retirement

III. Old Business:

Bloodborne Pathogen Protocols:

N BUA No. 1043B BBP (est human cells) BSL: 2, no agts Rev: pb

Title: <u>Nano-engineering approach towards regulation of cellular signaling cascades</u> Project Summary:

Current research indicates that nanoengineering of surfaces play an important role in regulating cellular behavior in diverse physiological and pathological processes including immune and inflammatory responses. Appling Atomic Force Microscopy enables: 1) sub-nanometer resolution in membrane structural features visualization of some systems, 2) new insights via cellular signaling processes as enabled by AFM imaging in conjunction with laser scanning confocal microscopy, and 3) single cell mechanics enabled by using modified AFM probes. Jurkat T cell, human aortic endothelial cells and other mouse cell lines will be studied in vitro to learn how the nanoengineered surface impacts cellular behaviors. No sharps will be used. Medical waste will be generated.

Tabled 04/15/2013 APPROVED (10-0-0)

IV. New Business:

1. BSL2:

N BUA No. 0099-04 NIH: Inf agts (animals) BSL: 2, RG: 1 Rev: mmm

Title: Culicine vector competence and its role in the transmission of avian malaria in Central California

Project Summary:

The goal of this research project is to determine all major and minor competent vectors of avian malaria parasites in and examine the level of vector specificity of avian malaria parasite lineages. Research involves infections of canaries with avian-specific malaria parasites (*Plasmodium* spp.) and use of insect vectors (*Culex* spp.). Sharps will be used for work with birds. Biological waste is disposed as medical waste.

APPROVED (10-0-0)

R BUA No. 102-02 NIH: Inf agts (zoonotic) BSL: 2, no agts Rev: pb
Title: Caprine arthritis-encephalitis virus (CAEV) infected cells in pre- and post-partum goats: Long term
CAEV follow up and Q fever prevalence

Project Summary:

Field samples of milk and vaginal secretions from normal and aborted goats in client herds will have DNA extracted for PCR of *Coxiella burnetii* (Q Fever) organism. Some, but not all samples may contain *Coxiella burnetii*. Sharps will be used (jugular vein blood collection) and medical waste will be generated. *TABLED*

Section 3 #1 and #6, CAEV was mentioned in the title, but there was no mention of work with CAEV

- 1. or of any risks posed by CAEV to personnel. Please discuss more how CAEV is involved in this project
- 2. In Section 3 #5, please indicate what risks are posed to personnel by CAEV
- 3. Section 3 #6, please discuss how the aborted fetus and placenta will be collected (and by whom), packaged, and transported from to your laboratory.

NIH: IIID3a(adeno), IIID3b(lenti), IIID3e(aav), IIID4a, IIID4b, BBP

(primary and est human and NHP cells, human and NHP blood and tissues),

IIIF8 (App CI)

Title: <u>Congenital and acquired diseases and corrective gene-based therapies</u> Project Summary:

Studies focus on cell and gene-based therapies to assess new treatments for human congenital and acquired disorders in nonhuman primates. Gene transfer is performed in utero using a variety of organ-targeted approaches and postnatally typically using an IV or similar approach (primarily lentiviral and adeno-associated viral vectors). Studies include fetal or infant SIV infection as a model of an acquired disease (HIV infection) to study a variety of questions related to disease, vaccines, and new gene therapy approaches. Sharps will be used and medical waste generated.

APPROVED (10-0-0)

R BUA No. 0547

NIH: IIID3a (adeno), IIID3e

R BUA No. 0707 (AAV), BBP (human brain tissue, est human and NHP cells), IIIF8 (App

CII, CVII)

Title: <u>Ion channels in the mammalian nervous system</u>

Project Summary:

Rats and mice will be used as a source of brain tissue for biochemical (unfixed) and immunohistochemical analyses (paraformaldehyde fixed) of neuronal channels and receptors and the generation of hybridomas secreting monoclonal antibodies. Mice will be immunized with antigens and after euthanasia spleens isolated for fusions to generate hybridomas. Human brain tissue will be used as a source of brain tissue for biochemical and immunohistochemical analyses (paraformaldehyde) of neuronal channels and receptors. In addition, various ion channels and receptors will be cloned into expression plasmid and adenovirus/AAV vectors so that they can be overexpressed in tissue culture cells (HEK and COS1 cells) and primary neuronal cultures.

Conditional (10-0-0)

- 1. Section 4, please indicate the source of the brain tissues.
- 2. Section 4, please detail how you are working with brain tissue (risk assessment, risk minimization,

and indicate if sharps will be used).

N BUA No. **0751-02**NIH: Inf agts (humans), BBP (est human cells)

NIH: Inf agts (humans), BBP (est human cells)

Title: The effect of Ibuprofen and Acetaminophen on prostaglandin E production of RSV infected respiratory epithelial cells

Project Summary:

Bronchiolitis is the most important lower respiratory tract infection in infants. An incidental finding in a human randomized controlled trial of ibuprofen and acetaminophen in fever found decreased wheezing in children who had been randomized to ibuprofen for upper respiratory tract symptoms. Epidemiological data shows an association between treatment of fever with acetaminophen and subsequent wheezing in adults. This raises the question as to whether acetaminophen is detrimental or ibuprofen beneficial in bronchiolitis. The project proposes infecting human epithelial cells with RSV and measuring the effect of treatment with ibuprofen and acetaminophen on prostaglandin E production. Sharps will not be used and medical waste generated.

APPROVED (10-0-0)

R BUA No. 0809 NIH: Inf agts (zoonotic) BSL: 2, RG: 2 Rev: pb

Rev: nld

Rev: pb

BSL: 2, RG: 2

Title: The effect of environmental tobacco smoke exposure on pulmonary immune development and

infection

Project Summary:

Dr. research will examine the effects of second-hand smoke on lung development and susceptibility to infection (influenza and *Staphylococcus aureus*) in rodent models. This will extend earlier studies in rodents on how exposure to second-hand smoke alters the development of the immune system by using infectious viral and bacterial agents to evaluate susceptibility.

APPROVED (10-0-0)

NIH: IIID3a(retro), IIID3b(lenti),

R BUA No. **0814** IIID4a, BBP (primary and est human **BSL: 2, RG: 2** Rev: nld

cells), IIIF8 (App CII)

Title: <u>Immunodeficient mouse models of stem cell-mediated tissue repair</u>

Project Summary:

This research involves studying genetically engineered human stem cells. These will be used in immune deficient mouse models (including a transgenic line developed in the lab) to study tissue injury and disease. Lentiviral and retroviral vectors will be used. Sharps will be used and medical waste generated.

APPROVED (9-0-1) GB abstained

R BUA No. **0904**NIH: IIID4(a), IIID4(b), BBP (primary NHP blood/tissue)

BUA No. **0904**Rev: nld**

Title: Studying neuronal connectivity and function in the mammalian visual system using modified viral

vectors

Project Summary:

The overal goal of the research project is to correlate neuroanatomical form with function in the visual system of the macaque monkey, ferret, and feline. Cell specific neuronal tracing will be combined with cell specific activation and/or inactivation of corticothalamic and thalamocortical pathways to understand their role in vision. Cells will be labeled with a G-deleted rabies virus and neurons will be activated/inactivated with AAV and lentiviral vectors. Sharps will be used and medical waste generated.

APPROVED (10-0-0)

R BUA No. **0910**NIH: IIID3e(baculo), BBP (est human cells), IIIF8 (App CI, CII)

BSL: 2, RG: 1

Rev: pb

Title: The mechanism of mRNA recruitment to the human ribosome Project Summary:

The research project will explore the role of endogenous and recombinant eukaryotic protein synthesis initiation factors in promoting mRNA recruitment to the ribosome. Initiation factors and components will be purified from mammalian cell lines (HeLa and 293), insect cells (Sf9) or bacteria (*E. coli*). Cell line growth and manipulation will be carried out in a safety cabinet. Medical waste will be generated and sharps will be used.

NIH: IIID3a(adeno),

R BUA No. 0917 IIID4a(adeno), BBP (est human BSL: 2, RG: 2 Rev: pb

cells, human tissue), IIIF8 (App CII)

Title: Regulation and role of protein kinase D in the heart

Project Summary:

Protein kinase D function is studied by adeneovirus-mediated expression of fluorescently tagged proteins or FRET-based activity sensors in cardiac myocytes from rabbit (adenovirus infection in vitro during culture of isolated myocytes) and mouse (adenovirus infection in vivo via cardiac injection or paint-on). So the types of potentially hazardous manipulations involved relate to medical waste generation and limited use of sharps.

APPROVED (10-0-0)

2. Bloodborne Pathogen Protocols:

N BUA No. 0100-02B BBP (primary human cells) BSL: 2, no agts Rev: mmm

Title: Function of PolySia DP on human stem cells and metastatic tumors of the H&N

Project Summary:

PolySia chains will be released from FcN-CAM by endo-beta-galactosidase, and subjected to HPLC chromatography. This work involves culture of human cells. Sharps will be used and medical waste will be generated.

APPROVED (10-0-0)

R BUA No. **0673B**BBP (est human cells), IIIE, IIIF8

(App CI, CII)

BSL: 2, 1

Rev: mmm

Title: Identification of proteins that interact with vimentin Ifs

Project Summary:

The goal of this project is to identify proteins interacting with vimentin filaments in transfected tissue culture cells. We will use *E. coli* strains for manipulation and propagation of plasmids. *E. coli* will also be used for protein expression. Plasmids will be transfected into human cell lines. Medical waste and biotechnology wastes are generated. No sharps are used with human cell lines.

APPROVED (10-0-0)

R BUA No. **0815-02B**BBP (human blood, tissues and est cell lines)

BSL: 2, no agts

Rev: pb

Title: HSP60, exosomes, and cardiomyopathy

Project Summary:

Human endothelial cells (HEC) are used to study the effects of changes in estrogen and aging. The investigators are also interested in what causes HEC to become senescent with age, and whether this is a benign change or associated with inflammatory consequences. Human heart samples from humans with heart failure and normal heart samples are used to determine if changes observed in rodent failing hearts are paralleled in the human disease. This is important in identifying new treatment targets and potential development of new drugs for human heart failure. Blood samples are used to investigate the relationship between HSP60 and disease as well as exosomes in heart failure.

R BUA No. **0921B** BBP (e

BBP (est human cells), IIIF8 (App

BSL: 2, no agts

Rev: mmm

Title: <u>Pre-clinical lymphoma research using human cell lines and mice studies</u> Project Summary:

Human lymphoma cell lines are grown and injected into mice. Chemical and/or antibodies are used in the human lymphoma cell lines and mice to study how effective the treatment is. Medical waste will be generated. Sharps (needles) will be used for the mouse injections (lymphoma cell injections, antibodies, drugs).

APPROVED (10-0-0)

N BUA No. **1049B** BBP (est human cells) **BSL: 2, no agts** Rev: nld Title: Growth and differentiation of human mesenchymal stem cells, prostate cancer, and breast cancer cells

Project Summary:

The goal of this research is to study interactions between cancers that metastasize to the bone marrow microenvironment and mesenchymal stem cells resident within the bone marrow. Human mesenchymal stem cells, prostate cancer cells, and breast cancer cells will be grown with and without differentiation media and then analyzed. Medical waste will be generated. No sharps will be used.

APPROVED (10-0-0)

3. **BSL1**:

R BUA No. 0507 NIH: Inf agts (plant), IIIF8 (App BSL: 1, RG: 1 Rev: mmm

Title: <u>Molecular characterization, biological study, and detection of viruses in horticultural crops</u> Project Summary:

To molecularly characterize the genome of the viruses found in horticultural crops in California with emphasis on those with partial or unknown etiology and to develop molecular methodologies (e.g., PCR and real time PCR) for their detection. Some cDNA cloning and sequencing is involved to achieve the goal. No potential hazardous manipulation is involved.

APPROVED (10-0-0)

4. IBC Notification Simultaneous with Initiation (NIH III-E):

R BUA No. 0069 NIH: IIIE2a, IIIF8 (App CII) BSL: 1, RG: 1 Rev: mmm

Title: Defining stress signaling networks in plants

Project Summary:

The research program focuses on the mechanism by which plants perceive and respond rapidly and transiently to environmental challenges. Specifically, the project is focused on better understanding of the role of oxylipins in plant stress responses. No medical waste is generated.

APPROVED (10-0-0)

R BUA No. **0918** NIH: IIIE2a, IIIF8 (App CI, CII, BSL: 1, RG: 1 Rev: mmm

Title: <u>Understanding endomembrane trafficking and cell wall biosynthesis in plants</u> Project Summary:

To understand the function of secretory proteins and cell wall biosynthetic enzymes recombinant DNA technology will be used to express these proteins either in heterologous systems like *E. coli* or in plants such as the model plant *Arabidopsis thaliana*, and potentially rice and branchypodium, and their subcellular location and activity will be investigated. Transgenic plants will be generated for this work and sharps are potentially used to manipulate plant materials. Work will occur in lab and closed growth chambers.

APPROVED (10-0-0)

5. Storage ONLY:

R BUA No. **0652** Rev: nld

Title: Storage Only: Clostridium botulinum (Types A, B, C, D and E)

APPROVED (10-0-0)

6. Exempt Protocols Approved by BSO: NONE

B. Amendments:

Amend **0662(A)** NIH: IIID4a **BSL: 2, RG: 2** Rev: nld

Title: <u>Modulation of the ErbB Receptors</u>

Amendment to add:

1. Injecting lentiviral transduced mouse cells into recipient mice

2. Oncogenic vector constructs: p53 knockdown, PvVmT

Exp date: 01/24/2014 APPROVED (10-0-0)

Amend 0769(A) NIH: Inf agts (humans) BSL: 2, RG: 3 Rev: pb

Title: Macaques as a model for influenza and AIDS pathogenesis, transmission, vaccine development and

antiviral therapy

Amendment to add: HIV and AT-2 (culture and analysis)

Exp date: 04/16/2015 APPROVED (10-0-0)

Amend 1002(A) NIH: Inf agts (plants) BSL: 1, RG: 1 Rev: mmm

Title: <u>Elucidating the functional role in pathogenesis and host specialization of genome structure, content</u>

and plasticity from fungal plant pathogens

Oidium neolycopersici (tomato powdery mildew): Infecting tomato plants and

Amendment to add: Sequence analysis

Exp date: 02/27/2015 APPROVED (10-0-0)

C. SOPs for Courses and Core Facilities: NONE

D. Conditional BUAs reviewed by ABSO, Final Approval by BSO: NONE

E. Terminated BUAs:

BUA No. **0815-01** Rev: nld

Title: <u>HSP60 and human cardiomyopathy</u>

BUA No. **0915-01B** Rev: nld

Title: <u>Targeting HER2 and AKT signaling pathways in breast cancer</u>

BUA No. **0926-01B** Rev: nld

Title: Impact of lipid mediators on human adipose cell function

V. Discussion Items:

1. Niki - Discuss use of BIO (on-line BUA system) for IBC members before implementing at whole campus. PI's on IBC will think about implementation methods and discuss with Philip (point person on BIO) during the June IBC meeting.

VI. Information Items:

- 1. Roger Belcourt will be the acting BSO until the position is filled.
- 2. Malendia notified IBC members that NIH is considering revision of requirements for human gene transfer research. Potential impact upon UCD IBC and research was discussed.

VII. IBC Training: NONE

VIII. BSL3 Laboratory Information: NONE

IX. Notifications: NONE

X. Subcommittee Topics: NONE

End Time: 5:30p.m.

Institutional Biosafety Committee, UC Davis Office of Environmental Health and Safety

MINUTES

June 17, 2013 (3-5p) - No quorum July 5, 2013 (4-5p) - special session

Hoagland Hall Rm 130

NOTE: Next IBC meeting: 07/15/2013

June 17th IBC mtg Start Time: 3:05 p.m.

In attendance:

Roger Belcourt Voting Member, Interim-Biosafety Officer & Occupational Health Services

Gerhard Bauer Voting Member, Vice-Chair, IM Div of Hematology/Oncology

Nicole Corley Voting Member, Campus Veterinary Services

Diane Hoffmann Voting Member, School of Medicine Sponsored Programs

Elizabeth Maga Voting Member, Animal Science Lyle Najita Voting Member, Public Member

IBC support staff in attendance:

Niki Drazenovich Associate BioSafety Officer, Environmental Health and Safety Malendia Maccree Associate BioSafety Officer, Environmental Health and Safety Philip Barruel Associate BioSafety Officer, Environmental Health and Safety

Excused:

Jill Blackwelder-Parker Non-Voting Ex-Officio Member, Associate Vice Chancellor, Safety Services

Neil Speth Non-Voting Ex-Officio Member, UCDMC Employee Health Services

Savithramma Dinesh-Kumar Voting Member, Plant Biology

Bruce Draper Voting Member, Molecular & Cellular Biology

Angela Gelli Voting Member, Chair, Pharmacology

Renee Tsolis Voting Member, Medical Microbiology & Immunology

Fred Jacobsen Voting Member, Public Member
Dan Kliebenstein Voting Member, Plant Science

Victor Lukas Non-Voting Ex-Officio Member, Attending Veterinarian

Guests: NONE

NO QUORUM - 6 MEMBERS IN ATTENDANCE - NO VOTES

July 5th IBC meeting Start Time: 4:03 p.m.

In attendance:

Roger Belcourt Voting Member, Interim-Biosafety Officer & Occupational Health Services

Gerhard Bauer Voting Member, Vice-Chair, IM Div of Hematology/Oncology

Nicole Corley Voting Member, Campus Veterinary Services

Savithramma Dinesh-Kumar Voting Member, Plant Biology

Diane Hoffmann Voting Member, School of Medicine Sponsored Programs

Dan Kliebenstein Voting Member, Plant Science Lyle Najita Voting Member, Public Member

Renee Tsolis Voting Member, Medical Microbiology & Immunology

IBC support staff in attendance:

Niki Drazenovich
Malendia Maccree
Associate BioSafety Officer, Environmental Health and Safety
Philip Barruel
Associate BioSafety Officer, Environmental Health and Safety
Associate BioSafety Officer, Environmental Health and Safety

Excused:

Jill Blackwelder-Parker Non-Voting Ex-Officio Member, Associate Vice Chancellor, Safety Services

Neil Speth Non-Voting Ex-Officio Member, UCDMC Employee Health Services

Bruce Draper Voting Member, Molecular & Cellular Biology

Angela Gelli Voting Member, Chair, Pharmacology Fred Jacobsen Voting Member, Public Member

Victor Lukas Non-Voting Ex-Officio Member, Attending Veterinarian

Elizabeth Maga Voting Member, Animal Science

Guests: NONE

I. Review of past IBC meeting minutes: May 20, 2013

NO VOTE (0-0-0) 6/17/2013 APPROVED (7-0-0) 7/5/2013

II. Announcements: NONE

III. **Old Business:**

BSL₂

R BUA No. 0102-02 Inf Agts (zoonotic) BSL: 2, no agts Rev: pb

Title: Caprine arthritis-encephalitis virus (CAEV) infected cells in pre- and post-partum goats: Long term

CAEV follow up and Q fever prevalence

Project Summary:

Field samples of milk and vaginal secretions from normal and aborted goats in client herds will have DNA extracted for PCR of Coxiella burnetii (Q Fever) organism. Some, but not all samples may contain Coxiella burnetii. Sharps will be used (jugular vein blood collection) and medical waste will be generated. Tabled 05/20/2013

Recommended for Approval NO VOTE (0-0-0) 6/17/2013 APPROVED (7-0-0) 7/5/2013

IV. **New Business:**

1. BSL2:

NIH: IIID2a, IIID4a, BBP (est

R BUA No. 0524 human cells, NHP blood and BSL: 2, RG: 2

tissues), IIIF8 (App CII)

Title: Pathogenesis of *Helicobacter pylori*

Project Summary:

This project is focused on the pathogenesis of *Helicobacter pylori*, a bacterium that infects the stomach of humans, and in about 10% of those infected, causes gastric cancer or peptic ulcer. Knockout H. pylori strains will be generated and WT and KO strains will be used with animal models and human gastric cell lines. Coinfection of H. pylori with both Salmonella and Influenza virus will also be studied. Sharps will be used and medical waste will be generated.

