NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE

Minutes
August 19, 2008
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:03 p.m. in the Building 549 Executive Boardroom with the following members in attendance:

Ms. Theresa Bell, Secretary	Dr. Melinda Hollingshead
Dr. Randall Morin, Chair	Dr. Stephen Creekmore
Dr. Serguei Kozlov	Dr. Stephen Hughes
Dr. David Derse	Dr. David Garfinkel
Dr. Bruce Crise	Ms. Dianna Boissey
Mr. Scott Jendrek	Ms. Alberta Peugeot
Mr. Lucien Winegar	

Members not in attendance: Dr. Henry Hearn, Dr. Michael Baseler, Dr. Eric Freed, Dr. Daniel McVicar

Others in attendance: Dr. Scott Keimig, Ms. Cara Leitch

Dr. Morin called the meeting to order. The June and July 2008 minutes were approved as written.

NEW BUSINESS

07-70 (Trinchieri) "*Toxoplasma gondii* and the Innate Response"

- This study involves propagation of T. gondii cysts in mouse brains for the purpose of infecting experimental animals.
- The proposal has been discussed at previous IBC meetings.
- The primary concern is with pregnant women and immunocompromised individuals who may be exposed to the material, but all of the potential risks are unknown.
- Although the material is generally acquired by ingestion or injection, certain lab manipulations may aerosolize the material thus exposing the mucous membranes; therefore, the material must be handled carefully and treated with respect.

- There may be a risk from fecal material, so animal facility staff must be informed of the potential hazards. EHS and OHS are to coordinate training.
- Cages and bedding must be bagged and autoclaved prior to disposal.
- The experimental endpoint is not clear in A1.
- The animal facility risk assessment form was recommended, which will now be used for all registrations involving animal work.

Dr. Morin made a motion to defer approval pending resolution of the above issues and completion of training, Dr. Hughes seconded, and all were in favor.

08-31 (Whitby) "ACVP Viral Oncology Section"

- This registration has two parts. One part is testing of epidemiological/clinical samples for multiple viruses (HIV, HTLV, KSHV, EBV, HCV, and HBV). The other part is herpesvirus research with KSHV and EBV.
- TB is listed in D1 as a potential sample manipulation. TB poses a major aerosol hazard. Is this listed just to cover the spectrum of samples or will they actually be receiving this material?
- What is being done with respect to each part of the research material? Need a description for analysis of clinical samples and herpesvirus research, how the work is being done, and where the specific activities are being performed (provide room numbers and personnel allocated to each activity).
- How will the herpesvirus work be kept temporally and physically separated from the samples coming in for testing?
- The statements are not clear regarding which work is BSL2 verses BSL2*.
- The HIV and adenovirus SOP should not be attached to this registration. There is no adenovirus work in this proposal.
- Where is the work that involves sharps and glassware located (BSL2 or BSL2*)?
- Which projects involve the use of sharps and glassware? Are other alternatives available? How will they use and dispose of the sharps?
- Page 41 of 50 in the SOP needs more information.
- Page 25, #15 needs more detail.

Dr. Morin made a motion to defer approval pending resolution of the above issues, Dr. Garfinkel seconded, and all were in favor.

08-50 (Klinman) "In Vivo Tumor Models used in the study of Vaccines and Modulators of Innate Immune System"

- This study involves in vivo tumor models and knockout mice.
- The IBC had no specific concerns regarding this registration.

Dr. Garfinkel made a motion to approve, Dr. Hughes seconded, and all were in favor.

08-51 (Sei) "Adeno-Associated Viral (AAV) Vectors Expressing shRNA for In Vitro Gene Silencing"

- This registration proposes to work with adeno-associated virus (AAV).
- All lead reviewer questions were previously answered and incorporated into the form.
- What other materials in the lab could be a helper for AAV? Verify that other virus work must be kept separate from the AAV work.

Dr. Crise made a motion to conditionally approve pending resolution of the above issues, Mr. Jendrek seconded, and all were in favor.

08-46 (Lockett) "STAT 3"
- STAT3 gene will be amplified and PCR will be used to introduce point mutations into the gene.
- Viral promoter used is not mobilizable.

