

NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES
MAY 17, 2011

CALL TO ORDER / ANNOUNCEMENTS

The NCI-Frederick Institutional Biosafety Committee was convened at 12:05 p.m. in Building 426 Conference Room with the following members in attendance:

Voting

- | | |
|--|--|
| <input checked="" type="checkbox"/> Michael Baseler | <input type="checkbox"/> Scott Jendrek (regrets) |
| <input checked="" type="checkbox"/> Theresa Bell | <input checked="" type="checkbox"/> Serguei Kozlov |
| <input checked="" type="checkbox"/> Stephen Creekmore (left at 1:10pm) | <input checked="" type="checkbox"/> Dan McVicar (Chair) |
| <input checked="" type="checkbox"/> Bruce Crise | <input checked="" type="checkbox"/> Randall Morin |
| <input checked="" type="checkbox"/> Eric Freed | <input checked="" type="checkbox"/> Shalini Oberdoerffer |
| <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"/> Sarah Hooper | <input checked="" type="checkbox"/> Rev. David Betzner |

Non-Voting

- Walter Hubert
- Kim DiGiandomenico

Sarah Hooper also introduced Dr. Stephan Mann. Dr. Mann is the occupational medicine consultant for SAIC-Frederick.

APPROVAL OF MINUTES FROM APRIL 19, 2010 MEETING

The April 19, 2011 meeting minutes were approved as written.

(A motion and second were made. (For: (13) Against: (0) Abstain: (0))

ACCIDENT REVIEWS

To be reported at the June IBC meeting

REVIEW OF PROTOCOLS

NEW REGISTRATIONS

P. Charles Lin 11-22: *Breeding of genetically engineered mice (GEM) for the Vascular Biology in Cancer Program* BREEDING ONLY *Notification to committee*

Thorkell Andresson 11-25: *Dynamic Measurement of Proteins* In this protocol, established cell lines will be grown for biochemical and microscopy studies of protein interactions. Cells will then be harvested for lysis and fixed with 4% formaldehyde to extract protein or used for microscopy-based experiments. The committee wanted the PI to confirm that the lab was only looking at endogenous proteins. If not, then additional information would be needed in the registry. Mike Baseler moved to approve pending PI's response to the aforementioned question. Bruce Crise seconded the motion. (For: 13 Against: 0 Abstain: 0)

Criss Tarr 11-27: *Chinese Hamster Ovary cell Line Cell Banking and Growth Studies* For this project, a Chinese Hamster Ovary (CHO DG44) cell line expressing the SIV gp120 envelope (env) protein from the SIV mac239 strain will be received from the Vaccine Research Center and used to create a frozen cell stock. This cell line will subsequently be used for vaccine process development studies to be performed at the Vaccine Pilot Plant. Any such work will be addressed in a separate IBC submission as an amendment to this application. During lead review, the PI was asked about the potential for seroconversion and also asked to confirm that the HIV testing assays would

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differentiate between anti-SIV and anti-HIV gp120. Both Eric Freed and Mike Baseler concurred that it is highly unlikely for someone to seroconvert. Dan McVicar moved to approve the registration. Theresa Bell seconded the motion. (For: 13, Against: 0 Abstain: 0)

RENEWALS

Zack Howard 11-18 (08-19): Chemoattractant and Chemoattractant Receptor Structure/Function Studies – Including Alarmins The continuing goal of the research in this IBC renewal is to better understand the role of chemoattractants in the initiation and prevention of diseases, specifically cancer and autoimmunity. Construction and expression on prokaryote and eukaryote expression vectors will be undertaken to express human and mouse chemoattractant and / or chemoattractant receptors in common cell lines. These vectors will be expressed in prokaryote, or eukaryote cell lines for functional studies *in vitro*. After discussions with the PI during the lead review, the registry was broken down into Projects, which made the research flow more easily understood. Lead reviewers confirmed that the PI no longer uses MLV-based vectors, as had been previously registered. Serguei Kozlov moved to approve. Eric Freed seconded the motion. (For: 13 Against: 0 Abstain: 0)