Recommended for Approval NO VOTE (0-0-0) 6/17/2013 APPROVED (7-0-0) 7/5/2013

NIH: Inf agt (animal), IIID4a, **R** BUA No. **0664** BSL: 2, RG: 1

Rev: nld Epizootic Bovine Abortion Agent (aoEBA): Organism characterization and development/use of a Title:

mouse model

Project Summary:

Part of the ongoing research in the Laboratory is vaccine development against an unnamed deltaproteobacterium that causes epizootic bovine abortion. The goal of this project is to: (A) further understand pathogenesis and host susceptibility via infection of immunodeficient mice and development of reagents, such as monoclonal antibodies, to serve as research tools (B) characterize this previously unidentified organism (C) vaccine development using both bacterialand recombinant-based antigens and (D) attempt in vitro cultivation. No medical waste will be generated, but sharps will be used and disposed of in a manner consistent with medical waste.

Recommended for Approval NO VOTE (0-0-0) 6/17/2013 APPROVED (7-0-0) 7/5/2013

Rev: nld

BBP (est. cells & prim. human blood from know HIV+ patients)

BSL: 2, no agts

Title: Immunology and virology research in HIV infected subjects **Project Summary:**

Biological specimens obtained from HIV positive subjects will be used for immunology and virology testing. HIV genes have been cloned and are maintained in the form of E. coli plasmids and Adenoviral vectors. These recombinant DNA materials are stored and currently not in use (BUA will be amended before initiating work with recombinant DNA). Heterologous expression of HIV gene products will be performed by collaborators which provide purified expression products to the label lab for use as antigens in the *in vitro* studies to evaluate T cell immune responses against the HIV-1 proteins. Medical waste is generated. Glass slides are disposed as sharps.

Recommended for Approval NO VOTE (0-0-0) 6/17/2013 APPROVED (7-0-0) 7/5/2013

N BUA No. **714-03**

R BUA No. 0674

BBP (est. cells & prim. human tissues and blood from know HIV+ patients)

BSL: 2, no agents Rev: mmm

Rev: mmm

Title: Immunology and virology research in HIV infected subjects **Project Summary:**

Biological specimens obtained from HIV positive subjects will be used for immunology and virology testing. This project involves the study of the cell-mediated immune response in HIV-1, HBV, HCV and or HPV infected humans. In order to study human cell-mediated immune response, it is essential to study humans infected with these viruses. Primary blood samples from virus infected humans will be used to access cell-mediated response by a variety of methods including:advanced flow cytometry, ELISPOT assay, ELISA assay and lymphocyte proliferation assay. Viruses will not be cultured or concentrated. Medical waste will be generated.

Recommended for Approval NO VOTE (0-0-0) 6/17/2013 APPROVED (7-0-0) 7/5/2013

R BUA No. **0718** NIH: Inf agts (zoonotic) Title: Ecological genetics and population health of wildlife BSL: 2 (no agts)

Rev: nld

Project Summary:

Wildlife samples (hair, feathers, tissue, feces, swabs) are analyzed to determine DNA sequence and to test for presence of certain pathogens (such as Avian pox virus, hemoparasites, leptospirosis, and *Trichinellosis*). Wildlife species include mammals (mountain lions, bears, etc) and birds (hummingbirds, magpies, raptors, etc) and potentially hazardous manipulations include use of sharps, medical waste generation, and handling of wild animal samples that may contain disease agents.

R BUA No. **0909-01**NIH: Inf agts (human), IIID4a,
BBP (human blood)

BSL: 2, RG: 2
Rev: nld

Title: Monitoring the role of neutrophils during skin wound healing and infection by tissue fluorescence

imaging

Project Summary:

These studies will assess the contribution of wound infection by *Staphylococcus aureus* and *Pseudomonas aeruginosa* on neutrophil extravasation and wound healing in EGFP-lysozyme knock-in mice. A mouse model of skin wound infection will be induced by inoculating bioluminescent *S. aureus* and/or *P. aeruginosa* bacteria onto a skin wound using a 30G needle syringe, and subsequently measuring neutrophil influx, wound bacterial burden, and wound closure during the progress of disease. Medical waste will be generated.

Recommended for Approval NO VOTE (0-0-0) 6/17/2013 APPROVED (8-0-0) 7/5/2013 R. Tsolis joined meeting

R BUA No. 0928 NIH: Inf agts (zoonotic, animal) BSL: 2, RG: 2 Rev: nld

Title: <u>Mammalian virology in a veterinary diagnostic laboratory</u> Project Summary:

The Mammalian Virology section will be attempting to isolate various animal viral pathogens, using established and novel approaches, from diagnostic specimens for purposes of diagnostics and the capture of novel viruses of diagnostic significance. Virus isolation will be attempted by inoculating specimens submitted from blood, tissue, and swab samples onto mammalian cell cultures. Specific reference viruses will be used on target cell cultures as positive controls in order to confirm cell sensitivity to the virus being isolated. The presence of viral growth will be confirmed using one or more of the following techniques: microscopically, for the presence of CPE (cell death), or fluorescence, using virus specific staining, electron microscopy, and PCR performed on the culture supernatant. Sharps will be used and medical waste will be generated.

NIH: Inf Agts (zoonotic), BBP (human & non-human primate blood and tissues), IIIF8 (App

N BUA No. 1050

BSL: 2, RG: 2 Rev: pb

CII)

Title: Therapeutic and prophylactic interventions against agents of chronic infection including HIV and HCV

Project Summary:

SIV infection of rhesus macaques is used as an animal model of HIV infection to study co-infection (e.g. *Plasmodium fragile*) and to test therapeutic and prophylactic interventions using a number of vaccine constructs (recombinant modified Vaccinia Ankara virus, BCG vaccine, delta-sec/delta-lys recombinant attenuated M. tb mc^2 5226, derivatives of rAMtb mc^2 5226, and rAd5-gag). The researchers will also use blood and tissue samples from HIV-infected and HCV-infected individuals to study viral reservoirs and immune responses. Some recombinant constructs are developed in-house and others received from outside sources. The researchers will use sharps and generate medical waste for these projects.

Recommended for CONDITIONAL NO VOTE (0-0-0) 6/17/2013

- Sec 1 Clarify the room number for the medical waste accumulation site and the freezer room.
- 2. Sec 3 Clarify how BCG will be used in your project, including any animal work (add the information in box #1 and #6).
- 3. Sec 3, #2 Clarify whether the plasmids listed in this box are going to be used for transfection?
- 4. Sec 3, #3 Clarify how the plasmids will be propagated.

Conditional questions were answered prior to 7/5/13 meeting APPROVED (8-0-0) 7/5/2013

N BUA No. 1052

Inf agts (human)

BSL: 2, RG: 2

Rev: mmm

Title: <u>Survival of vegetative pathogens in acidified foods</u>

Project Summary:

University of California Laboratory for Research in Food Preservation (UCLRFP) in Dublin CA, perfoms microbiological and food safety consulting and analyses for state agencies and stakeholders under contract with UC Davis Food Science and Technology Department. Food safety tests are performed with acid-adapted cells, which will be inoculated into sterile containers of commercially sterile acidified foods. Time to reduce the inoculum at least 5 logs will be determined using standard plating techniques. All open work to be done in a biological safety cabinet. Medical waste will be generated. No sharps are used in this work.

IIID4a (xenografts), BBP

N BUA No. 1053 (primary and est. human cell BSL: 2, no agents Rev: mmm

lines)

Title: <u>Noncoding RNAs in regulation of drug disposition and cell proliferation</u>
Project Summary:

Our research will involve (1) the construction and generation of plasmids carrying noncoding RNAs and their targeted gene sequences using *E. coli*, (2) culture and transfections of established human cell lines with plasmids, and (3) administration of plasmids to human cell lines in xenograft mouse models. All recombinant DNA vectors, *E. coli* strains, and human carcinoma cell lines are commercially available; and there are no infectious agents and radioactive materials to be used. Medical waste will be generated and sharps are used for injections of mice and manipulation of tissues.

Recommended for CONDITIONAL NO VOTE (0-0-0) 6/17/2013

Sec 4, BBP project summary - More information was requested on use and handling of mice: Will mice be anesthetized during injections and blood draws? This is not required, but it can lower risk of

- 1. animal bites and incidents, if animals are not fully conscious during injections. An IBC review requested that we also inform you of the availability of isoflourine for use in anesthetizing animals for routine injections.
 - Sec 4, BBP project summary Blood collection from animals should be more clearly described.
- 2. Reference is made to blood collection from animals, but no further details have been provided for this work. How often will blood be collected from mice and what will the blood be used for?

Conditional questions were answered prior to 7/5/13 meeting APPROVED (8-0-0) 7/5/2013

2. Bloodborne Pathogen Protocols:

NIH: BBP (human tissue, est.

R BUA No. 0707-02 human and NHP cells), IIIE, BSL: 2, RG: 1 Rev: pb

IIIF8 (App CI, CII)

Title: <u>Ion channels in the mammalian nervous system (NeuroMab)</u>

Project Summary:

Rats and mice will be used as a source of brain tissue for biochemical (unfixed) and immunoistochemical analyses (paraformaldehyde) of neuronal channels and receptors and the generation of hybridomas secreting monoclonal antibodies. Mammalian cell lines will be used to express recombinant channels from plasmids and human brain samples may be used in immunoblot screening of monoclonal antibodies produced by our hybridomas. Medical waste will be generated and sharps will be used.

Recommended for Approval NO VOTE (0-0-0) 6/17/2013 APPROVED (8-0-0) 7/5/2013

R BUA No. 0908B BBP only (est. human cells) BSL: 2, no agents Rev: mmm

Title: <u>Lipid-droplet formation in human monocytes by exposure to lipolysis products</u>

Project Summary:

Human cell lines will be exposed to lipids and a variety of analyses will be performed on the cells. No recombinant or synthetic DNA constructs are involved. Medical waste is generated and glass Pasteur pipets are disposed in red sharps containers.

BBP (prim. & est. human cells and blood), IIIE, IIIF8 (App CI)

R BUA No. 0923

Rev: mmm

Title: Characterization of genes and proteins associated with ionizing radiation exposure Project Summary:

This project will develop technology to identify and characterize specific genes, DNA, RNA and protein fragments present in saliva and blood using array-based protocols. Once proteins and genes are established as present the array will be used to profile their respective levels and any modifications induced in response to varying IR dose and time post-exposure. Recombinant expression hosts include E. coli, rodent cell lines, and human cells. Human blood and primay human cells are also used in this work. Medical and sharps waste is generated.

Recommended for Approval NO VOTE (0-0-0) 6/17/2013 APPROVED (8-0-0) 7/5/2013

R BUA No. 0924-01B

BBP only (est. human and NHP cells), IIIF8 (App CI, CII)

BSL: 2, 1

BSL: 2, RG: 1

Rev: pb

Title: Cellular and molecular mechanisms of neurotoxicity

Project Summary:

The investigators are interested in identifying cellular and molecular mechanisms by which environmental toxicants including pesticides and persistent organic pollutants interfere with neuronal morphogenesis and function. One tool to be used in these studies are cell lines, including the THP-1 human monocyte line, the SK-N-SH human neuroblastoma cell line, the HEK 293 human embrionic kidney cells and the non-human primate cell line COS-7. Additional tools to be used in these studies include cDNA, which will be used to transfect primary rat neuronal cell cultures using lipid-mediated delivery systems (e.g., Lipofectamine, Fugene) or Amaxa nucleofection. cDNA used in these studies include: MAP2B-eGFP, td tomato and neuroligin as well as siRNA primer constructs specific for RyR isoforms, mTOR, RAPTOR and Rictor. Sharps will be used; medical waste will be generated.

Recommended for Approval NO VOTE (0-0-0) 6/17/2013 APPROVED (8-0-0) 7/5/2013

R BUA No. 0929B

BBP only (est. human cells), IIIF8 (App CI, CII)

BSL: 2, 1

Rev: pb

Title: <u>Functions of selenoproteins in human cells</u>

Project Summary:

We use established human cell lines transiently and/or stably transfected with siRNA, shRNA and/or cDNA constructs to decrease or increase expression of selenoprotein W, other small thioredoxin-like selenoproteins, and putative interacting proteins to work out the selenoproteins' functions by measuring receptor activation, cell growth, cell cycle, and apoptosis outcomes which generates medical waste. Site-directed mutagenesis of human cDNAs is performed by PCR and recombinant DNA vectors (usually containing antibiotic resistance genes and CMV promoters) are maintained in K-12 *E. coli* cultures. Sharps will be used

N BUA No. 1051

NIH: IIIE, BBP (human blood

BSL: 2, RG: 1

Rev: mmm

and est. cells), IIIF8 (App CI)

Title: Determination of immunoreactivity to fetal brain proteins

Project Summary:

We express commerically procured cloned human fetal brain proteins in human cells (HEK 293) and *E. coli* to use as a substrate for testing maternal autoantibodies from mothers of children with autism. Medical waste and sharps waste is generated.

Recommended for Approval NO VOTE (0-0-0) 6/17/2013 APPROVED (8-0-0) 7/5/2013

3. IBC Notification Simultaneous with Initiation (NIH III-E):

R BUA No. 0030 NIH: IIIE, IIIF8 (App CII) BSL: 1, RG: 1 Rev: nld

Title: Transcriptional control of early developmental gene expression in *Myxococcus xanthus* Project Summary:

Identifying the hierarchical genetic regulatory network controlling growth and development in the soil bacterium *Myxococcus xanthus*. This is done by identifying candidate genes, making null mutations and introducing reporters to monitor growth and development. Sharps will be used no medical waste will be generated.

Recommended for Approval NO VOTE (0-0-0) 6/17/2013 APPROVED (8-0-0) 7/5/2013

R BUA No. **0208** NIH: IIIE, Inf. Agts, (animals), IIIF8 (App CII)

Title: Studies on Respiratory Syncytial Virus: Experimental bovine respiratory syncytial

virus infection for evaluation of vaccine candidates and anti-virals

Project Summary:

The investigators are studying bovine RSV (BRSV) vaccines as well as anti-viral drug efficacy in bovine infections. BRSV and *Histophilus somni* co-infection studies will also be performed. The investigators will not generate medical waste but will dispose of laboratory waste as medical waste (Vet School practice); hypodermic needles will be used.

Recommended for Approval NO VOTE (0-0-0) 6/17/2013 APPROVED (8-0-0) 7/5/2013

- 4. Storage ONLY: NONE
- 5. Exempt Protocols Approved by BSO: NONE

B. Amendments:

Amend **0224(A)** NIH: IIIE, IIIF8 (App CII) **BSL: 1, RG: 1** Rev: pb

Title: Novel amiloride compounds selectively kill gliomas

Amendment to add: E. coli BL21 (DE3) - for expression

Exp date: 12/20/2013

Recommended for Approval NO VOTE (0-0-0) 6/17/2013

APPROVED (8-0-0) 7/5/2013

Amend 0347-02(A) NIH: Inf agts (human) BSL: 3, RG: 3 Rev: nld

Title: <u>Titration of Mycobacterium tuberculosis by bacterial culture</u>

Amendment to add: *Mycobacterium tuberculosis* culture with established human cells

Exp date: 10/15/2013

Recommended for Approval NO VOTE (0-0-0) 6/17/2013

APPROVED (8-0-0) 7/5/2013

MC Amend **0824(B)** NIH: IIID4a, IIIF8 (App CII) **BSL: 1, RG: 1** Rev: pb

Title: Studying the mechanisms of nuclear positioning (new title)

Amendment to add: Zebrafish – create transgenic zebrafish that express recombinant KASH proteins

(C-tail-anchored membrane proteins, which are targeted specifically to the outer

membrane of the nuclear envelope).