Dr. Garfinkel made a motion to approve, Mr. Jendrek seconded, and all were in favor.

08-49 (Hou) "Developing a Mouse Model to Induce Ectopic Gene Expression in Double Marked Cells following Mitosis"
- This study involves the creation of five transgenic mouse lines, and no infectious material.
- Question B5 should be answered yes since a CMV promoter is being used, and all sub-questions are to be addressed.
- Tamoxifen, which requires respiratory protection, is mentioned in the Animal Study Proposal and not in the IBC form. Chemical hazards are addressed by the ACUC.

Dr. Kozlov made a motion to approve, Dr. Derse seconded, and all were in favor.

08-52 (Sherman) "Markers for IHC Antigen Stability"
- Human tumor cell lines will be injected into mice to generate xenograft tumors.
- Statement of acknowledgement regarding the hazards associated with injection of human tumor cell lines into animals should be provided in A3.
- Depending on the type of injection performed, mouse restraints should be used.
- Who is performing the injection and how is this being done safely, especially since CDTD mice are not "pathogen-free".

Dr. Hughes made a motion to conditionally approve pending resolution of the above issues, Mr. Winegar seconded, and all were in favor.

RENEWALS

08-53 (Chen/Wang) "Development of Transgenic Mouse Strains Overexpression Leukocyte Chemoattractant Receptor FPR2; Development

of Systemic and Conditional mFPR2 Knockout Mice; The role of FPR2 in the Pathophysiology of Infection with *Listeria Monocytogenes*"

- This registration has two parts. One part is to generate FPR2 transgenic and knockout mice. The second part is to study mouse responses to *Listeria monocytogenes.*
- *L. monocytogenes is* a pretty serious bacteria that targets the CNS.
- There are antibiotics available for post-exposure prophylaxis, but no vaccine available for *L. monocytogenes*.
- More information is needed for handling the animals and their cages.
- EHS will counsel animal staff on proper procedures for this work.

Dr. Garfinkel made a motion to defer approval pending resolution of the above issues and completion of training, Ms. Bell seconded, and all were in favor.

AMENDMENTS

06-70 (Wiltrout) "The use of Diphtheria Toxin"

- Proposal to inject Diptheria Toxin into mice.
- DT is normally not an issue for aerosols until manipulating at a cellular level.
- One other person should be present at the time of manipulation.
- PI to specify what is meant by "slow, meticulous resuspension". Need Additional details on how the material will be handled, stored, and aliquotted.
- Provide more detail on how injections will be performed
- OHS will look into whether a vaccination, boost, or administration of an anti-toxin is recommended.
- OHS and EHS to provide information session to the staff.

Dr. Kozlov made a motion to conditionally approve pending resolution of the above issues and completion of training, Dr. Crise seconded, and all were in favor.

OTHER BUSINESS

- The Bloodborne Pathogen Program is 96.5% compliant.

- OHS reported a non-human primate injury to a worker located in Bethesda.

- Dr. Melinda Hollingshead discussed the human pathogen screening for cell lines conducted by LMT. John Cunningham Virus (JCV) is one of the pathogens currently being screened; however, the reagent is difficult to get for testing this, so the research community has pending screening results waiting for this test to be completed. JCV is an uncommon virus and Dr. Hollingshead asked the IBC to consider if this test is necessary. If we keep the test, can screening results be released without this test until an alternative method can be determined (i.e. obtain DNA in the cloned form or other controls to be used as alternatives). Dr. Morin agreed to perform some epidemiological research into causative agents of human disease. Dr. Hughes will forward comments and emails on the subject

matter to Dr. Morin for IBC discussion and a vote on how to proceed. IBC and AUC will coordinated their decision and inform LMT appropriately

The meeting ended at 1:00 p.m.

_____	_____
Theresa D. Bell, MPH, CBSP IBC Secretary Biological Safety Officer, EHS	Ms. Cara Leitch IBC Coordinator Sr. Safety Specialist, EHS

APPROVED:

_____	_____
Randall S. Morin, Dr. P.H. Chairman, NCI-Frederick IBC Director, EHS	Date

xc: Dr. Reynolds
Mr. Wheatley
Dr. Arthur
Mr. Bufter