

NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES
SEPTEMBER 21, 2010

CALL TO ORDER / ANNOUNCEMENTS

The NCI-Frederick Institutional Biosafety Committee was convened at 12:05 p.m. in Building 549 Executive Board Room with the following members in attendance:

Voting

- | | |
|---|--|
| <input type="checkbox"/> Michael Baseler (regrets) | <input type="checkbox"/> Serguei Kozlov (regrets) |
| <input checked="" type="checkbox"/> Theresa Bell | <input checked="" type="checkbox"/> Dan McVicar (Chair) |
| <input checked="" type="checkbox"/> Stephen Creekmore | <input type="checkbox"/> Randall Morin (regrets) |
| <input checked="" type="checkbox"/> Bruce Crise | <input checked="" type="checkbox"/> Shalini Oberdoerffer |
| <input checked="" type="checkbox"/> Eric Freed | <input checked="" type="checkbox"/> Alberta Peugeot |
| <input type="checkbox"/> Melinda Hollingshead (regrets) | <input checked="" type="checkbox"/> Raja Sriperumbudur |
| <input type="checkbox"/> Stephen Hughes (regrets) | <input checked="" type="checkbox"/> Lucien Winegar |
| <input checked="" type="checkbox"/> Scott Jendrek | <input checked="" type="checkbox"/> Rev. David Betzner |

Non-Voting

- Dianna Conrad
- Kim DiGiandomenico

Other

- Tim Rowe (regrets)
- Karen Barber (regrets)
- Robert Thomas

APPROVAL OF MINUTES FROM AUGUST 17, 2010 MEETING

The August 17, 2010 meeting minutes were approved as written.
(A motion and second were made. (For: (11) Against: (0) Abstain: (0))

ACCIDENT REVIEWS

Theresa Bell reported one needlestick accident, which occurred with a 25-year veteran employee. The needle scraped the surface of the individual's hand and did not contain any biological materials.

REVIEW OF PROTOCOLS

NEW REGISTRATIONS

Lynda Evans 10-40: Effect of L1CAM expression on the development of brain metastases This laboratory studies the biology of breast cancer brain metastasis as well as tests the efficacy of drugs in slowing metastatic progression in the brain. The project described is set to determine if L1CAM expression is related to the development of brain metastases. The lab has developed brain-seeking breast cancer cells with decreased expression of L1CAM. Either cells that express L1CAM or that have L1CAM knocked down will be injected into animals and brain metastases will be quantitated. Only the animal work with transduced cell lines will be conducted at NCI-Frederick; all other research is performed in Bethesda. The committee requested the following clarifications: 1. confirm the timeframe between transduction of cells

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and administration into animals and 2. revise the language in B6a and E9 regarding the hazards of autoinoculation. In the event of self-inoculation, it is possible for a tumor/nodule to form and could have additional effects on an immunocompromised individual. In the event of a needlestick, the area should be scrubbed for 15 minutes and then the individual should report to occupational health. The committee had no additional comment. Bruce Crise motioned to conditionally approve the registry pending the requested modifications. Raja Sriperumbudur seconded the motion. (For: 11 Against: 0 Abstain: 0)

Jeff Gildersleeve 10-42: *Carbohydrate Microarray Analysis of Serum Antibodies from Non-Human*

Primates This lab plans to evaluate levels of anti-carbohydrate antibodies in monkeys before vaccination, after vaccination with an HIV/SIV vaccine, and after challenge with SIV. The samples will be heat inactivated using standard industry methods. The lead reviewers met with the PI and lab staff during the pre-review and confirmed the method of transporting samples to a BSC for inactivation prior to manipulation in a chemical fume hood in the PI's laboratory. In addition, temporal and physical separation of research materials was requested. The committee had no additional comment. (For: 11 Against: 0 Abstain: 0)

Vineet KewalRamani 10-43: *Cell Culture Models for Retroviral Infection* This lab is engaged in research studies to better understand the replication of retroviruses, including primate lentiviruses as well as gammaretroviruses. The primary platform for these studies is transformed human cell lines. They are interested in the host factor requirements for retroviruses, how they cause disease, and the development of improved cell culture and animal models in which to study retroviral replication. None of the animal work is conducted by this laboratory. The main concern by the lead reviewers was the potential mixing and matching of different viral components due to the numerous viruses being used in the lab. The committee felt the PI sufficiently addressed this within his registry as well as addressed the hazards in his SOPs. The committee had no additional concerns. (For: 11 Against: 0 Abstain: 0)