Exp date: 09/20/2013

Recommended for Approval NO VOTE (0-0-0) 6/17/2013

APPROVED (8-0-0) 7/5/2013

Amend **0863-02(A)** NIH: IIID4a (transduced human **BSL: 2, No New Agts** Rev: pb

cells into mice), BBP(est.

human cells)

Title: Generation of induced pluripotent stem cell and neural cells derived from human embryonic stem

cells (new title)

Amendment to add: 1. H9 cells (to be differentiated into neural cells, then implanted into mice)

2. Injection of previously approved replication defective lentivirus into mouse

brain

Exp date: 08/20/2015

Recommended for Approval NO VOTE (0-0-0) 6/17/2013

APPROVED (8-0-0) 7/5/2013

Amend **0900-03(B)** NIH: Inf agts (human) **BSL: 2, RG: 2** Rev: nld

Title: Human pathogenic fungal research

Amendment to add: 1. Aspergillus flavus, A. fumigatus (culture and susceptibility assays)

2. Cryptococcus neoformans h99, h99 cap 59 and h99 cap 64 (co-culture with est

human cells)

Exp date: 05/21/2015

Recommended for Approval NO VOTE (0-0-0) 6/17/2013

APPROVED (8-0-0) 7/5/2013

Amend **0979(B)** NIH: Inf agts (humans) **BSL: 2, RG: 2** Rev: nld Title: CD4 T cell responses to Salmonella; Typhoid priority antigen identification and vaccine development

Amendment to add: 1. Salmonella enterica serovar Typhi (host: mice)

Exp date: 07/18/2014

Recommended for Approval NO VOTE (0-0-0) 6/17/2013

APPROVED (8-0-0) 7/5/2013

C. SOPs for Courses and Core Facilities: NONE

D. Conditional BUAs reviewed by ABSO, Final Approval by BSO:

BUA No. **0492-04** Reviewer: mmm

Title: Sustained correction of hemophilia A

Conditional 02/25/2016

E. Terminated BUAs:

BUA No. 0925 Reviewer: nld

Title: Survival of vegetative pathogens in acidified foods

BUA No. 0634-02 Reviewer: nld

Title: <u>Prostate cancer: understanding the effects of receptor mediated androgen independent</u>

growth, viral activation and viral gene expression, autographic cell death and

methylation induced gene silencing

V. Discussion Items:

1. Niki - requests 2 mo extension on her BUA (798, exp date 7/19/13), to renew in Sept. 2013 (got deferred to July 5th special IBC session) **APPROVED (8-0-0) 7/5/2013**

- 2. Roger/Philip Discuss establishment of an MOU for UCD IBC review of protocols at VA Mather (deferred to July 15th IBC meeting)
- 3. Philip Discuss BIO roll-out review BUAs at Aug IBC (EM, GB, AG, RT, & DK BUAs)
- 4. Malendia Update on UC-BSO/ABSA response to proposed NIH guidelines revision reagarding human gene transfer research. (deferred to July 15th IBC meeting)

VI. Information Items:

1. Lyle N. will not be at the July 15th IBC meeting

VII. IBC Training: NONE

VIII. BSL3 Laboratory Information: NONE

IX. Notifications: NONE

X. Subcommittee Topics: NONE

End Time: 5:26 p.m. 6/17/2013 End Time: 4:47 p.m. 7/5/2013

Institutional Biosafety Committee, UC Davis Office of Environmental Health and Safety

MINUTES July 15, 2013 (3-5p)

Hoagland Hall Rm 130

NOTE: Next IBC meeting: 8/19/2013

Start Time: 3:05pm

In attendance:

Nicole Corley Voting Member, Campus Veterinary Services

Savithramma Dinesh-Kumar Voting Member, Plant Biology

Bruce Draper Voting Member, Molecular & Cellular Biology

Angela Gelli Voting Member, Chair, Pharmacology

Diane Hoffmann Voting Member, School of Medicine Sponsored Programs

Fred Jacobsen Voting Member, Public Member
Dan Kliebenstein Voting Member, Plant Science
Elizabeth Maga Voting Member, Animal Science

Renee Tsolis Voting Member, Medical Microbiology & Immunology

Roger Belcourt Voting Member, Interim Biosafety Officer and Occupational Health Services

Victor Lukas Non-Voting Ex-Officio Member, Attending Veterinarian

IBC support staff in attendance:

Niki Drazenovich Associate BioSafety Officer, Environmental Health and Safety
Philip Barruel Associate BioSafety Officer, Environmental Health and Safety
Malendia Maccree Associate BioSafety Officer, Environmental Health and Safety

Excused:

Jill Blackwelder-Parker Non-Voting Ex-Officio Member, Associate Vice Chancellor, Safety Services

Neil Speth Non-Voting Ex-Officio Member, UCDMC Employee Health Services

Gerhard Bauer Voting Member, Vice-Chair, IM Div of Hematology/Oncology

Lyle Najita Voting Member, Public Member

Guests: ****

None

I. Review of past IBC meeting minutes: July 5, 2013 (special June IBC session)

APPROVED (6-0-3)

II. Announcements:

1. Two protocols (785-04, 785-06) accidentally left off of July agenda. Neither BUA involves recombinant DNA, IBC can review and approve via e-mail. Assign 4 reviewers per BUA (04: Gelli, Belcourt, Draper Corley), 06: Gelli, Belcourt, Corley, Maga). Ask for comments via email, by Friday 7/19.

III. Old Business: NONE

IV. New Business:

1. Human Gene Transfer Protocol:

R BUA No. 0714-02

NIH: IIIC-1, Inf agts (HIV+ve human blood)

Rev: mmm

Title: A randomized, double blind, Phase 2B study testing the efficacy and safety of AGS-004 on host

control of HIV replication during analytical treatment interruption

Project Summary:

Argos Therapeutics, Inc. (Argos) is investigating the induction of cytotoxic T lymphocyte (CTL) responses in HIV-infected subjects by AGS-004, an autologous HIV-1 immunotherapeutic agent made from autologous dendritic cells (DCs) co-electroporated with CD40L in vitro transcribed (IVT) RNA along with amplified IVT RNA encoding 4 HIV-1 antigens (Gag, Rev, Vpr, and Nef) from an autologous plasma sample taken immediately prior to the initiation of ART. Ongoing study.

APPROVED (9-0-0)

2. BSL2:

R BUA No. 0578-02 NIH: IIID3b(lenti), BBP (primary and est human cells), IIIF8 (App CII)

Title: <u>Human and transgenic mouse models of neurological disorders</u>
Project Summary:

For Part A: Culture of human derived cells to study Fragile X Syndrome (FXS), Fragile X Associated Tremor Ataxia Syndrome (FXTAS), and FMR1 premutation. For Part B: Transdifferentiation of fibroblasts into neuronal cell types using transcription factors and lentivirus. For Part C: Production of C57BL6 transgenic mice at MTGL (or similar) facility. The purpose of this project is to create transgenic mice that express recombinant CaV1.1 .1 with inserted biotin acceptor domains and YFP to allow studies of the interactions between RyR1 and CaV1.1. In addition, transgenic mice will be created that express a Ca2+ reporter in their sarcoplasmic reticulum that will allow measurement of free Ca2+ in the SR. Medical waste will be generated; sharps will be used.

APPROVED (9-0-0)

N BUA No. 1055

NIH: IIID3b(lenti), BBP (est human cells), IIIE, IIIF8 (App CII)

BSL: 2, RG: 2

Rev: pb

Title: <u>Investigation of Wnt</u>-induced cytoskeletal dynamics in development and disease Project Summary:

The project is focused on examining the molecular mechanisms by which the *Wnt* family of secreted growth factors direct cytoskeletal rearrangements via *Ror* family cell surface receptors. A variety of cultured mouse, human and fly cell lines will be used to investigate the biochemical and cell biological processes controlled by *Wnt-Ror* signaling. Protein overexpression or RNA interference-based knockdown approaches will be used to dissect the functions of proteins involved in *Wnt-Ror* signaling. Genes of interests or RNAi constructs will be introduced into cultured cell lines by transient transfection of plasmid DNA or via lentiviral transductions. Recombinant proteins will be overexpressed in *E. coli* or mammalian cells to study their roles in regulating cytoskeletal rearrangements in vitro. The project is expected to involve some aerosol generating procedures, use of sharps, and medical waste generation.

3. Bloodborne Pathogen Protocols:

R BUA No. 0580B BBP (human blood) BSL: 2, no agts Rev: nld

Title: Elucidating the dynamic and kinetic behavior of nutrient metabolism in humans

Project Summary:

The project aims to determine the dynamic and kinetic behavior of micronutrients in healthy human subjects using tracer isotope technology. Blood, urine and stool samples collected previously from human subjects will be analyzed for the concentration of the administered nutrient and its chemical form will be identified. Sharps will not be used and medical waste will be generated.

APPROVED (10-0-0)

R BUA No. 0821-02B BBP (NHP tissues) BSL: 2, no agts Rev: nld

Title: Naphthalene metabolism in tissue pieces of the respiratory tract from NHP

Project Summary:

The purpose of these studies is to compare the metabolism of naphthalene in target and nontarget tissues of rats and nonhuman primates. NHP nasal epithelium will be dissected and radiolabeled for determination of metabolite profiles. Sharps will be used to cut tissue and medical waste will be generated.

APPROVED (10-0-0)

R BUA No. 0922B BBP (human blood) BSL: 2, no agts Rev: nld

Title: Microfluidic investigation of human red blood cells

Project Summary:

Microfluidic channels are used to impose hydrodynamic forces on RBCs to gauge the effect on vasodilatory signaling. The imposed flow rates in the microchannels are very slow (approx 2-5 microliters / minute), thus the risk of aerosolization in the event of a malfunction of the machine is very small. We will be using sharps (needles and glass microscope slides) and generating medical waste.

APPROVED (10-0-0)

N BUA No. 1054B BBP (human blood) BSL: 2, no agts Rev: mmm

Title: <u>Biophysical properties of blood cell</u>

Project Summary:

The project is aimed at understanding the physical properties of red and white blood cells and how they contribute to their biological functions. Blood samples will be collected from healthy donors. Cell isolation from whole blood will performed to separate out immune cells: neutrophils, monocytes or eosinophils. Sharps will be used and medical waste generated.

APPROVED (10-0-0)

4. BSL1:

R BUA No. **0075-02** NIH: IIID3e (baculo), IIIF8 (App **BSL: 1, RG: 1** Rev: pb

Title: The endocrine system of GWSS, a viable insecticide target

Project Summary:

Juvenile hormone esterase and juvenile hormone epoxide hydrolase encoding genes will be cloned from the insect glassy-winged sharpshooter (GWSS) genome so that the enzymes can be characterized. *E. coli* (K-12) will be used and a baculoviral vector will be used with insect cells (Sf9 and High-five cell lines) to express the genes of interest. Sharps will not be used. No medical waste will be generated.

NIH: Inf agts (plants), IIIE2a,

R BUA No. **0235-04** IIIE2b(3), IIIE2b(4), IIIF8 (App BSL: 1, RG: 1 Rev: mmm

CII)

Title: Plant virus (Cucumber mosaic virus (CMV) and Tobacco mosaic virus (TMV)) replication and

expression of heterologous proteins in transgenic/non-transgenic plants and plant cell lines

Project Summary:

This project involves development of plant viral vectors and inducible expression systems. Plant viruses and plant viral genes are manipulated in plasmid vectors and in plant hosts. Constructs are delivered via *Agrobacterium* -mediated transformation to wildtype and transgenic tobacco plant hosts. Work is conducted in laboratories, growth chambers, and greenhouses. Sharps are used for manipulation of plant tissues.

APPROVED (10-0-0)

R BUA No. 0312 NIH: Inf agts (animals), IIID4a BSL: 1, RG: 1 Rev: nld

Title: <u>Experimental manipulation of ecdysteroid levels during insect development</u> Project Summary:

The overall goal of this project is to manipulate the steroid hormone signal transduction pathway in *Drosophila melanogaster* in order to better understand how the hormone controls critical aspects of immune system development and function and tissue morphogenesis. This project will use *Drosophila melanogaster* transgenic lines with standard P-element insertions that contain sections of or complete *Drosophila* genes, RNAi constructs, and/or the gene encoding the yeast transcription factor GAL4 or its binding site UAS. For some experiments, these *Drosophila* stocks will be infected with bacteria (*Micrococcus luteus* and *E. coli*) and fungus (*Beauveria bassiana*). Sharps will be used and no medical waste will be generated.

APPROVED (10-0-0)

R BUA No. 0316-02

NIH: Inf agts (plants), IIIE2(b)3,
IIIE2a, IIIF8 (App CII)

BSL: 1, RG: 1

Rev: mmm

Title: Characterization of plant pathogenic fastidious prokaryotes

Project Summary:

The primary focus of the research involves *Xylella fastidiosa*, the bacterial pathogen that causes Pierce's disease of grapevines. The role of various pathogenicity genes will be assessed using transposome mutagenesis and pathogenicity assays on grapevines. Two *X. fastidiosa* genes will be evaluated for reducing Pierce's disease symptoms in transgenic grapevines.

APPROVED (10-0-0)

R BUA No. **0413-02**NIH: IIID3e (baculo), IIID4a
(baculo), IIIF8 (App CII)

BSL: 1, RG: 1

Rev: pb

Title: Dynamics and mechanics of mitosis in *Drosophila*

Project Summary:

The purpose of this research is to understand the mechanism of anaphase B. Recombinant *D. melanogaster* is generated to express tagged proteins of interest for live imaging and use bacteria and the baculovirus expression system to express and purify proteins for in vitro studies. No sharps will be used. Medical waste will not be generated.

R BUA No. 0598 NIH: IIIE, IIIF8 (App CII) BSL: 1, RG: 1 Rev: nld

Title: Characterization of proteins from *Moraxella bovis*, *Moraxella bovoculi and Moraxella ovis*Project Summary:

The project is intended to characterize proteins from *M. bovis*, *M. bovoculi* and *M. ovis* and assess their utility in the development of a vaccine against bovine infectious keratocunjunctivitis (IBK). Standard methods of bacterial culture, gene cloning, protein expression, antisera production and determination of antigenic capability of the proteins of interest will be used (note: sharps and biohazardous waste will be produced and disposed of as medical waste). Antisera production will be done by a private commercial laboratory not associated with UC Davis).

APPROVED (10-0-0)

R BUA No. **0647**NIH: Inf agts (plants), IIIE, IIIF8

(App CII)

BSL: 1, RG: 1

Rev: mmm

Title: <u>Mycoviral disruption of normal developmental pathways of *Cryphonectria parasitica* Project Summary:</u>

The research focuses on the interaction of the CHV1 hypovirus, and the fungal host *Cryphonectria parasitica*. *C. parasitica* infects chestnut trees and rapidly kills them by destroying the vascular cambium. When infected with CHV1, pathogenicity of the fungus is greatly reduced, and the infected tree is able to survive. We are characterizing the interactions of virus and host that are responsible for virulence reduction as well as disruption of normal developmental pathways of *C. parasitica*.

APPROVED (10-0-0)

R BUA No. **0920** NIH: IIID4a, IIIF8 (App CII) BSL: 1, RG: 1 Rev: mmm

Title: Comparative proteomics of animal circadian clock

Project Summary:

The overall goal of this project is to profile the temporally-regulated and dynamic interactions between the circadian oscillator protein complex and cellular machineries that exert precise control on animal physiology, and determine how this crucial protein module and its connections to other protein complexes evolve. The research involves the use of recombinant DNA technology in basic *E. coli* bacterial culture, insect cell tissue culture, and transgenic *Drosophila melanogaster*. No medical waste or sharps waste will be generated.

APPROVED (10-0-0)

R BUA No. **0927**NIH: Inf agts (plants), IIIE2a,
IIIE2b(3)

BSL: 1, RG: 1

Rev: mmm

Title: Walnut Improvement Program

Project Summary:

This project uses *Agrobacterium* vectors to insert genes to develop and test fruit and nut crop species with new agronomically useful traits such as disease resistance and imporved nut quality. The work primarily involves walnut scion and rootstock development and may include challenge tests using horticulturally relevant and locally abundant wildtype pathogens and plant pests from Calfornia orchards (*Agrobacterium* or nematodes).

Transgenic plants are grown and studied in and greenhouse studies. Challenge organisms are only used in lab

5. IBC Notification Simultaneous with Initiation (NIH III-E):

R BUA No. 0070 NIH: IIIE BSL: 1, RG: 1 Rev: nld

Title: Structural studies of proteins

Project Summary:

The X-ray crystal structure of proteins will be analyzed to help determine functional properties. Genes will be cloned into an *E. coli* expression system to express the protein of interest. Sharps will not be used and medical waste will not be generated.

APPROVED (10-0-0)

6. Storage ONLY: NONE

7. Exempt Protocols Approved by BSO: NONE

B. Amendments:

Amend **0099-04(A)** Location: ABSL3 **BSL: 3, RG: 1** Rev: mmm

Title: <u>Culicine vector competence and its role in the transmission of avian malaria in Central California</u>

Amendment to add: Location: Use of to house avian malaria infected birds

Exp date: 05/20/2016 APPROVED (10-0-0)

Amend 0492-03(A) NIH: IIIC (HGT) Clinical Sites Rev: mmm

Title: A phase 1/2 clinical trial of adeno-associated virus serotype 8 factor IX (FIX) gene therapy in adults

with hemophilia B

Amendment to add: Change to dose escalation plan based on serious adverse event at another study site

Exp date: 12/17/2015
APPROVED (10-0-0)

Amend **0670-01(C)** NIH: Inf agts (human) **BSL: 2, RG: 2** Rev: nld

Title: water and foodborne disease laboratory

Amendment to add: 1. Inoculate deer mice with varying concentrations of *E. coli* O157:H7

2. Analysis of deer mice feces for the presence of *E. coli* O157:H7

Exp date: 06/20/2014 APPROVED (10-0-0)

Amend **0739-01(B)** NIH: IIID4a **BSL: 2, RG: 2** Rev: nld

Title: Molecular mechanisms of synapse formation in the CNS

Amendment to add: Stereotactic injection of lentiviral particles expressing mouse SynDIG into mice

Exp date: 01/24/2014 APPROVED (10-0-0)

Amend **0833(C)** BBP (primary human tissues and blood) BSL: 2, no agts Rev: nld

Title: Marine and terrestrial mammal viral disease diagnosis and surveillance

Amendment to add:

RNA extraction from human samples (blood, organ tissues, and fluids including

urine, feces, and saliva)

Exp date: 01/24/2014

APPROVED (10-0-0)

Amend **0873(A)** NIH: Inf agts (zoonotic) **BSL: 3, RG: 3** Rev: pb

Title: <u>Arbovirus surveillance, vector competence and host pathogenesis</u>

Amendment to add: Culture of West Nile Virus in embryonated eggs

Exp date: 01/23/2015 APPROVED (10-0-0)

Amend **0917(A)** NIH: IIID4a (AAV) **BSL: 1, RG: 1** Rev: pb

Title: Regulation and role of protein kinase D in the heart

Amendment to add:

1. Intravenous injection of AAV constructs into mice

2. AAV gene inserts: protein kinase D bio-sensors; WT and mutated PKD; fluorescent proteins (CFP, YFP, GFP, tagRFP, *mcherry*); CaMKII activity bio-

sensors

Exp date: 05/20/2016 APPROVED (10-0-0)

Amend **0964(A)**NIH: Inf agts (plants), IIIE2b(2),
BSL: 1, RG: 1
Rev: mmm

IIIE2a

Title: <u>Crop improvement and disease resistance</u>

Amendment to add: 1. Add Gene contruct:

in pepper plant host

2. Add plant virus: in pepper plant host

Exp date: 03/21/2014 APPROVED (10-0-0)

Amend 1044(A) NIH: Inf agts (plants) BSL: 1, RG: 1 Rev: mmm

Title: Ecology, epidemiology, and control of fungal disease and post-harvest contaminants of fruit and nut

crops and vines

Amendment to add: Procedure: Non-destructive analyses of almonds infected with A. flavus

Exp date: 04/15/2016 APPROVED (10-0-0)

C. SOPs for Courses and Core Facilities: NONE

D. Conditional BUAs reviewed by ABSO, Final Approval by BSO:

NIH: IIID3a (adeno), IIID3e

R BUA No. 0707-01 (AAV), BBP (human brain tissue, est BSL: 2, RG: 2 Rev: pb

human and NHP cells), IIIF8 (App

CII, CVII)

Title: Ion channels in the mammalian nervous system

Review Date: 05/20/2013

E. Terminated BUAs:

BUA No. **0081** Rev: nld

Title: Stress signal transduction pathway in Schizosaccharomyces pombe

BUA No. **0235-05** Rev: nld

Title: Torradovirus biology and molecular biology

V. Discussion Items:

- 1. Philip IBC approved (10-0-0) the following BBP training requirements. BBP is an annual requirement per Cal-OSHA. It can be satisfied by reading the lab-specific BBPECP annually. In addition, every three years personnel will also be required to complete one of the following classes: Diane Hoffmann's "Laboratory Safety" class, EH&S "Biological Safety and Medical Waste Management" or the on-line class "Bloodborne Pathogens". This information will be posted on the Safety Services website.
- 2. Malendia IBC approved (10-0-0) the process change for human gene transfer BUAs. HGT BUAs will no longer have an expiration date; the BUA will expire when the study is over. The IBC will review annual HGT documents.
- 5. Niki The IBC voted against reviewing and e-mailing comments for BBP and IIIE protocols before the regularly scheduled IBC meeting. They **approved** (10-0-0) reviewing BBP and IIIE protocols before the meeting (no change to current process) and approving them as a whole set of protocols (i.e. not discussing them individually) unless a committee member thinks a protocol warrants further discussion with the whole committee.
- 6. Roger/Philip Discussed draft MOU and made minor clarifications. IBC **approved** (10-0-0) the draft MOU with the modifications. Philip will e-mail Angie with the revised MOU and verbiage to send to campus counsel for further review.

VI. Information Items: NONE

- 1. As a side topic arising from the MOU the committee felt that verbiage should be added to the appointment letters regarding confidentiality.
- 4. Malendia Discussed using WIRB as a pre-review for HGT protocols. Current practice at UCSD. Malendia will gather more information and bring it back to the committee at a later date.

VII. IBC Training: NONE

VIII. BSL3 Laboratory Information:

1. Philip - Update on BSL3 reverification. IBC approved (10-0-0) it's continued operation for another year.

IX. Notifications: NONE

X. Subcommittee Topics: NONE

End Time: 5:25p.m.

Institutional Biosafety Committee, UC Davis Office of Environmental Health and Safety

MINUTES

August 19, 2013 (3-5p)

Hoagland Hall Rm 130

NOTE: Next IBC meeting: 09/16/2013

Start Time: 3:05pm

In attendance:

Philip Barruel Voting Member, BioSafety Officer, Environmental Health and Safety

Gerhard Bauer Voting Member, Vice-Chair, IM Div of Hematology/Oncology

Nicole Corley Voting Member, Campus Veterinary Services

Savithramma Dinesh-Kumar Voting Member, Plant Biology

Bruce Draper Voting Member, Molecular & Cellular Biology

Angela Gelli Voting Member, Chair, Pharmacology

Diane Hoffmann Voting Member, School of Medicine Sponsored Programs

Fred Jacobsen Voting Member, Public Member
Dan Kliebenstein Voting Member, Plant Science
Elizabeth Maga Voting Member, Animal Science

Victor Lukas Non-Voting Ex-Officio Member, Attending Veterinarian

Roger Belcourt Non-Voting Ex-Officio Member, Occupational Health Services

IBC support staff in attendance:

Niki Drazenovich Associate BioSafety Officer, Environmental Health and Safety Malendia Maccree Associate BioSafety Officer, Environmental Health and Safety

Excused:

Jill Blackwelder-Parker Non-Voting Ex-Officio Member, Associate Vice Chancellor, Safety Services

Neil Speth Non-Voting Ex-Officio Member, UCDMC Employee Health Services

Magalie Guilhabert Voting Member, Public Member Lyle Najita Voting Member, Public Member

Renee Tsolis Voting Member, Medical Microbiology & Immunology

Guests: NONE

I. Review of past IBC meeting minutes: July 15, 2013

APPROVED (8-0-1)

II. Announcements:

1. New BSO

III. Old Business: NONE

IV. New Business: NONE

A. BUA's:

1. **BSL3P**:

N BUA No. 0793-02 NIH: Inf agts (plants) BSL: 3P, RG: 1 Rev: mmm

Title: Longitudinal study of HLB-induced volatile organic compound (VOC) release

Project Summary:

A novel method of disease detection has been established based on identifying specific "fingerprint" biomarkers of released volatile organic compounds (VOCs) that emanate trees infected with *Candidatus Liberibacter asiaticus*, CLas. In this project capabilities will be established of the volatiles monitoring method for disease detection in infected trees under controlled greenhouse conditions (BL3P) in

. No viable plant materials will be removed from the containment facility.

APPROVED (10-0-0)

2. BSL2:

NIH: IIID3e (baculo), IIIE, BBP

R BUA No. **0817** (est human cells), IIIF8 (App CII, BSL: 2, RG: 1 Rev: mmm

VII)

Title: <u>Intracellular protein transport</u>

Project Summary:

The laboratory studies how proteins traffic inside the cell by using animal cell lines, recombinant constructs, purified proteins, and mice. We will use sharps and generate medical waste.

Conditional (10-0-0)

Sec 2D: Use of the pSUPER.retro.puro shRNA expression vector was not described in the BUA.

1. Please provide more information regarding the expression host(s) and gene(s) of interest used with this plasmid in the project summary or in vector information section (2D#4).

R BUA No. **0938**NIH: IIID3b(lenti), BBP (primary and est human cells)

BSL: 2, RG: 2
Rev: mmm

Title: <u>Investigation into human biomarkers for cancer detection and use of chimeric antigen receptors</u>

(CARs) for cancer immunotherapy

Project Summary:

The research projects involve the use of human body fluids for biomarker discovery and primary human lymphocytes and NK cells for activation and functional research studies. Downstream work with these materials involving recombinant DNA technology will be performed. Medical waste will be generated. Sharps (27 gauge needle) will be used for lymphocyte isolation. Lentiviral vectors will be used.

NIH: Inf agts (human and animal),

IIID3b(lenti), IIID4a, BBP (human BSL: 2, RG: 2 Rev: nld

blood)

Title: <u>Lentiviral transduction of siRNA constructs for in vitro and in vivo use, and continued therapies</u>

against xenograft tumors and influenza infections

Project Summary:

N BUA No. 0942-03

It has recently been discovered that an immune paralysis in naïve CD4 T cells occurs following strong stimulation. The research is focused on investigating the role of SOCS3 in this paralysis as it is upregulated following stimulation and has been shown to inhibit immune responses. Therefore, the goal is to deliver shRNA to knockdown its production in primary cells for use in downstream applications in vivo and in vitro. For in vivo studies in mice, lentiviral transduced cells will be injected intravenously along with tumor cells or influenza virus. The effects of the immune paralysis of CD4 T cells and the anti-viral and immunoregulatory roles of NK cells will be studied in influenza virus in mice as a pathologic and clinical model. For ongoing xenograft experiments, human natural killer cells will be engrafted into tumor-bearing immunocompromised mice. This therapy will be primarily used against human tumor lines. Sharps will be used and medical waste generated.

APPROVED (10-0-0)

3. Bloodborne Pathogen Protocols:

R BUA No. **0937B**BBP (human and NHP blood and tissue)

BSL: 2, no agts
Rev: pb

Title: <u>Immunological investigations into neurodevelopmental disorders</u>

Project Summary:

Research involves isolating immune cells from peripheral blood (of humans and non-human primates) and culturing these cells in the presence of neuronal cell lines and/or non-infectious immune stimulants (such as PHA, poly I:C). The objectives are to ascertain immune differences in children with autism compared with typically developing controls, and determine if animal models of autism display similar immune profiles. Medical waste will be generated; sharps will not be used.

APPROVED (10-0-0)

N BUA No. 1057B BBP (human brain tissue) BSL: 2, no agts Rev: pb

Title: Processing and storage of unfixed human tissue for the BEARS program

Project Summary:

Brain tissue, after extracted from the donor by medical examiners, will be transferred to a research facility at the . Once the extracted brain tissue arrives at the lab, it is to be processed for long term storage only. Currently the plan is to section half of the fresh human brain into 1cm slices, place each slice into individually labeled bags and store indefinitely in the -80C. Medical waste will be generated; sharps will be used for sectioning.

APPROVED (10-0-0)

4. BSL1: NONE

5. IBC Notification Simultaneous with Initiation (NIH III-E):

R BUA No. **0708** NIH: IIIE **BSL: 1, RG: 1** Rev: pb

Title: Cloning of insect olfactory genes and expression of the proteins they encode

Project Summary:

The investigators will identify olfactory proteins, including odorant receptors, odorant-binding proteins, and odorant-degrading enzymes, from insect genomes or by amino acid sequencing isolated proteins. Then, the investigators will clone the cDNA encoding these proteins and express them in *E. coli* for biochemical, biophysical, and functional analysis. No medical waste will be generated. Sharps will be used.

APPROVED (10-0-0)

6. Storage ONLY: NONE

7. Exempt Protocols Approved by BSO:

R BUA No. **0724** NIH: IIIF8 (App CII) **BSL: 1, RG: 1** Rev: pb

Title: Evolution of bacterial pathways for the degradation of nitroaromatic compounds

Project Summary:

The project is focused on degradation of aromatic compounds and chemotactic responses to these chemicals. This includes cloning genes encoding enzymes in the degradation pathways, chemotaxis genes encoding receptors and signal transduction proteins, and regulatory genes that encode transcriptional proteins that control gene expression. The proteins will also be purified to characterize them, make mutant strains lacking specific genes and test their phenotypes, and use the strains in physiological assays to monitor swimming in response to added chemicals.

APPROVED

B. Amendments:

Amend 0347-01(A) NIH: Mouse tissue samples (WNV +ve) BSL: 2 (no agts) Rev: nld

Title: Molecular and cell studies with infectious agents

Amendment to add: Serum and tissue samples from mice experimentally infected with West Nile Virus

(analysis only-no culture)

Exp date: 07/18/2014
APPROVED (10-0-0)

Amend **0662(B)** NIH: IIID4a (retro) **BSL: 2, RG: 1** Rev: nld

Title: Modulation of the ErbB Receptors

Amendment to add:

1. Injecting transduced human glioma cell lines into mouse brains to form

xenograft tumors

2. Injecting genetically engineered mouse brains with viral particles containing an

oncogene (PDGF) to form de novo gliomas

3. Vector: Ecotropic retrovirus (pQC-PDGF-BHA-I-Cre recombinase),

Gene: Oncogenic vector construct, PDGF

4. Xenografting human breast cancer cells onto mice

Exp date: 01/24/2014 APPROVED (10-0-0) Amend 0739-01(A) NIH: BBP (est human cells) BSL: 2 (no agts) Rev: nld

Title: Molecular mechanisms of synapse formation in the CNS

Amendment to add:

1. Human cells - DAOY (culture)

2. Potential oncogenes: Mxd3, Nmyc

Exp date: 01/24/2014 APPROVED (10-0-0)

Amend **0905(A)** NIH: IIID3b (lenti) **BSL: 2, RG: 2** Rev: nld

Title: Cellular signaling mechanisms

Amendment to add: 1. Vector: pFUW lenitiviral transfer vector (host: human iPSCs)

2. Genes: Ngn2 and rtTa

Exp date: 02/25/2016 APPROVED (10-0-0)

Amend 0966(A) NIH: Inf agts (human) BSL: 2, RG: 3 Rev: nld

Title: Investigating mechanisms of HIV transfer using advanced fluorescence microscopy

Amendment to add: 1. HIV-1 BAP11-Gag-iCherry (culture and microscopy)

2. HIV-1 Wild Type NL4-3 (culture and microscopy)

Exp date: 04/18/2014
APPROVED (10-0-0)

MC Amend 0975(A) NIH: IIID3b (lenti) BSL: 2, RG: 2 Rev: pb

Title: <u>In vivo arthritis model</u>

Amendment to add: Lentiviral vector to introduce DAP12 single-point mutations in human cells

(PBMC)

Exp date: 06/20/2014 APPROVED (10-0-0)

C. BUAs in BIO

BIO BUA No. R1469 (replaces NIH: Inf agts (animals), IIID4a BSL: 2, RG: 1 Rev: pb

Title: The use of milk from transgenic animals to prevent and treat diarrhea

Project Summary:

The overall goal of this work is to use milk from transgenic livestock containing human milk antimicrobial proteins and the pig as a human-relevant animal model to investigate the role human milk components play in mitigating damage to the intestine caused by *E. coli* induced diarrhea and malnutrition. Transgenic goats expressing human lysozyme in their milk and transgenic cows expressing human lactoferrin will be bred to maintain the transgenic lines and generate milk for study. The milk will be fed to young pigs fed a standard diet or a nutrient restricted diet and orally challenged with a porcine-specific enterotoxigenic *E. coli* (ETEC) either before or after supplementation with milk from lysozyme transgenic goats, lactoferrin transgenic cows, a mix of these two milks or milk from nontransgenic control animals. Blood will be collected for standard CBC and chemical panel analysis as well as metabolite profile determination. Intestinal segments will be collected for histology, immunohistochemistry and gene expression studies and feces and intestinal contents for microbiota analysis using next generation sequencing. Sharps will be used.

BIO protocols not approved-BIO will be deployed Jan 2014

NIH: Inf agts (human), IIID3b

BIO BUA No. R1477 (replaces 0854-01) (lenti), BBP (est and primary human BSL: 2, RG: ** Rev:

cells), IIIF8 (App CII)

Title: Gene therapy for HIV/AIDS

Project Summary: See BIO (too long)

BIO protocols not approved-BIO will be deployed Jan 2014

BIO BUA No. R1479 (replaces NIH: Inf agts (plants), IIIE2a BSL: 1, RG: 1 Rev: mmm

Title: Quantitative genomics of plant metabolism and pathogen interactions

Project Summary:

The primary aim of the project is to understand the link between genome variation in Arabidopsis thaliana and variable phenotypes between individual plants. Transgenic Arabidopsis are generated and used to test the role of specific genes in controlling the phenotype of interest. These transgenic Arabidopsis lines are largely limited to the insertion of T-DNAs into specific genes to abolish their function or using T-DNA to insert natural alleles from the plant back into a genotypically null background to recreate natural variation. The project also utilizes 100s of natural genotypes of the pathogen, Botrytis cinerea. There are no transgenic pathogens generated and these are only used to infect natural or transgenic Arabidopsis as well as naturally occuring genotypes of other plants including Tomatoes, cucurbits, basil, grapes, soybean and pepper.

BIO protocols not approved-BIO will be deployed Jan 2014

D. SOPs for Courses and Core Facilities: NONE

E. BUAs reviewed and approved by IBC assigned reviewers via e-mail (no recombinant work)

R BUA No. 0785-04 NIH: Inf agts (zoonotic), BBP BSL: 2, RG: 2 Rev: pb

(NHP blood and tissues)

Title: Mucosal immunity to respiratory pathogens

Project Summary:

This study is designed to develop an influenza infection model in infant monkeys. Infant and juvenile monkeys will be inoculated with H1N1 A/California/04/09 (while housed indoors). Swab and lavage samples are centrifuged in sealed containers in 1243 for RNA and protein collection. Serum is collected from blood samples by centrifugation. All processing takes place in the and Medical waste will be generated. Sharps will be used for blood draws only.

Approval DATE: 7/19/2013

R BUA No. 0785-06 NIH: Inf agts (zoonotic), BBP BSL: 2, RG: 2 Rev: pb

(NHP blood and tissues)

Title: Host–microbe cross-talk and pregnancy outcomes

Project Summary:

Pregnant rhesus macaques will undergo an intra-amniotic injection of *Ureaplasma*. Decidua and placental tissues will be collected for analyses including flow, gene expression and protein studies in order to understand inflammatory responses in Ureaplasma-exposed fetuses. Medical waste will be generated. Sharps will be used during blood draw and tissue collection.

Approval DATE: 7/19/2013

F. Conditional BUAs reviewed by ABSO, Final Approval by BSO: NONE

G. Terminated BUAs:

BUA No. **0739-02** Rev: nld

Title: Generation of tumor stem cell lines for directed therapeutics of brain cancer

BUA No. **0785-02** Rev: nld

Title: Role of eotaxin-3/CCL26 in allergic asthma

BUA No. 0813

Title: Storage Only: E. coli EC5

V. Discussion Items:

- 1. Niki Discuss removing requirement for BBPECP for unfixed NHP tissues and cells. Tabled to Sept
- 2. Roger Discuss post-exposure prophylaxis for lentiviral vector exposure. Tabled to Sept
- 3. Roger Discuss Occupational Health Surveillance System (OHSS)
- 4. Philip Vote whether or not to use BIO for UC Davis BUAs Approved to start research BUAs in Jan. 2014 and approved HGT BUAs immediately (HGT BUAs do not expire).
- 5. Malendia Update: confirming phenotype of correct strain of Salmonella. Tabled to Sept

VI. Information Items:

1. PB - Informed committee that we received the CDC Select Agent inspection letter

VII. IBC Training: NONE

VIII. BSL3 Laboratory Information: NONE

IX. Notifications:

- 1. CDC Inspection letter received
- 2. MOU forwarded to Campus Counsel

X. Subcommittee Topics: NONE

End Time: 5:24p.m.

Institutional Biosafety Committee, UC Davis Office of Environmental Health and Safety

MINUTES

September 16, 2013 (3-5p)

Hoagland Hall Rm 130

NOTE: Next IBC meeting: 10/21/2013

Start Time: 3:07pm

In attendance:

Philip Barruel Voting Member, BioSafety Officer, Environmental Health and Safety

Savithramma Dinesh-Kumar Voting Member, Plant Biology

Angela Gelli Voting Member, Chair, Pharmacology

Diane Hoffmann Voting Member, School of Medicine Sponsored Programs

Fred Jacobsen Voting Member, Public Member Elizabeth Maga Voting Member, Animal Science Lyle Najita Voting Member, Public Member

Renee Tsolis Voting Member, Medical Microbiology & Immunology Victor Lukas Non-Voting Ex-Officio Member, Attending Veterinarian

Roger Belcourt Non-Voting Ex-Officio Member, Occupational Health Services

IBC support staff in attendance:

Niki Drazenovich Associate BioSafety Officer, Environmental Health and Safety Malendia Maccree Associate BioSafety Officer, Environmental Health and Safety

Excused:

Jill Blackwelder-Parker Non-Voting Ex-Officio Member, Associate Vice Chancellor, Safety Services

Neil Speth Non-Voting Ex-Officio Member, UCDMC Employee Health Services

Gerhard Bauer Voting Member, Vice-Chair, IM Div of Hematology/Oncology

Nicole Corley Voting Member, Campus Veterinary Services
Bruce Draper Voting Member, Molecular & Cellular Biology

Dan Kliebenstein Voting Member, Plant Science

Guests:

George Thompson, MED: MMI

Greg Hodge, MED: MMI

I. Review of past IBC meeting minutes: August 19, 2013

APPROVED (7-0-0)

II. Announcements: NONE

III. Old Business: NONE

IV. New Business:

1. BSL2:

R BUA No. **0671**NIH: Inf agts (human), IIID2a,
BBP (est human cells), IIIF8 (App CII)

BSL: 2, RG: 2

Rev: nld

Title: <u>Human fungal pathogenesis: Resolving the molecular basis of the fungal-brain endothelium</u>

interrelationship

Project Summary:

The project seeks to better understand how *Cryptococcus* spp., invades the central nervous system (CNS) by resolving the molecular interactions between *Cryptococcus* and the brain endothelium. A multidisciplinary approach will be used to identify and characterize both pathogen and host proteins in an effort to develop new therapeutic approaches to prevent fungal disease and to exploit the invasion tactics of *Cryptococcus* in order to develop novel drug-delivery vehicles for the brain. This project will involve proteomic screens, RNAseq, nanotechnology, an in vitro model of the human blood-brain barrier and animal models to validate the role of the target proteins in CNS invasion and to develop a prototype of a brain-specific drug delivery system. Medical waste will be generated and sharps will be used.