RENEWALS

Jeff Gildersleeve 10-41 (06-69): *Carbohydrate Microarray Analysis of Serum Antibodies in Human Sera* For the renewal, this laboratory will continue to evaluate levels of anti-carbohydrate antibodies in human serum on a carbohydrate microarray. The objective is to identify changes in antibody levels that correlate with diagnosis and/or prognosis of cancer or correlate with a beneficial response to a cancer vaccine. There was much discussion regarding the processing of these samples inside a chemical fume hood, as was previously approved. The committee majority concurred that these samples must be manipulated inside a biological safety cabinet. Dan McVicar motioned to conditionally approve the registry until a biosafety cabinet could be located in which the research could be conducted. Theresa Bell seconded the motion. (For: 10 Against: 1 Abstain: 0)

Laura Schmidt/W. M. Linehan 10-44 (07-38): *Study of inherited kidney cancer syndromes, the causative genes, and mouse models of renal cancer* This is a renewal for research focused on understanding the causes of inherited renal cancer syndromes and identifying renal cancer susceptibility genes through development of mouse models of renal cancer. The PI clearly identified activities that are no longer being conducted on the NCI-F campus by the laboratory, which warranted a reduction in the bio- and animal biosafety levels. Prior to full committee review, lead reviewers obtained clarification on what occasional injections will be done by the staff. The committee had no further comment. Eric Freed moved to approve the registry with the inclusion of what is being injected into the animals. Bruce Crise seconded the motion. (For: 11 Against: 0 Abstain: 0)

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OUTSTANDING ITEMS

Frank Ruscetti 10-31 (09-47): Mechanism of Transmission of Human Lymphotropic Virus (HTLV) and Xenotropic MuLV-Related Virus (XMRV) Sixteen questions for additional clarification were sent on July 2, 2010. Since then, 4 additional reminders were sent to the lab contact – no responses to the questions were provided. (Only lead review required to release approval.) Dan McVicar motioned that he would personally speak to the lab manager and PI and if a response was not received within a week, then the delinquency policy should be enacted. Bruce Crise seconded the motion. The committee voted unanimously to accept the motion.

AMENDMENTS

Thirteen amendments were processed and approved between the August and September meetings; while three were processed but remained outstanding (i.e. waiting for PI response) as of the IBC meeting date.

In addition, two of the outstanding amendments for Dr. George Pavlakis (received in June and July) were discussed. Bruce Crise motioned to request a response from the PI regarding the amendment clarifications by the October IBC meeting and if no response is received, then activate the delinquency policy. Scott Jendrek seconded the motion. All were in favor.

POLICY

- *Delinquency Policy*: In conjunction with the new IBC webpages, a revised policy for delinquent IBC registrations was distributed to the committee for review and approval. The committee voted unanimously to accept the policy.
- *Animal Facility Working Group*: The animal facility working group provided an update to the IBC regarding the status of the animal facilities as compared to the guidance found in the 5th edition of the CDC/NIH publication, *Biosafety in Microbiological & Biomedical Laboratories*. The working group identified some deficiencies in the facilities and will reconvene to determine if any resolutions can be developed. The IBC will be provided a status report once more information is available.

OTHER BUSINESS

- *rDNA in Animal Models*: A guidance document regarding the use of rDNA in animal models was distributed to the committee for re-evaluation prior to posting on the new IBC webpages. The documents had originally been located on the ACUC website, but the ACUC committee voted to remove it, as they believed it pertained more to IBC related review information rather than direct ACUC review.
- *10-39 (Swing)*: After the August meeting, Debbie Swing contacted the IBC administrator to contest the assigned biosafety levels (BSL2/ABSL2), as work at this level is not conducted in her lab, nor does she want to conduct work at this safety level. The Ms. Swing updated her registry and microinjection request form to indicate that only BSL1/ABSL1 work would be accepted and conducted in the lab. If a request was received that warranted a higher safety level, Ms. Swing would either reject it or file a new registry to demonstrate how BSL2/ABSL2 containment would be

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met. Dan McVicar motioned to accept the lower safety levels; Bruce Crise seconded the motion (For: 10 Against: 0 Abstain: 0).

- *Definition of Infectious* – Theresa Bell prompted a brief discussion with the committee regarding the definition of “infectious” due to a recent amendment that was processed. The committee concurred that a strict definition should not be posted on the new IBC website and that questions regarding terminology can be addressed on an as-needed basis.
- *Hurwitz – DT injection observations*: EHS is still waiting to schedule, although as of the meeting date, Dr. Hurwitz had been in contact with EHS regarding tentative experiment dates.

ADJOURNMENT

The meeting was adjourned at 1:40pm.

Next meetings:

October 19, 2010 (549 EBR)

November 16, 2010 (549 EBR)