APPROVED (7-0-1) (A. Gelli abstained)

R BUA No. **0730**NIH: IIID4a, BBP (est human cells),
IIIF8 (App CII)

BSL: 2, RG: 1

Rev: nld

Title: Reproduction, embryo development and growth of the fish

Project Summary:

The goal of the research is to identify the molecular mechanisms of fertilization, oocyte growth and embryogenesis such as the cardiovascular system development in the embryo of the fish. Another goal is to identify the function of proteins related to establish immune system in the body and relationship between the effects of salmon milt extract in the cells and the molecular mechanisms of immune system development and cell differentiation and proliferation. Transgenic medaka and zebrafish will be generated to assess the endocrine disrupting substances in the water. They will also be generated to understand the functions of immune-system-development related molecules during embryogenesis and in the mature body. Established human cell lines will be used not only to understand the mechanisms of immune system development in the cells acquired by addition of the salmon milt extract in the media but also to understand the relationship between the molecular mechanisms of immune system development and cell differentiation and proliferation. Furthermore, Cultured lined cells, particularly, MCF7 cells will be used to assess the endocrine disrupting substances in the water. No sharps will be used and medical waste generated.

CONDITIONAL (8-0-0)

- Sec 1, Risk minimization checkboxes, sharps safety You've indicated that you won't be using sharps however sharps will be used to inject DNA into the embryos of fish. Please complete the sharps information in this section, specifically what would happen if the trans-gene was accidentally auto-inoculated into a person.
- Sec 6, Training It was noted at the committee meeting that you had no training specified and upon review of the on-line training system it appears that you still need to take a Biosafety and Medical Waste Management course and the on-line Safe Use of BSC class. You can access both classes at the following website: lms.ucdavis.edu.

NIH: IIID4a, IIIE, BBP (est human and NHP cells), IIIF8 (App CI, CII, CIII)

R BUA No. 0824

Rev: pb

Title: The role of nuclear positioning in development

Project Summary:

The investigators will generate and work with transgenic *Caenorhabditis elegans* that express fluorescent proteins and nematode DNA to study the role of nuclear positioning in development. Investigators will also study how KASH and SUN proteins are targeted to the nuclear envelope and how they function in HeLa cells. These studies are an extension of the studies in *C. elegans*. Investigators will also create transgenic zebrafish that express recombinant KASH proteins (C-tail-anchored membrane proteins, which are targeted specifically to the outer membrane of the nuclear envelope) to study collective cell migration in development. Medical waste will be generated.

APPROVED (8-0-0)

R BUA No. 0781

NIH: Inf agts (zoonotic, plants), BBP (nhp est cells), IIIE, IIIF8 (App CI, CII)

BSL: 2, RG: 3

Rev: pb

BSL: 2, RG: 1

Title: <u>Structural studies on virus replication cycles</u>

Project Summary:

The aim of the research is to analyze the morphological changes of both virus and its host cell during virus entry process with the combination of electron and optical microscopies. First, electron microscopy will be used to determine the structure of virus or viral components. Second, by combining electron tomography and optical fluorescence microscopy, the replication pathway will be analyzed to understand how the virus interacts with the receptors, traveling within the cell to understand the mechanism the virus uses to rearrange the cellular membrane system. Third, in collaboration with the virus-like particles of hepatitis E virus will be modified to create an oral delivery system for better activation of mucosal immunity. Medical waste will be generated.

TABLED

Special IBC session via conference call was held on 9/23/2013 at 11:05 a.m. Attendees included: Lyle N, Gerhard B, Savithrama D, Nicole C, Diane H, Angela G, Philip B, Renee T and Malendia M. IBC discussion:

- Semliki Forest Virus has been removed from the BUA renewal.
- The researchers have explained the HEV-VLP (page 10 of the BUA).
- Dinesh Rice dwarf virus (do they have an import permit for importing this material?). How are they getting a P2 protein-deleted virus and then looking at its structure(if P2 is needed to assemble the virus)? If the P2 is the capsid protein, what are the lab actually doing to create a virus and get it to the US?

Researcher response – "We had permit for import of the rice dwarf virus. Because we do not plan to import more virus from Japan in the next two years so we did not renew the permit after that one is expired. We will apply for a new permit if we do need virus from Japan."

Dinesh – was OK with this response and asked that their BUA is clarified to explicitly state that they will only work with rice dwarf virus that that they already have. Should they need additional rice dwarf virus from Japan, they will re-activate their import permit.

Meeting adjourned: 11:31am

NIH: Inf agts (animals), IIID4a, IIID3a (adeno), IIID3e(mcmv), BBP (est human and nhp cells), IIIF8 (App

R BUA No. 0553

BSL: 2, RG: 2 Rev: nld

CID

Title: <u>Development of vaccines for treatment of cancer and prevention of infectious diseases</u>

Project Summary:

The goals of experiments are i) to characterize antiviral immune responses in specific pathogen-free cats after inoculation with pathogenic feline corornavirus isolates; ii) to characterize immune responses in pet dogs and cats (clinical cases from the UCD Veterinary Oncology Service) either diagnosed with various cancer syndromes or dogs vaccinated with the commercial canine melanoma vaccine; iii) to characterize murine cytomegaloviruses as vaccine vectors for cancer vaccines in dogs; iv) mammalian and bacterial expression plasmids for individual FIV genes (wild type and mutant vif and orf-A) will be used for assessment of function in the virus replication cycle and in cell viability and cell function and v) to characterize cellular immune responses in research beagles immunized by a cancer vaccine approach based on expression of selected universal xenogenic cancer antigens expressed by an expression plasmid (DNA) (priming and boosting immunizations) and a replication incompetent adenovirus type 5 (boosting immunization). Sharps will be used and medical waste generated.

APPROVED (8-0-0)

2. Bloodborne Pathogen Protocols:

R BUA No. 0636B

BBP (human and NHP blood and tissues)

BSL: 2, no agts

Rev: pb

Title: <u>Assays and procedures for measuring metabolic analytes in humans and non-human primates</u>
Project Summary:

The investigators will analyze human and non-human primate blood and tissues for various metabolic analytes (e.g. assay various hormones and metabolites related to obesity and diabetes). They will be using sharps and generating medical waste.

APPROVED (8-0-0)

R BUA No. 0909-02B BBP (primary and est human cells) BSL: 2, no agts Rev: nld
Title: In vitro study of primary cells involved in inflammation in human models of health and disease
Project Summary:

These studies will use primary human endothelial cell lines and established cell lines to study the process of differentiation in myeloid cells, specifically focusing on differentiation into mature neutrophils. In addition, primary monocytes and circulating isolated from human blood will be used to study the expression and function of membrane adhesion molecules during recruitment in the context of atherogenesis and cardiovascular disease. Sharps will be used and medical waste generated.

APPROVED (8-0-0)

R BUA No. **0931B**BBP (human and NHP tissue and est human cells)

BSL: 2, no agts

Rev: nld

Title: Metabolic mechanisms of naphthalene toxicity in lung

Project Summary:

The lab studies potential adverse effects of various agents on the human lung using NHP tissue and human cells. Medical waste will be generated and sharps will be used.

BBP (primary human blood/cells, primary

NHP cells, est human and NHP cells),

IIIF8 (App CII)

Title: Potassium channels as novel pharmacological targets for the treatment of autoimmune diseases,

cardiovascular pathologies and neurological disorders

Project Summary:

R BUA No. 0944B

The laboratory is designing new potassium channel modulators as research tools and as potential drugs. Of particular interest are the voltage-gated Kv1.3 and the calcium-activated KCa3.1 channels in immune cells and in the calcium-activated KCa2/3 channels in the cardiovascular and nervous system. Another project involves the design of activators of small- and intermediate-conductance calcium-activated potassium channel modulators as potential therapeutics for the treatment of ataxia, epilepsy and hypertension. Work will involve primary human blood and cells, primary NHP cells as well as established human and NHP cell lines. Sharps will be used and medical waste generated.

APPROVED (8-0-0)

R BUA No. 0939B

blood), IIIF8 (App CI, CII, CVII, CVIII)

BSL: 2, RG: 1

Rev: nld

Rev: mmm

Title: Expression of the fragile X gene

Project Summary:

The project is focused on the mechanism(s) by which the fragile X (FMR1) gene gives rise to a variety of neurodevelopmental and neurodegenerative disorders. Studies involve blood cells and tissues derived from patients with these disorders, control patients, including those with unrelated neurodevelopmental/degenerative disorders as outgroup controls models for both small FMR1 CGG-repeat expansions and normal FMR1 controls. Human cells and *E. coli* K12 strains are used as hosts for plasmids. Medical waste will be generated. Sharps will be used for tissue dissection.

APPROVED (8-0-0)

R BUA No. 0936B BBP (human tissues and cells) BSL: 2, no agts Rev: mmm

Title: Isolation and study of human primary skin and blood cells

Project Summary:

Isolate and irradiate cells in order to study the effects of Low Dose Ionizing Radiation. Currently only human primary skin cells are being used, but human blood cells may also be used in the future. Scalpels and razor blades will be used to cut skin for cell isolation. Following isolation, all cells will be grown in vitro. Cell manipulation includes pipeting and centrifugation. Medical waste and sharps waste will be generated.

APPROVED (8-0-0)

3. **BSL1**:

R BUA No. 0827 NIH: IIID4a, IIIE, IIIF8 (App CII) BSL: 1, RG: 1 Rev: pb

Title: Genetic and developmental mechanisms of evolutionary innovations

Project Summary:

The research is focused on studying the mechanisms of transcriptional regulation in *Drosophila* by generating reporter constructs consisting of native *Drosophila* non-coding DNA and coding sequences of standard reporter proteins Gal4, GFP, and RFP. Non-coding regulatory sequences, but not proteins, will be modified as needed to study gene regulation. Recombinant constructs will be introduced into *Drosophila* embryos by microinjection. None of the components or their combinations are known to be hazardous.

APPROVED (8-0-0)

4. IBC Notification Simultaneous with Initiation (NIH III-E):

R BUA No. **0021-02** NIH: IIIE2a **BSL: 1, RG: 1** Rev: mmm

Title: <u>Functional studies of parasitic plant genes</u>

Project Summary:

Genes active in the parasitic plant species *Triphysaria versicolor* and *T. pusilla* will be cloned in into *Agrobacterium*-based vectors and transformed into parasitic (*Triphysaria*) and non-parasitic (tomato, *Arabidopsis, Medicago*) plants to investigate their expression patterns and biological functions. The bacteria used in plant transformations are attenuated versions of naturally occurring plant pathogens and symbionts.

APPROVED (8-0-0)

R BUA No. 0081 NIH: IIIE, IIIF8 (App CII, CII) BSL: 1, RG: 1 Rev: pb

Title: <u>Stress signal transduction pathway in Schizosaccharomyces pombe</u>

Project Summary:

The investigators will study the function of stress response genes in the fission yeast *Schizosaccharomyces pombe*, which is used to brew millet beer. The investigators will perform knockout of stress genes in *S. pombe* and expression of them in *E. coli* and in *S. cerevisiae* for the analysis of the gene products. No medical waste or sharps will be used.

APPROVED (8-0-0)

R BUA No. 0715 NIH: IIIE2a, IIIF8 (App CII) BSL: 1, RG: 1 Rev: mmm

Title: <u>Investigation of genes controlling quantitatively inherited traits in tomato</u>

Project Summary:

The research program involves genetic and genomic analyses of quantitatively inherited traits in cultivated tomato (*Solanum lycopersicum*) and wild tomato spp. Analysis will involve QTL mapping, candidate gene identification and functional analyses. Methods will include gene cloning, *Agrobacterium*-mediated transformation, and gene silencing to determine the causal genes involved. will be conducted according to USDA-APHIS

APPROVED (8-0-0)

R BUA No. 0798 NIH: IIIE2a, IIIE, IIIF8 (App CII) BSL: 1, RG: 1 Rev: mmm

Title: Molecular and biochemical aspects of aroma production and regulation in fruits

The overall project goal is to discover genes involved in aroma production in plants. DNA corresponding to these plant genes will be inserted into attenuated strains of *E. coli* or plant-specific *Agrobacterium* strains to study their function by knock-down or overexpression in a plant system. Transgenic plants will be generated and studied in the lab and greenhouse.

APPROVED (8-0-0)

R BUA No. 0820 NIH: IIIE3 BSL: 1, no agts Rev: nld

Title: <u>Cell lineage specific manipulation of gene expression in the mouse nervous system</u> Project Summary:

This BUA covers development of novel mutant mouse strains. Our research projects require animal models in which the expression of a gene of interest is manipulated in a specific cell lineage in the nervous system to discriminate its direct effects on the lineage from indirect effects through other cell lineages or by defects in other organs. Those mice will be analyzed histologically, and cells from those mice will be prepared for in vitro assays. Sharps will be used.

APPROVED (8-0-0)

R BUA No. 0932 NIH: IIIE2a (plants only) BSL: 1, no agts Rev: mmm

Title: Signaling in root nodule symbioses

Project Summary:

Transgenic *Lotus japonicus* seedlings expressing β -glucuronidase (GUS) reporter gene are used in a bioassay to test root responses to a suite of potential nod factor-like molecules that we will extract from wild-type Frankia (*Actinomycetales*). Plants were previously transformed at the and current research is limited to propagation of existing plant lines by seed. No plant transformations will be conducted. Transgenic plants and materials mixed with or contaminated with transgenic plant parts will be autoclaved before disposal.

APPROVED (8-0-0)

5. Storage ONLY:

Title: STORAGE ONLY: Human cell lines

APPROVED (8-0-0)

Title: STORAGE ONLY: Established human cell lines

APPROVED (8-0-0)

6. Exempt Protocols Approved by BSO: NONE

B. Amendments:

Amend **0982(B)** NIH: BBP (est human cells) **BSL: 2, no agts** Rev: nld

Title: Sample preparation for oligosaccharide analysis

Amendment to add: Culture of established human cells

Exp date: 08/15/2014 APPROVED (8-0-0)

Amend **0818(B)** NIH: IIID4a **BSL: 2, no agts** Rev: nld

Title: Congenital Myasthenic Syndromes: Pathogenic mechanisms

Amendment to add: Injecting lentiviral transduced mouse cells expressing ColQ into mice

Exp date: 12/20/2013
APPROVED (8-0-0)

Amend **0050(A)** NIH: IIIE **BSL: 1, RG: 1** Rev: nld

Title: Mitochondrial dynamics in mammalian systems

Amendment to add: E. coli BL21 cells will be transformed with a Vps1-containing plasmids for

protein over-expression

Exp date: 04/18/2014
APPROVED (8-0-0)

Amend 1001B(A) NIH: BBP (human tissue) BSL: 2, no agts Rev: pb

Title: Systemic and local inflammation in renal transplantation

Amendment to add: 1. Experimentation with unfixed human and sheep kidneys

2. Culture human and sheep stem cells derived from renal, bone, skin, fat, and

placental tissues

Exp date: 02/27/2015
APPROVED (8-0-0)

Amend 0347-01(B) NIH: Inf agts (animal) BSL: 2, RG: 1 Rev: nld

Title: Molecular and cell studies with infectious agents

Amendment to add: Mouse inoculations with non-zoonotic murine infectious agents and recombinant

proteins

Exp date: 07/18/2014 APPROVED (8-0-0)

Amend 1044(B) NIH: Inf agts (plants) BSL: 1, RG: 1 Rev: mmm

Title: Ecology, epidemiology, and control of fungal disease and post-harvest contaminants of fruit and nut

crops and vines

Amendment to add: Procedure: mechanical slicing test of A. flavus infected almonds in Bainer Hall

Rm 1324A

Exp date: 04/15/2016 APPROVED (8-0-0)

Amend 0785-05(A) NIH: Inf agt (zoonotic) BSL: 2, RG: 2 Rev: pb

Title: Th17 Cells and Tregs in Candidal vaginal colonization of macaques

Amendment to add: Culture Candida spp. at the

Exp date: 11/19/2015 APPROVED (8-0-0)

MC Amend **0900-03(C)** NIH: Inf agts (human) **BSL: 2, 3, RG: 3** Rev: nld

Title: <u>Human pathogenic fungal research</u>

Amendment to add: 1. Coccidioides immitis and C. posadasii (culture and analysis)

2. Coccidioides co-culture with human cells

3. Analysis of environmental samples (likely to contain *Coccidioides*)

4. C. immitis and C. posadasii experimental infections of mice and Galleria

mellonella (moth)

Exp date: 05/21/2015 APPROVED (8-0-0)

C. SOPs for Courses and Core Facilities: NONE

D. Conditional BUAs reviewed by ABSO, Final Approval by BSO: NONE

E. Terminated BUAs:

BUA No. **0346** Rev: nld

Title: Genetic analysis of root-knot nematodes

BUA No. 0628B Rev: nld

Title: <u>Neurological studies on non-human primates</u>

BUA No. **0901** Rev: nld

Title: RNAi identification of wild caught C. elegans

BUA No. **0942-01** Rev: nld

Title: <u>Human NK cell mediated therapies against xenogeneic tumors</u>

V. Discussion Items:

- 1. Niki Discuss removing requirement for BBPECP for unfixed NHP tissues and cells. IBC agreed researchers using NHP materials do not need to complete a Bloodborne Pathogen Exposure Control Plan.
- 2. Roger Discuss post-exposure prophylaxis for lentiviral vector exposure.
- 3. Malendia Update: confirming phenotype of correct strain of Salmonella. No update

VI. Information Items:

- 1. Philip IBC non-disclosure agreement (NDA PDF sent with IBC agenda). Passed out and will collect signed forms from all committee members.
- 2. Philip IBC Operating Procedure changes Biggest change is the proposal to change Vet & Occ Health Doctors to voting members, (the revised SOP will be emailed to IBC members before next meeting). Vote to take place at the beginning of the October 2013 IBC meeting and if approved will go into effect at that meeting.

VII. IBC Training: NONE

VIII. BSL3 Laboratory Information: NONE

IX. Notifications: NONE

X. Subcommittee Topics: NONE

End Time: 5:02p.m.

Institutional Biosafety Committee, UC Davis Office of Environmental Health and Safety

MINUTES

October 21, 2013

Hoagland Hall Rm 130

NOTE: Next IBC meeting: 11/18/2013

Start Time: 3:05pm

In attendance:

Gerhard Bauer Voting Member, Vice-Chair, IM Div of Hematology/Oncology

Nicole Corley Voting Member, Campus Veterinary Services

Savithramma Dinesh-Kumar Voting Member, Plant Biology

Bruce Draper Voting Member, Molecular & Cellular Biology

Angela Gelli Voting Member, Chair, Pharmacology

Diane Hoffmann Voting Member, School of Medicine Sponsored Programs

Fred Jacobsen Voting Member, Public Member Elizabeth Maga Voting Member, Animal Science

Roger Belcourt Voting Ex-Officio Member, Occupational Health Services

IBC support staff in attendance:

Malendia Maccree Associate BioSafety Officer, Environmental Health and Safety

Present via ReadyTalk:

Philip Barruel Voting Member, BioSafety Officer, Environmental Health and Safety

Niki Drazenovich Associate BioSafety Officer, Environmental Health and Safety

Excused:

Jill Blackwelder-Parker Non-Voting Ex-Officio Member, Associate Vice Chancellor, Safety Services

Neil Speth Non-Voting Ex-Officio Member, UCDMC Employee Health Services

Dan Kliebenstein Voting Member, Plant Science

Renee Tsolis Voting Member, Medical Microbiology & Immunology Victor Lukas Voting Ex-Officio Member, Attending Veterinarian

Guests:

Marc Dall'Era, School of Medicine, Dept of Urology

Lou Adamson, CCM

I. Review of past IBC meeting minutes: September 16, 2013

APPROVED (9-2-0) NC & BD abstained

II. Announcements:

1. Vote on adopting revised IBC Operating Procedures and including Vic L and Roger B as voting members

III. Old Business: NONE

IV. **New Business:**

Human Gene Transfer:

N BUA No. C1491 NIH: IIIC BSL: 2, no agts Rev: mmm

Title: An Integrated Phase II/III, Open Label, Randomized, Parallel and Controlled Study of the Safety and Efficacy of CG0070 Oncolytic Vector Regimen in Patients With Non-Muscle Invasive Bladder

Carcinoma In Situ Disease and Who Have Failed BCG Therapy and Refused Cystectomy

Project Summary:

The primary objective of this clinical trial is to investigate whether the study drug, CG0070, is safe and effective for the treatment of NMIBC patients with high grade carcinoma in situ (CIS) or CIS with Ta and/or T1 disease who have failed live Mycobacterium bovis (BCG) therapy and refused cystectomy. If proven effective, the ultimate objective of the trial is to delay or avoid cystectomy in this group of patients. The secondary objectives of the trial are to compare the effects of CG0070 and control therapy with respect to cystectomy-free survival, overall survival, complete response survival, and time to progression to muscle invasive disease. The rationale for the present study is based on the unmet need for drug therapies in the above-mentioned population.

Conditional (11-0-0)

Informed consent document: Informed consent document must be revised to inform participants of

- previous issue with adenoviral vector drugs and clarify difference in current study drug which 1. distinguishes it from previous drug trials.
- IRB review: UC Davis IRB approval must be obtained before enrolling patients in the study at UC 2.
- Davis (using revised informed consent form).

2. BSL3:

NIH: Inf agts (human), BBP (est R BUA No. 0347-02 Rev: nld BSL: 3, RG: 3 human cells and NHP tissues)

Titration of Mycobacterium tuberculosis by bacterial culture Title:

Project Summary:

This project will analyze M.tb. bacterial load in lung and lymphoid tissue from macaques experimentally infected with the clinical M.tb. Erdman strain. In addition, this project will infect and analyze human macrophage cell lines in human lung cells with the clinical M.tb.Erdman strain. Sharps will not be used and medical waste will be generated.

APPROVED (11-0-0)

BSL2: 3.

N BUA No. 0459-05 NIH: Inf agts (zoonotic), IIID1a BSL: 2, RG: 2 Rev: mmm

Title: Social hierarchy influences immunomodulatory nutrient consumption and rate of transmission of

Salmonella enteritidis

Project Summary:

A dose of green fluorescent protein-labeled Salmonella enterica serovar Enteritidis (SE) will be given to Hy-Line W-36 chicks to induce a subclinical immune response. The immunomodulatory nutrients lutein, vitamin E and/or Poly-unsaturated fatty acids will be added to the feed to determine appropriate doses for treatment. Sharps will be used and medical waste generated.

Conditional (11-0-0)

Principal Investigator must complete required biosafety training 1.

R BUA No. 0829-02

(primary human cells)

BSL: 2, RG: 2 Rev: nld

Title: <u>Labeling mesenchymal stem cells (MSCs) for tracking in vivo and in vitro</u>

Project Summary:

Lentiviral vectors are used for the transduction of primary cells (transferring specific genes into MSCs). Such transduced cells will then be tested in vitro and in vivo, for localization, homing, and cell migration studies. By tracking MSCs after injection into animals, the hope is to ascertain whether injected cells remain localized in regions of tissue repair. Transduction will be confirmed by fluorescence microscopy and/or flow cytometry. Transduced cells will be used for in vitro and in vivo (horse, dog, sheep and mice) cell localization, homing, and migration studies. Sharps will be used and medical waste generated.

TABLED (11-0-0)

Sec 1, Disposal practices, animal carcasses – The animals injected with recombinant cells need be

- 1. euthanized and incinerated (via Stericycle) at the end of the study. Please indicate that carcasses will be disposed by Stericycle well as biopsy and tissue samples.
- 2. Sec 1, Risk minimization checkboxes, animal work I indicated that you will identify the animals inoculated with transduced cells as transgenic.
- 3. Sec 2D, #6 The committee had a few concerns on how the animals injected with transduced cells would be housed (were they going to be segregated from other non-transgenic animals?). Sec 2D, #6 In addition, it needs to be specified how the animals (mice, dogs, sheep and horses) injected with transduced cells will be handled after the study is over and what the timing of that will
- be in regards to when the study ends. Will they be euthanized immediately after the study or will you be using them for other studies?

R BUA No. 0941

 $NIH:\,IIID4a,\,BBP\;(\text{est human cells}),$

IIIF8 (App CII, CVII, CVIII)

BSL: 2, RG: 1

Rev: pb

Title: <u>Investigating the molecular and genetic mechanisms of neural development using recombinant vectors and transgenic mice</u>

Project Summary:

The investigators are researching molecules that are hypothesized to be regulators of brain development affecting patterning, migration, and connectivity of various neuronal cell types. FVB and BL6 breeds of mice, Invitrogen pcDNA and TOPO mammalian expression vectors will be used. The experiments will involve hazardous manipulations include pipetting, surgical procedures (needles, scalpels, tweezers), generation of medical waste (mouse carcasses/lab waste), and generation of sharps waste (needles, razors).

APPROVED (10-1-0) pb abstained

R BUA No. 0955

NIH: Inf agts (animals), BBP (human blood)

BSL: 2, RG: 1

Rev: pb

Title: The blood clot as an agent of the innate immune system

Project Summary:

The blood clot can immobilize select microorganisms that become entrapped in the fibrin clot. The researcher will investigate whether the blood clot is, in addition, adhesive to various microorganisms and will investigate the survival/cytolysis of microorganisms entrapped within or bound to the fibrin clot. Microorganisms will be non-pathogenic bacteria and *Trypanosome brucei brucei* a human non-pathogenic trypanosome. Medical waste will be generated. Sharps will be used for the collection of blood.

APPROVED (10-1-0) pb abstained

N BUA No. 1062 NIH: IIID3b(lenti), IIIE, BBP (est

human cells), IIIF8 (App CII)

Title: Decoding signaling dynamics at the single-cell level

Project Summary:

In this project, recombinant DNA plasmids are designed and constructed to encode fluorescent biosensors of protein activity. These plasmids are then introduced into human, murine, or C. elegans cell lines by direct transfection, or by generation of retroviral or lentiviral vectors. The resulting cell lines are propagated and studied by live-cell microscopy. Medical waste will be generated. No sharps will be used.

BSL: 2, RG: 2

Rev: mmm

APPROVED (11-0-0)

4. Bloodborne Pathogen Protocols:

R BUA No. 0919B BBP (human tissue) BSL: 2, no agts Rev: nld
Title: Human progenitor cells for accelerating bone repair, neovascularization, and wound healing
Project Summary:

Human adipose stem cells will be isolated and cultured after digestion of human adipose tissue from healthy donors. After expansion to a sufficient number, adipose stem cells will be incorporated in novel biomaterials, and their capacity to promote neovascularization and bone formation will be examined using both in vitro and in vivo models. Sharps (scalpels, needles) will be used during biomaterial fabrication and medical waste will be generated.

TABLED (11-0-0)

Sec 4, BBP Research Project, Animal work – It cites (16316) which details injecting mice with lentiviral transduced cells. You are listed on the roster of that ACUP but

- not on his BUA as an authorized user. Depending on your involvement and what materials you will be handling please make one of the following modifications:
- a. If you are not handling any of the lentiviral transduced material (either cells or tissue containing the cells) please delete all the project information from this BUA.

If you are handling the transduced material you can either be added to BUA as an authorized user (via amendment) if the work you are doing is covered by his BUA or if you are receiving the material and then doing your own research with it (not detailed in BUA) the

- the work just needs to be more fully described here (i.e. what material exactly you will be working with and that you are getting the recombinant material from lab via his ACUP).
- R BUA No. 0950B BBP (primary human blood and cells) BSL: 2, no agts Rev: pb
 Title: Analyses of DNA/RNA from human blood in neurological and neurodevelopmental disorders
 Project Summary:

Multiple projects in the laboratory examine genetic and transcriptional information of patients with various underlying pathologies (primarily ischemic or hemorrhagic stroke) or neurodevelopmental disorders (autism, Tourette Syndrome). All these studies share the common link of using human blood samples as the source from which DNA or RNA is isolated. Solid medical waste is generated and no sharps are used in these protocols.

APPROVED (10-1-0) pb abstained

R BUA No. 0954B BBP (human blood and tissues) BSL: 2, no agts Rev: mmm

Title: Fragile X molecular diagnosis of human specimens

Project Summary:

DNA and RNA will be isolated in order to analyze for Fragile X in human blood, tissue (e.g. brain) and cells (e.g. leukocytes). Blood samples will also be received from patients with other neurodevelopmental disorders including ASD and 22q deletion syndrome. Sharps will be used and medical waste generated.

APPROVED (11-0-0)

N BUA No. 1060B BBP (human blood and primary cells) BSL: 2, no agts Rev: nld

Title: Randomized trial of L-arginine in severe asthma patients grouped by exhaled nitric oxide levels Project Summary:

A subset of adult severe asthma patients supplemented with L-arginine will be studied to derive the clinical benefits from the addition of this therapy to standard-of-care medicine. Samples collected will be human blood, tracheobronchial epithelial cells and bronchial alveolar lavage. Sharps will not be used and medical waste generated.

APPROVED (11-0-0)

5. BSL1:

R BUA No. **0089** NIH: IIID4a, IIIIE1, IIIF8 (App BSL: 1, RG: 1 Rev: mmm

Title: Thyroid and glucocorticoid control of gene expression during development and homeostasis Project Summary:

The project is focused on studying the mechanisms of gene expression changes in response to extracellular signals like thyroid hormone and glucocorticoids, during amphibian metamorphosis or mammalian skeletal muscle atrophy. Frogs and mice will be used, as well as cultured cell lines. Recombinant plasmids will be created for studies in transfected cultured cells and transgenic animals, and needles will be used to inject hormones into frogs.

APPROVED (11-0-0)

N BUA No. 1058 NIH: IIID4a, IIIF8 (App CVII) BSL: 1, RG: 1 Rev: mmm

Title: Optogenetic stimulation of the rostral ventromedial medulla in mice

Project Summary:

It is known that serotonin- and noradrenalin-containing neurons in the rostral ventromedial medulla (RVM) are involved in descending pain modulation. The goal is to selectively activate or deactivate serotonergic and noradrenergic neurons in RVM optogenetically while the animal (mouse) is engaged in pain-related (nocifensive) behavior or itch-related scratching behavior. To selectively target serotonergic neurons in the RVM, a doublefloxed (DIO) Cre-dependent adeno-associated virus (AAV) vector expressing channelrhodopsin-2 (ChR2) fused with enhanced yellow fluorescent protein (eYFP) will be injected into mice. Mouse carcasses will be disposed in medical waste stream. All other biological waste will be treated with beach or autoclaved.

APPROVED (11-0-0)

N BUA No. 1059 NIH: Inf agts (plant) BSL: 1, RG: 1 Rev: mmm

Title: Genomics of disease resistance and fungal pathogenicity in grape

Project Summary:

The research focuses on the interaction between plants and microorganisms. Genomics and computational biology will be used to study how plants respond to pathogen infections and how microorganisms cause disease in plants. Current studies are focused on fungal pathogens and Grapevine (Vitis spp.) hosts. Plant infections will be conducted in the lab and growthchamber. Sterile scalpels and spatulas are used for manipulation of plant pathogenic fungi. Infectious wastes are inactivated before disposal.

APPROVED (11-0-0)

6. IBC Notification Simultaneous with Initiation (NIH III-E):

N BUA No. 1061 NIH: IIIE, IIIF8 (App CII) BSL: 1, RG: 1 Rev: mmm

Title: The engineering of antibacterial artificial cells

Project Summary:

The research aims to engineer protocells using phospholipid membranes and genetic constructs. The genetic constructs consists of coding sequences of antimicrobial peptides and promoters from phages. Research will be conducted in non-infectious *E. coli* strains such as Dh5 alpha and BL21. Expressed DNA does not code for vertebrate toxins, or enhance pathogenicity of the host bacteria. All microbiological waste will be bleached or autoclaved before disposal.

APPROVED (11-0-0)

7. Storage ONLY: NONE

8. Exempt Protocols Approved by BSO: NONE

B. Amendments:

Amend 0383(A) NIH: Inf agts (animal) BSL: 1, RG: 1 Rev: nld

Title: Molecular and epidemiologic characterization of bluetongue virus infection in California ruminants

Amendment to add: Culicoides sonorensis midges (colony strain) experimentally infected with Blue

Tongue Virus (BTV)

Exp date: 08/14/2014
APPROVED (11-0-0)

Amend 0544-02 NIH: Inf agts (animal), BBP (est BSL: 2, RG: 1 Rev: nld

human cells)

Title: Molecular ecology of avain influenza viruses in wild birds and mammals

Amendment to add: 1. Agent: Seal Influenza virus (marine isolate)

2. Procedure: Co-culture of A549 cells (est human cell line) and LPAI (avian and

marine isolates)

3. Procedure: Infecting marine tissue explants with LPAI (avian and marine

isolates)

Exp date: 08/20/2015
APPROVED (11-0-0)

Amend 0683(B) NIH: Inf agts (human) BSL: 2, RG: 2 Rev: nld

Title: <u>Infectious diseases of dogs and cats and zoonotic bloodborne bacterial infections</u>
Amendment to add: <u>Staphylococcus aureus</u> and <u>S. pseudintermedius</u> (culture only)

Exp date: 08/15/2014

APPROVED (11-0-0)

Amend 0753(A) NIH: BBP (est human cells) BSL: 2, no agts Rev: nld

Title: Leukemia stem cells ligand screening/Bladder cancer ligand screening, imaging/Personalized therapy

in NSG mice carrying PDX (new title)

Amendment to add:

1. Human bladder cancer tissues

2. Xenografting bladder tumor tissue onto mice

Exp date: 08/15/2014
APPROVED (11-0-0)

Amend 0796-02(A) NIH: IIID4b BSL: 2, no agts Rev: mmm

Title: Use of human blood/tissue/cell lines and animal models to identify cancer targeting ligands (title

change)

Amendment to add: Use of non-infectious Hepatitis E virus-like particle containing recombinant

plasmid DNA in mice

Exp date: 02/25/2016 APPROVED (11-0-0)

Amend **0915-02B(A)** NIH: BBP (est human cells) **BSL: 2, no agts** Rev: pb

Title: <u>Targeting Signal Transduction Pathways in Cancer</u>

Amendment to add: Intracranial and subcutaneous injection of human cancer cells into mice

Exp date: 02/28/2014

APPROVED (10-1-0) pb abstained

Amend 0996(B) NIH: Inf agts (animal) BSL: 2, RG: 1 Rev: nld

Title: Understanding the molecular and cellular mechanisms of host-pathogen interactions

Amendment to add:

1. Culture low pathogenic avian influenza virus (LPAIV) in chicken embryos and

an established chicken cell line

2. E. coli K12 (culture and infection of day old chicks)

3. New Castle Disease Virus vaccine (LaSota strain-live virus) (host: chickens)

Exp date: 12/19/2014

APPROVED (11-0-0)

Amend 1043(A) NIH: IIID3e (baculo), BBP (est BSL: 2. RG: 1 Rev: pb

human cells)

Title: Nano-engineering approach towards regulation of cellular signaling cascades

Amendment to add: 1. Addition of a human cell line: Primary human umbilical vein endothelial cells

(HUVEC)

2. Baculovirus transfection of human cells

3. Genes: actin and tubulin

Exp date: 05/20/2016

APPROVED (10-1-0) pb abstained

C. SOPs for Courses and Core Facilities: NONE

D. Conditional BUAs reviewed by ABSO, Final Approval by BSO:

R BUA No. 0730 NIH: IIID4a, BBP (est human cells),

BSL: 2, RG: 1 Rev: nld

IIIF8 (App. CII)

Title: Reproduction, embryo development and growth of the fish

Review Date: 09/16/2013

NIH: IIID3e (baculo), IIIE, BBP R BUA No. 0817 BSL: 2, RG: 1 Rev: mmm

(est human cells), IIIF8 (App CII, CVII)

Title: Intracellular protein transport

Review Date: 08/19/2013

E. Terminated BUAs:

BUA No. 0632-02B Rev: nld

Title: Autism phenome project immunohistochemical screening

BUA No. 0822 Rev: nld

Title: Role of Myosin Binding Protein-C in the Regulation of Myocardial Contraction

V. **Discussion Items: NONE**

Information Items: NONE VI.

VII. IBC Training: NONE

VIII. BSL3 Laboratory Information: NONE

IX. **Notifications: NONE**

X. **Subcommittee Topics: NONE**

End Time: 5:23p.m.

Institutional Biosafety Committee, UC Davis Office of Environmental Health and Safety

MINUTES

November 18, 2013 (3-5p)

Hoagland Hall Rm 130

NOTE: Next IBC meeting: 12/16/2013

Start Time: 3:09pm

In attendance:

Philip Barruel Voting Member, Biosafety Officer, Environmental Health and Safety

Nicole Corley Voting Member, Campus Veterinary Services

Savithramma Dinesh-Kumar Voting Member, Plant Biology

Bruce Draper Voting Member, Molecular & Cellular Biology

Angela Gelli Voting Member, Chair, Pharmacology
Fred Jacobsen Voting Member, Public Member
Elizabeth Maga Voting Member, Animal Science
Lyle Najita Voting Member, Public Member

Victor Lukas Voting Ex-Officio Member, Attending Veterinarian

Roger Belcourt Voting Ex-Officio Member, Occupational Health Services

IBC support staff in attendance:

Niki Drazenovich Associate BioSafety Officer, Environmental Health and Safety Malendia Maccree Associate BioSafety Officer, Environmental Health and Safety

Excused:

Renee Tsolis Voting Member, Medical Microbiology & Immunology
Diane Hoffmann Voting Member, School of Medicine Sponsored Programs
Gerhard Bauer Voting Member, Vice-Chair, IM Div of Hematology/Oncology

Dan Kliebenstein Voting Member, Plant Science

Jill Blackwelder-Parker Non-Voting Ex-Officio Member, Associate Vice Chancellor, Safety Services

Neil Speth Non-Voting Ex-Officio Member, UCDMC Employee Health Services

Magalie Guilhabert Voting Member, Public Member

Guests: ****

Richard Michelmore <u>rwmichelmore@ucdavis.edu</u>

Deling "Randy" Ruan Plant Pathology dlruan@ucdavis.edu

I. Review of past IBC meeting minutes: October 21, 2013

APPROVED (8-0-0)

II. Announcements:

1. Discuss tabled BUAs and risk assessment process: VL to follow-up with IACUC on animals in 859-02 protocol

III. Old Business:

1. BSL2:

R BUA No. 0829-02 NIH: IIID3b(lenti), IIID4a, BBP BSL: 2, RG: 2 Rev: nld

Title: <u>Labeling mesenchymal stem cells (MSCs) for tracking in vivo and in vitro</u>

Project Summary:

Lentiviral vectors are used for the transduction of primary cells (transferring specific genes into MSCs). Such transduced cells will then be tested in vitro and in vivo, for localization, homing, and cell migration studies. By tracking MSCs after injection into animals, the hope is to ascertain whether injected cells remain localized in regions of tissue repair. Transduction will be confirmed by fluorescence microscopy and/or flow cytometry. Transduced cells will be used for in vitro and in vivo (horse, dog, sheep and mice) cell localization, homing, and migration studies. Sharps will be used and medical waste generated.

Tabled 10/21/2013

APPROVED (10-0-0)

R BUA No. 0919 BBP (human tissue) BSL: 2, no agts Rev: nld

Title: <u>Human progenitor cells for accelerating bone repair, neovascularization, and wound healing</u> Project Summary:

Human adipose stem cells will be isolated and cultured after digestion of human adipose tissue from healthy donors. After expansion to a sufficient number, adipose stem cells will be incorporated in novel biomaterials, and their capacity to promote neovascularization and bone formation will be examined using both in vitro and in vivo models. Sharps (scalpels, needles) will be used during biomaterial fabrication and medical waste will be generated.

Tabled 10/21/2013

APPROVED (10-0-0)

IV. New Business:

1. BSL2:

R BUA No. **0488**NIH: IIID3e(baculo), BBP (est human cells), IIIE, IIIF8 (App CII, CII)

Rev: pb

Title: Expression, purification, and charaterization of DNA repair proteins

Project Summary:

The focus of the laboratory's research is the biochemical mechanism of DNA repair, and the function of proteins involved in that process. To that end, we express, purify, and characterize proteins that are involved in this process in bacteria, archaea, and eucharya. The proteins are expressed typically in *E. coli, S. cerevisiae*, insect cells (e.g. Sf9), or established cultured human cell lines (e.g. HEK-293). All work that might create hazardous aerosols is performed in a certified biological safety cabinet; any sharps (e.g., scalpels or needles) generated are disposed in specially designated 'sharps' containers; and all material contaminated with human cells are disposed as medical waste.

APPROVED (9-0-0) (pb abstained)

R BUA No. 0740

NIH: IIID3e(retro), IIIE, BBP (est human cells), IIIF8 (App CI, CII)

BSL: 2, RG: 2

human cells), HIF & (App CI, CII)

Title: Destruction of brain tumors through loss-of-function of ATF5

Project Summary:

To develop a translational therapeutic to selectively eradicate brain gliomas and other cancers by systemic delivery of cell penetrating dominant negative ATF5. 1. To test the hypothesis that systemic delivery of recombinant or synthetic dominant negative ATF5 protein (d/n-ATF5) fused with a cell-penetrating domain (CP-d/n-ATF5; Penzip or Tatzip) triggers apoptosis of gliomas in different mouse glioma tumor models while sparing normal cells in brain and other organs. 2. To find the optimal therapeutic dosing for CP-d/n-ATF5 treatment by determining ED90 and TD50 values as well as the plasma and organ half-lives of CP-d/n-ATF5 in brain and other organs in vivo. The in vivo potential will also be explored for cardiotoxicity, hepatotoxicity, nephrotoxicity, and neurotoxicity as well as toxicity in other organs resulting from treatment with the peptide. 3. To test the hypothesis that CP-d/n-ATF5 completely eradicates gliomas without recurrence and if not, that it may be used to retreat recurrent tumors. Sharps will be used and medical waste generated.

APPROVED (10-0-0)

NIH: Inf agt (human, animal), BBP

R BUA No. 0833 (primary and est human and nhp blood, BSL: 2, RG: 2 Rev: nld

tissues and blody fluids)

Title: Marine and terrestrial mammal viral disease diagnosis and surveillance

Project Summary:

The laboratory serves as a marine and terrestrial animal health and disease diagnostic, surveillance and research laboratory. Samples in the form of fresh or frozen feces, blood, serum, swabs and tissues are submitted to us for diagnostic and research purposes. The samples are from live and dead captive, rehabilitating and free-ranging marine mammals and terrestrial wildlife including rodents, bats, carnivores, and primates; as well as from humans. For marine mammal samples the lab primarily focuses on the detection of RNA and DNA viruses including understanding their natural history, pathogenesis, transmission, molecular genetics and association with lesions and disease. This may entail maintaining tissue cultures for virus isolation, molecular analysis, serologic methods and immunohistochemistry and electron microscopy. For human and terrestrial wildlife samples, the laboratory focuses on the detection and characterization of viral RNA and DNA using PCR. Additionally, the laboratory will attempt to detect protozoal DNA from terrestrial wildlife samples using molecular methods, such as PCR. Medical waste and sharps will be generated.

APPROVED (10-0-0)

R BUA No. 0947 NIH: HCV, HBV +ve human BSL: 2, no agts Rev: nld

blood

Title: GI/Hepatology clinical trials, including viral Hepatitis

Project Summary:

Patients will be treated in clinical trials with hepatitis C, hepatitis B, and other liver disease states. Treatment includes the drawing of blood from patients known to have HCV and/or HBV. Blood will be centrifuged in the lab, hematology slides made and serum shipped to a central lab. Sharps will be used and medical waste generated.

APPROVED (10-0-0)

Rev: nld

N BUA No. 1028-02 NIH: Inf agts (human, animal) BSL: 2, RG: 2 Rev: nld

Title: Research in prevention and understanding of poultry diseases

Project Summary:

The rapidly growing world poultry industry has accepted laborsaving technologies in order to improve their management, nutrition, and disease control practices. The first part of the project is looking at in-ovo immunization of chickens. Right now it is one of the most revolutionary and laborsaving technologies and is performed during the chick's embryonic stage. Adjuvants have been used in vaccination to improve the immunogenicity of vaccines especially in killed products. This project will research the efficacy of the diatom *Thalassiosira pseudonana* as a new adjuvant for killed Newcastle disease virus in ovo. The 2nd part of the project is to investigate the shedding patterns and relative virulence of *Salmonella* Heidelberg (SH) under different experimental treatments in order to identify practical methods of reducing SH shedding from broilers at the farm and practical treatments that reduce the presence and virulence of SH in the processing plant. This will involve growing *Salmonella* and subjecting the isolate to different environmental conditions. Sharps will be used and medical waste generated.

APPROVED (10-0-0)

N BUA No. 1063

NIH: IIID3e (aav), IIID4a, BBP (est human cells), IIIF8 (App CII)

BSL: 2, RG: 1

Rev: nld

Title: <u>Investigation of the retinoid cycle of vision in the mammalian</u>

Project Summary:

The long-term goals of this study are to understand and define the functioning of the retinoid cycle of vision in the vertebrate eye. This will advance basic knowledge regarding retinal biology, genetics and evolution, and will lead to more informed diagnosis, treatment, and prevention of devastating human eye diseases. These functional studies in photoreceptor biology will have the potential for eye tissue regeneration, and the molecular basis of human congenital and acquired eye diseases. The goal is to develop molecular sensors of the retinoid cycle. These sensors are fusion proteins in which retinoid binding proteins involved in the visual cycle are fused to fluorescent proteins. These fusion protein sensors will be created in the pUS2 plasmid construct and tested in bacteria (e.g. DH5alpha E. coli) and mammalian cells (e.g. HeLa cells). Once their retinoid sensing ability is verified in vitro, in vivo testing with mice will be done using AAV expressing retinoid sensors. Sharps will be used and medical waste generated.

APPROVED (10-0-0)

N BUA No. 1064 NIH: Inf agts (animal) BSL: 2, RG: 1 Rev: nld

Title: Endometrial tissue concentrations of ceftiofur after intrauterine infusion in healthy mares and those with experimentally induced endometritis

Project Summary:

Bacterial endometritis is a leading cause of infertility in the mare and a major source of economic loss to the equine industry. The use of intrauterine ceftiofur to treat bacterial endometritis is common practice, however evidence-based guidelines for effective dose rates, treatment intervals and lengths are strictly empirical. The aim of this study is to determine pharmacokinetic data of ceftiofur for intrauterine infusion, to help determine an optimal dosing interval for treating mares with bacterial endometritis. The antibiotic ceftiofur will be infused into uteri of both normal mares with healthy uteri and mares with experimentally induced endometritis (*Streptococcus equi* subsp zooepidemicus). Uterine biopsy samples will then be taken over various time points to determine how long ceftiofur remains active in endometrial tissue under healthy and inflammed conditions. Waste generated will be disposed as medical waste.

APPROVED (10-0-0)

2. Bloodborne Pathogen Protocols:

R BUA No. 0869-02B BBP (est human cells) BSL: 2, no agts Rev: nld

Title: <u>Use of human cell lines for cancer research</u>

Project Summary:

The lab will store and culture established human cancer cell lines for the purpose of cancer research. Cell lines will be stored in liquid nitrogen and ultra low temperature lab freezers. Cells will be cultured in the lab for experimental use which will include protein, DNA and/or RNA extraction. Sharps will be used and medical waste generated.

APPROVED (10-0-0)

N BUA No. **0949-03B** BBP (human blood and tissues) **BSL: 2, no agts** Rev: mmm

Title: Developmental issues and environmental exposures associated with autism and other

neurodevelopmental disorders (MARBLES study)

Project Summary:

Research is focused on developmental issues and environmental exposures associated with autism and other neurodevelopmental disorders. Research experiments will involve analysis and manipulation of tissue, blood and other bodily fluids from human subjects. Medical waste will be generated and sharps (scissors) will be used in this work.

APPROVED (10-0-0)

R BUA No. **0953B** BBP (human blood and body fluids) **BSL: 2, no agts** Rev: pb

Title: <u>Human carotenoid metabolism</u>

Project Summary:

Studies on human carotenoid metabolism using foods rich in carotenoids such as beta-cryptoxanthin and beta-carotene, such as tangerines and biofortified cassava. Human subjects will be fed meals containing carotenoid-rich foods, and their blood, urine and feces collected. Blood will be collected by catheter or sharps, with no aerosols generated. Medical waste will be generated, sharps will be used.

APPROVED (9-0-0) (pb abstained)

3. BSL1:

NIH: Inf agts (plants), IIIE2a,

R BUA No. **0274-02** III32b(2)(3)(4), IIIF8 (App CII, **BSL: 1, RG: 1** Rev: mmm

CIII)

Title: Comparative and functional genomics of disease resistance in plants

Project Summary:

Our research involves the comparative and functional genomics of disease resistance in plants, particularly Arabidopsis, tomato and lettuce. This work involves production of transgenic plants, transient assays in plants and microbes, use of plant viral vectors and use of RNAi strategies. Additionally, manipulations of plant pathogenic agents are conducted including plant inoculations, cloning and analysis of entire genomes and specific genetic elements from plant pathogens. All work is performed in greenhouses, lab and growth chambers. Razor blades are used for manipulation of plant material and agarose gels.

APPROVED (10-0-0)

NIH: Inf agts(plant), IIID5a,

IIIE2a, IIIE2b(3), IIIE, IIIF8 (App BSL: 2P, RG: 1 Rev: mmm

CII, CIII)

Title: Rice as a model species to explore plant stress responses and cell wall modification

Project Summary:

R BUA No. 0508

Rice is used as a model species for transformation and the select agent, as an infectious agent. Additional projects in the lab include research in biofuel crops, submergence tolerance, and the plant pathogen *Magnaportha oryzae*. Sharps used for manipulation of plant materials and no medical waste is generated.

APPROVED (10-0-0)

4. IBC Notification Simultaneous with Initiation (NIH III-E):

R BUA No. **0948** NIH: IIE2a, IIIE, IIIF8 (App CII, BSL: 1, RG: 1 Rev: mmm

CII)

Title: Root transcriptional networks

Project Summary:

The investigators study tissue-specific transcriptional networks in plant roots. Plants studied are *Arabidopsis*, tomato, *Sorghum* and *Nicotiana* sp. Transgenic plants (e.g., *Arabidopsis*, tomato, *Nicotiana*) are produced in the lab and grown in growth chambers. Razor blades are used to section roots.

APPROVED (10-0-0)

5. Storage ONLY: NONE

6. Exempt Protocols Approved by BSO: NONE

B. Amendments:

Amend 0732-03(A) BSL change BSL: 2, no agts Rev: pb

Title: Primate pathogen research and detection for SPF and animal model development

Amendment to add: Change of procedures in from BSL2 "Enhanced" to just BSL2

Exp date: 03/19/2015

APPROVED (9-0-0) (pb abstained)

Amend **0923(A)** NIH: IIID3e (baculo) **BSL: 1 RG: 1** Rev: mmm

Title: Characterization of genes and proteins associated with ionizing radiation exposure

Amendment to add: Host: insect cell line (Sf9)

Vectors: pENTR/D-TOPO, BaculoDirect N-term Linear DNA

Exp date: 07/05/2016 APPROVED (10-0-0)

Amend **0999(D)** NIH: IIID3b(lenti), IIID4b **BSL: 2, RG: 2** Rev: pb

Title: Biological examination and potential therapeutic applications of placental tissue

Amendment to add: Lentiviral-GFP transduction of human placental cells (Host: sheep and rats)

Exp date: 01/23/2015

APPROVED (9-0-0) (pb abstained)

Amend 1022(A) NIH: IIID3e(aav), IIID4a BSL: 2, RG: 2 Rev: pb

Title: Retinoic acid, its receptors, and the liver

Amendment to add: 1. Host - Transgenic mice (PPAR α -KO, hPPAR α -commercially purchased) /(host

for adenoviral vector)

2. Host - 293 cells (for packaging adenoviral vector)

3. Vector/Gene - Adenoviral vector (w/ fibroblast growth factor 21 (Fgf21))

Exp date: 11/19/2015

APPROVED (9-0-0) (pb abstained)

C. SOPs for Courses and Core Facilities: NONE

D. Conditional BUAs reviewed by ABSO, Final Approval by BSO: NONE

F. 4 BIO BUAs for review see BIO generated agenda

R R1507 (replacing BUA 0651-02) APPROVED (10-0-0)

R R1509 (replacing BUA 0738) APPROVED (10-0-0)

(BD now serving as chair, AG left, 9 voting members remain)

R R1505 (replacing BUA 854-03) APPROVED (9-0-0)

R R1506 (replaing BUA 0854-02B) APPROVED (9-0-0)

E. Terminated BUAs:

BUA No. 0757

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

BUA No. **0826** Rev: nld

Title: Alternative Splicing of Fibronectin in Osteoarthritis and Automated High throughput Fibronectin

Biomarker Immunoassays

BUA No. **0859-02B** Rev: nld

Title: Mechanisms of increased lean-mass associated with insulin resistance in PCO

BUA No. 0946 Rev: nld

Title: Effects of nucleus accumbens signaling on social withdrawal behavior

V. Discussion Items:

1. Philip - Review of protocol voting procedures - reminder: a <u>unanimous</u> vote is not needed from committee

2. Philip - Discuss Room/Lab Safety Sheet Biosafety Office review - CDPH states that bedding/feces generated from studies with infected agents is NOT medical waste and does not need to be treated as such.

VI. Information Items: NONE

VII. IBC Training: NONE

VIII. BSL3 Laboratory Information: NONE

IX. Notifications: NONE

X. Subcommittee Topics: NONE

End Time: 4:53pm

UNIVERSITY of CALIFORNIA

Institutional BioSafety Committee

Minutes for 11/18/2013 Final **UC Davis**

Environmental Health and

Safety

Phone : (530) 752 1493 Fax : (530) 752 4527

Status of BUAs Pending from Previous Meetings - Completed

BUA#	Principal Investigator	Department	Request Type	Biosafety Level
R1507		MOLECULAR &	New	BSL: 2
		CELLULAR BIO		ABSL:
Action:	Approved			
Review Stage:	Completed			

A novel mechanism linking DNA replication with anaphase resolution of sister chromatids

Motion

Project Title

Reviewer	IBC
Review date	November 17, 2013
Comments	on his older BUA, as stated on the form had E.coli and S.cerevisisae cultures being aspirated into a vacuum flask with 10% bleach and sitting for 30 minutes minimum, I assume this is the same protocol although it wasn't explicitly stated in the Risk Assessment section. He also has no active personnel listed, so he's doing all the work himself?
Reviewer	Biostaff
Review date	November 4, 2013
Comments	1. Review questions sent to PI 11/4/2013 (nld) 2. Protocol ready for IBC review 11/6/13 (nld)

Applicable NIH Guidelines

Section	Explanation	
IIIE	IIIE (BL21)	
IIIF	IIIF8 (App CI, CII, CIII)	

BUA#	Principal Investigator	Department	Request Type	Biosafety Level
R1509		MED:MEDICAL MICROBIOLOGY & IMM	New	BSL: 2 ABSL: 2

Action: Approved

Review Stage: Completed

Project Title Molecular mechanisms of Salmonella pathogenesis

Motion

Reviewer	Biostaff
Review date	November 5, 2013
Comments	1. Sent review questions to PI 11/5/13 (nld), 2. Protocol revised and submitted for IBC review 11/8/13 (nld)

Applicable NIH Guidelines

Section	Explanation
IIID	IIID1a, IIID2a, IIID4a, IIID4b
IIIE	IIIE
IIIF	IIIF8 (App CII)

Report printed on Dec 9, 2013 5:35 PM

BUA#	Principal Investigator	Department	Request Type	Biosafety Level
R1505		MED: DIV OF INTERNAL MED	New	BSL: 2 ABSL:

Action: Approved

Review Stage: Completed

Project Title Quality control of the USP 14 Day Sterility Test using test organisms

Motion

Reviewer	Biostaff
Review date	November 2, 2013
Comments	Review questions e-mailed to PI on 11/2/2013 (nld) PI addressed questions, revision ready for IBC (nld)

Applicable NIH Guidelines

Section	Explanation
None Apply	

Report printed on Dec 9, 2013 5:35 PM

BUA#	Principal Investigator	Department	Request Type	Biosafety Level
R1506		MED: DIV OF	New	BSL: 2
		INTERNAL MED		ABSL:

Action: Approved

Review Stage: Completed

Project Title Clinical grade laboratory tests on human blood, bone marrow, other human body fluids and

human cell cultures

Motion

Reviewer	Biostaff
Review date	November 2, 2013
Comments	1. Review questions e-mailed to PI 11/2/13 (nld) 2. Revised BUA ready for IBC review 11/6/13 (nld)

Applicable NIH Guidelines

Section	Explanation
None Apply	

Report printed on Dec 9, 2013 5:35 PM

Agenda: page 5 of 5

Institutional Biosafety Committee, UC Davis Office of Environmental Health and Safety

MINUTES

December 16, 2013 (3-5p)

Hoagland Hall Rm 130

NOTE: Next IBC meeting: 1/27/2014

Start Time: 3:05p.m.

In attendance:

Philip Barruel Voting Member, Biosafety Officer, Environmental Health and Safety

Gerhard Bauer Voting Member, Vice-Chair, IM Div of Hematology/Oncology

Nicole Corley Voting Member, Campus Veterinary Services

Savithramma Dinesh-Kumar Voting Member, Plant Biology

Bruce Draper Voting Member, Molecular & Cellular Biology

Diane Hoffmann Voting Member, School of Medicine Sponsored Programs

Fred Jacobsen Voting Member, Public Member Elizabeth Maga Voting Member, Animal Science Lyle Najita Voting Member, Public Member

Renee Tsolis Voting Member, Medical Microbiology & Immunology Victor Lukas Voting Ex-Officio Member, Attending Veterinarian

Roger Belcourt Voting Ex-Officio Member, Occupational Health Services

IBC support staff in attendance:

Niki Drazenovich Associate BioSafety Officer, Environmental Health and Safety Malendia Maccree Associate BioSafety Officer, Environmental Health and Safety

Excused:

Angela Gelli Voting Member, Chair, Pharmacology

Jill Blackwelder-Parker Non-Voting Ex-Officio Member, Associate Vice Chancellor, Safety Services

Neil Speth Non-Voting Ex-Officio Member, UCDMC Employee Health Services

Guests: none

I. Review of past IBC meeting minutes: November 18, 2013 (including BIO generated minutes)

APPROVED (7-0-2) GB, DH abstained

II. Announcements:

1. Philip - Discuss committee membership changes: Dan K. & Dinesh K. last meeting

III. Old Business: NONE

IV. New Business:

1. BSL3:

R BUA No. 0945

NIH: NHP tissues (including

lung) from Mtb inf animals

BSL: 3, no agts

Title: Genetic characterization of non-human primates and human populations

Project Summary:

The goal of this study is to create a multi-factorial genetic/epidemiological model predicting susceptibility to tuberculosis (TB). The most important genes in this case would be the genes regulating biochemical mediators in a granulomatous reaction in a case infected with Mycobacterium tuberculosis. The impact of genetic polymorphism and differences in the level of expression will be measured, as well as the interaction terms of these variables in TB case samples relative to control samples. The investigators will extract DNA and RNA from lung and inguinal tissue from cynomolgus and rhesus macaques currently enrolled in an experimental M. tuberculosis infection study at and infected with M. tuberculosis CDC and infected with be digested in tissue lysis buffer to extract DNA and RNA for quantitative PCR to measure relative transcript abundance in lung tissues and inguinal tissues. Medical waste will be generated. Sharps will APPROVED (10-0-0)

2. BSL2:

R BUA No. **0224**NIH: IIID3a(retro), BBP (primary and est human cells), IIIE, IIIF8 (App CII)

BSL: 2, RG: 1

Rev: pb

Title: Novel amiloride congeners selectively kill highly metastatic human cancers Project Summary:

The investigators are researching the efficacy, pharmacokinetics, and mechanism of action of several investigational anti-cancer drugs. Human cancer cells will be drug-treated *in vitro* and *in vivo* (mouse xenograft model) to determine efficacy. Cells/tissues will then be collected and analyzed to determine the drug's mechanism of action and pharmacokinetic properties; several different analytical techniques will be used: microplate assays, western blots, histology and liquid chromatography—mass spectrometry. Knockdowns of selected components will be performed to see if they confer drug resistance. Lastly, the investigators will use recombinant protein purification techniques to study the structural details of the pharmacophore to facilitate further drug design and development. The investigators will be using sharps, producing aerosols and generating

APPROVED (10-0-0) RB arrived

R BUA No. **0721**NIH: IIID3b(lenti), IIID3a(retro),
BBP (est human cells), IIIF8 (App CII)

BSL: 2, RG: 2

Rev: pb

Title: Role of signaling pathways in keratinocyte differentiation and in response to toxic agents

Project Summary:

Cultured human and rat epidermal cells are treated with various toxic agents, principally inorganic arsenic. To determine the degree of perturbation of intracellular signaling, the cultures are dissolved in strong denaturants such as detergents, guanidine thiocyanate, phenol and combinations of these agents. Helping to find the mechanism of action of arsenic (and other agents), the cultures are sometimes transduced with viral vectors that code for enzymes or shRNAs that knock down expression of certain genes. The cultures are often analyzed for mRNA levels by real time PCR or by passaging for analysis of growth. Occasionally, similar experiments are conducted with epithelial cells cultured from tilapia fish. Medical waste will be generated. Sharps will be used.

Conditional (10-0-1)PB abstained, RT arrived
Section 2D #2, indicate the source of the fish cells.

Rev: nld

 $NIH:\,IIID3e({\rm retro}),\,BBP\;({\rm human}$

blood, tissue and est cell lines), IIIF8 BSL: 2, RG: 1 Rev: nld

(App CII)

Title: Congenital myasthenic syndromes: Pathogenic mechanisms

Project Summary:

R BUA No. 0818

The project aims to diagnose new types of Congenital Myasthenic Syndromes (CMS), finding new target genes for mutations causing CMS using novel techniques of DNA analysis, and in particular, developing newer effective forms of treatment for CMS. The genes involved in the project are those that govern the development, maintenance and function of the neuromuscular junction. The work does not involve gene discovery, but rather finding the association between disease and genetic defects in known genes. Mutational analysis will be performed on genomic DNA extracted from patient blood and microelectrode physiological studies will be performed on human muscle tissue. Genes are inserted into cloning and expression vectors, transfected into cells (human or animal cell lines) and the function of the gene and protein-protein interactions are studied by physiological, microscopic and biochemical techniques. Sharps will be used and medical waste generated.

APPROVED (11-0-0)

R BUA No. **0956**NIH: IIID3b(lenti), BBP (human tissues and stem cells)

BSL: 2, RG: 2

Rev: pb

Title: Urothelial tissue regeneration

Project Summary:

The investigators aim to isolate, culture and evaluate tissue/cells from various specimen including human, porcine, rat and mouse to study urothelial tissue regeneration (lining of cells inside the urinary bladder). This project will involve manipulation of tissue for isolation of cells, cell culture, propagation and in vitro and in vivo studies. Human adult tissues and stem cells will be obtained from various hospitals and tissue banks. Hazardous manipulations include pipetting and centrifugation. Use of sharps includes tissue dissection, tissue sectioning, and needles for animal injections. Medical waste will be generated: red bag waste, human pathological waste, animal pathological waste and cell culture liquid waste.

APPROVED (10-0-1) PB abstained

N BUA No. 1065 NIH: Inf agts (human) BSL: 2, RG: 2 Rev: nld

Title: Research in prevention and understanding of poultry diseases

Project Summary:

Safe disposal of animal and food waste is required to protect public health. In this research pathogen inactivation will be tested in food and animal waste after pasteurization and anaerobic digestion process. Inactivation of *E. coli* (O157:H7), *Salmonella, Listeria*, and *Clostrium perfringens* will be tested. No sharps will be used and medical waste will be generated.

APPROVED (11-0-0)

3. Bloodborne Pathogen Protocols:

R BUA No. 0022-03B

BBP (est human and nhp cells), IIIF8

(App CI, CII)

BSL: 2, RG: 1

Rev: pb

Title: Molecular mechanisms of action of Endocrine Disrupting Chemicals (EDCs)

Project Summary:

The work on these projects involves manipulation of plasmid DNA, plasmid expression vectors, expression of recombinant proteins, generation and use of transient and stably transfected recombinant mammalian cell lines (rat, mouse, guinea pig, human, monkey). The use of glass pipettes used for cell/media transfer generates sharps and the use of human and monkey cell lines generate medical waste.

APPROVED (10-0-1) PB abstained

R BUA No. 0644B BBP (human blood) BSL: 2, no agts Rev: nld

Title: Genomic analysis of nucleic acids isolated from human blood for the study of neurodevelopmental

disorders and other human disease

Project Summary:

As part of larger cross-disciplinary studies, human blood is collected by phlebotomists from individuals for the study of autism and other neurodevelopmental disorders. These blood samples are delivered to our laboratory for the purification of RNA and DNA. The laboratory's role in these projects is to perform the purifications and subsequent genomic analyses. No sharps will be used and medical waste will be generated.

APPROVED (11-0-0)

4. BSL1:

R BUA No. **0933**NIH: IIID3e, IIIE2a, IIIE2b(2),
(3),(4)

Rev: mmm

Title: Cloning and expression of genes of plants, phytoplasmas and viruses infecting almond, grapevines,

stonefruits, and walnuts

Project Summary:

This project involves generation of *E. coli* and *Agrobacterium* strains containing expression vectors. Genes from phytoplasmas and plants, and full or a fraction of the genomes of plant viruses infecting almonds, grapevines, tree fruits (apricots, cherries, nectarines, peaches, pluots, pomegranates, strawberries) and walnuts will be cloned into expression vectors. The gene clones will be used for protein expression to prepare antisera using bacterial and/or plant expression vectors in bacterial and plant hosts. Recombinant full-length infectious clones of viruses infecting the perennial fruits and nuts in California will be generated to study plant-virus interactions in growth chambers and/or greenhouse.

APPROVED (11-0-0)

5. IBC Notification Simultaneous with Initiation (NIH III-E):

N BUA No. 1066 NIH: IIIE3 BSL: 1, no agts Rev: nld

Title: Auditory transduction in genetically modified mice

Project Summary:

The study is focused on the structure and function of the inner ear, as it pertains to hearing. Mice that lack functional proteins will be used to investigate the role and importance of these proteins in the inner ear, specifically ion channels found on hair cells in the cochlea. Electrophysiological techniques, such as patch clamp, auditory brain stem and otoacoustic emission recording experiments, as well as molecular biology approaches will be used to foster a greater understanding of the process of hearing.

APPROVED (11-0-0)

6. Storage ONLY:

BUA No. **0522** Rev: nld

Title: Storage only: Vaccinia virus, MVA, measle vaccines, measles vector and virus seed stocks, Herpes

virus papio, Raji cells, H. papio transformed monkey B cells

APPROVED (11-0-0)

Title: Storage Only: SIV (nhp tissues, blood, csf)

APPROVED (10-0-1) PB abstained

7. Exempt Protocols Approved by BSO:

R BUA No. R1515 NIH: IIIF8 (App CII) BSL: 1, RG: 1 Rev: nld

See BIO generated agenda

B. Amendments: NONE

Amend **0812(A)** NIH: Inf agts (plants) **BSL: 3P/1P, RG: 1** Rev: mmm

Title: Biochemistry, molecular biology and control of bacterial plant pathogens

Amendment to add: 1. Extraction of RNA and protein from Huanglongbing (HLB, Candidatus

Liberibacter)-infected plant tissue

2. Use of non-viable extracts from HLB-infected plants

Exp date: 04/15/2016

APPROVED (12-0-0) VL arrived

C. SOPs for Courses and Core Facilities:

SOP No. **S0010** NIH: IIID3b(lenti), IIID3e(aav), BSL: 2, RG: 2 Rev: nld

BBP (est human cells)

Facility: The Molecular Construct and Packaging Core (MCPC)

Abstract:

This project is focused on the making DNA constructs and packaging of the constructs into viral vectors for neuroscience research, specifically for vision research. AAV and lentivirus will be produced to express candidate genes and send directly to researchers. The Core Facility will not do functional studies. Medical waste will be generated.

APPROVED (12-0-0)

D. Conditional BUAs reviewed by ABSO, Final Approval by BSO:

N BUA No. **0459-05**NIH: Inf agts (zoon-bird), IIID1a,
IIID4a

BSL: 2, RG: 2

Rev: mmm

Title: Social hierarchy influences immunomodulatory nutrient consumption and rate of transmission of

Salmonella enteritidis

Review Date: 10/21/2013

E. BIO BUAs for review see BIO generated minutes:

R R1469 (replacing 0828) APPROVED (10-0-2) PB, EM abstained

R R1499 (replacing 0835) APPROVED (11-0-1) PB abstained

R R1513 (replacing 0418) *APPROVED* (12-0-0)

R R1515 (replacing 0958) Exempt

R R1517 (replacing 0104-02) **APPROVED** (12-0-0)

R R1522 (replacing 0534) APPROVED (11-0-1) PB abstained

F. Terminated BUAs:

BUA No. 0831 Rev: nld

Title: The Role of NADPH oxidase in erectile dysfunction

BUA No. 0878

Title: Intracranial therapy for malignant glioma

BUA No. 0943B

Title: In-vitro 3D culture of engineered human MSC to generate bone-ligament-bone grafts

V. Discussion Items:

- 1. Philip Discussion of animal waste inactivation (autoclaving vs medical waste). IBC *APPROVED* (11-0-1 vL abastained) autoclave infected animal waste instead of disposing as med. waste.
- 2. Malendia Modify audits and biosafety support of plant research BUAs to include permit compliance component (e.g., include specific regulatory compliance elements in lab audit and BUAs, develop and provide template documentation for use in USDA/CDFA permit acquisition, continue work with USDA-APHIS compliance branch and CDFA in outreach activities)
- 3. Philip Discuss IBC member alternates. New IBC members I. Stergiopoulos & J. Leveau APPROVED (10-0-0)

VI. Information Items:

- 1. Malendia Lab audits moving to online SIT program in January 2014
- 2. Malendia BQMS program revision: results of 3 year pilot test with PIPRA and plans for future: will now be PI-lead

VII. IBC Training: NONE

VIII. BSL3 Laboratory Information:

1. Malendia - BSL3P reverification report: report write up will be completed in Jan. 2014

IX. Notifications: NONE

X. Subcommittee Topics: NONE

End Time: 4:45p.m.

UNIVERSITY of CALIFORNIA

Institutional BioSafety Committee

Minutes for 12/16/2013 Final UC Davis

Environmental Health and

Safety

Phone : (530) 752 1493 Fax : (530) 752 4527

Status of BUAs Pending from Previous Meetings - Completed

BUA#		Principal Investigator	Department	Request Type	Biosafety Level
R1517			MOLECULAR &	New	BSL: 1
			CELLULAR BIO		ABSL:
Actio	n:	Approved			
	.	0 1.1			
Revie	w Stage:	Completed			
Proje	ct Title	Structural studies of	f plant-pathogen interaction	ns	
•					
Motio	n				
	Reviewer	Biostaff			
	Review date	November 19, 2013			

1. Assigned to nld, 2. Send PI Q's 11/25, 3. BUA finalized 12/2

Applicable NIH Guidelines

Comments

Section	Explanation
IIIE	IIIE - BL21
IIIF	IIIF8 (App CII) - E. coli K12

BUA#	Principal Investigator	Department	Request Type	Biosafety Level
R1499		MED: BIOCHEM &	New	BSL: 2
		MOLECULAR MED		ABSL: 2

Action: Approved

Review Stage: Completed

Project Title Role and functional mechanism of coregulators in cancer

Motion

Reviewer	IBC
Review date	December 16, 2013
Comments	IBC approved BUA.
Reviewer	Biostaff
Reviewer Review date	Biostaff December 2, 2013

Applicable NIH Guidelines

Section	Explanation
IIID	IIID3b (lenti), IIID3a (adeno)
IIIE	(E. coli non-K12 strains)
IIIF	IIIF8 App CII

Report printed on Jan 19, 2014 12:33 PM

BUA# Principal Investigator Department Request Type Biosafety Level

R1515 MED:PHYSIOLOGY & New BSL: 1

MEMBRANE BIOL ABSL:

Action: Approved

Review Stage: Completed

Project Title Probes for ion channel identification

Motion

Reviewer	Biostaff
Review date	November 14, 2013
Comments	1. BUA assigned to NLD. 2. 11/25 send Q's to PI 3. BUA finalized 12/2

Applicable NIH Guidelines

Section	Explanation
IIIF	IIIF8 (App CII) - E. coli K12

Report printed on Jan 19, 2014 12:33 PM

BUA# Principal Investigator Department Request Type Biosafety Level

R1513 MED:CELL BIOLOGY New BSL: 1
& HUMAN ANAT ABSL: 1

Action: Approved

Review Stage: Completed

Project Title Intermediate Filament Biology

Motion

Reviewer	Biostaff
Review date	November 14, 2013
Comments	1. Assigned to MM 11/4/13. 2. 11/22/13 sent PI questions. 3. 11/26/13 PI responded to questions, BUA was revised. 4. 12/9/13 BUA posted for IBC review.

Applicable NIH Guidelines

Section	Explanation
IIIE	Use of plasmid constructs in E. coli
IIIF	Exemptions under NIH guidelines:
	Appendix CIRecombinant or synthetic nucleic acid molecules containing less than one-half of any eukaryotic viral genome that are propagated and maintained in cells in tissue culture.
	Appendix CIIUse of E. coli K-12 strains (non-hazardous gene inserts)
	Appendix CVIIIThe breeding of two different transgenic rodents or the breeding of a transgenic rodent and a non-transgenic rodent with the intent of creating a new strain of transgenic rodent that can be housed at BL1 containment (not expected to contain more than one-half of an exogenous viral genome).

BUA#	Principal Investigator	Department	Request Type	Biosafety Level
R1522		VM: POPULATION HLTH & REPROD	New	BSL: 2 ABSL: 2

Action: Approved

Review Stage: Completed

Project Title Investigation of Bartonella and other zoonotic infections

Motion

Reviewer	IBC
Review date	December 16, 2013
Comments	IBC approved BUA
Reviewer	Biostaff
Review date	November 25, 2013
Comments	Assigned to PB. Pre-review questions and suggestions emailed by PB: 12/3/2013

Applicable NIH Guidelines

Section	Explanation	
None Apply		

Report printed on Jan 19, 2014 12:33 PM

BUA#	Principal Investigator	Department	Request Type	Biosafety Level
R1469		ANIMAL SCIENCE	New	BSL: 2
				ABSL: 1

Action: Approved

Review Stage: Completed

Project Title The use of milk from transgenic animals to prevent and treat diarrhea

Motion

Reviewer	IBC	
Review date	December 16, 2013	
Comments	IBC approved BUA	
Reviewer	IBC	
Review date	August 18, 2013	
Comments	THIS REVIEW IS FOR ASSESSING BIO.	
	Section Cells, Tissues, Body Fluid: Max Concentration = 2500000000, Max Dose	
	25000000000 ? Needs clarification. Animal Primary Cells: Vertebrate Maximum Concentration = 500 Dose, Vertebrate	
	Maximum Dose = 1000 Dose? Needs clarification.	
Reviewer	Biostaff	
Review date	August 2, 2013	
Comments	1. Assigned to PB (8/2/2013).	
	2. Sent to IBC for review of BUA during IBC's December 2013 meeting.	

Applicable NIH Guidelines

Section	Explanation
IIID	IIID4a

Agenda: page 7 of 7