Alan Perantoni 11-19 (07-16): Role of Stat1 activation during nephrogenesis BREEDING ONLY Notification to committee

Larry Keefer 11-20 (08-26): Human lung adenocarcinoma cells for xenograft studies of nitric oxide-releasing drugs This renewal is for continuing research with a mouse xenograft model of human lung adenocarcinoma. Once tumor formation is noted, mice are then treated with therapeutic agents against lung cancer in the hopes of finding new lung cancer therapeutics. The lead reviewers had no outstanding concerns with the registry; however it was recommended that the PI use a needle holder during animal injections, rather than just placing the needle on the work surface of the BSC, as noted in Part A of the registry. Shalini Oberdoerffer moved to approve the registry with the noted recommendation. Mike Baseler seconded the motion. (For: 13 Against: 0 Abstain: 0)

Robert Blumenthal 11-23 (P110797RBA03): Mechanism of viral entry and pathogenesis This laboratory is renewing their current IBC registry which uses influenza virus to study its mechanism of entry. They are also developing some inactivation techniques that are tested on influenza virus. There was discussion regarding the need for seasonal and H1N1 vaccination. Steve Creekmore noted that the laboratory is working with strains that are not in the current vaccine and if proper PPE and engineering controls are properly used, then the vaccine is not warranted. Additionally, the committee requested information for the following: (1) Provide details of the fixation process used. Are the overlaid plaque assays fixed? (2) More detail in the SOP is needed regarding how waste streams are processed – especially since multiple agents are used in the laboratory; (3) Is a USDA permit needed for the strains of virus being transported to the laboratory – Theresa Bell will follow-up on this. Steve Creekmore moved to conditionally approve the registry pending responses to the aforementioned questions and updates to the SOP. Review and approval release was deferred to the lead reviewers and IBC chairman. Serguei Kozlov seconded the motion. (For: 13 Against: 0 Abstain: 0)

Robert Blumenthal 11-24 (P180897RBA01): Working with Vaccinia recombinants for protein expression and the study of viral entry Recombinant Vaccinia viruses are used to express a variety of viral proteins and/or receptor molecules on the surface of cells. Additionally, studies are undertaken to study the interaction of Vaccinia virus with cells and it's mechanism of entry. The committee felt the SOP lacked pertinent operational information for the room(s) in which this research was conducted, how waste streams are handled after Vaccinia experiments, use of the sonicator, and how unvaccinated persons are excluded from the space (i.e. is there a dedicated BSC/incubator/sonicator for the work; if so, is it marked? Is this equipment ever used by unvaccinated persons). Also due to the design of the laboratory, the committee felt the procedural concerns lacking in the SOP may be best

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addressed by visiting the lab. A subcommittee was selected to visit the lab which consisted of Mike Baseler and/or Bruce Crise, Theresa Bell, Dan McVicar, Kim DiGiandomenico and if scheduling permitted, Sarah Hooper. Dan McVicar motioned to *defer* the registry until the subcommittee has a chance to visit the laboratory and the SOPs are further expanded, as previously described. (For: 13 Against: 0 Abstain: 0)

William Kopp 11-28 (05-60, 06-39, 06-50, 07-54): *Laboratory operations of the Clinical Support Laboratory*
The Clinical Support Laboratory (CSL), Applied/Developmental Research Directorate, provides clinical trial support to NCI and other institutes as well as serving as a core laboratory for flow cytometry and cytokine testing. The laboratory is composed of 3 laboratory sections; Clinical Monitoring, Lymphokine Testing and Flow Cytometry. The primary function of the Clinical Monitoring Section is to receive and process blood and blood components for storage and/or provide materials for real time testing and at times, also receive other body fluids as well as punch biopsies of skin for generation of primary fibroblast cell lines. The Flow Cytometry Section performs analysis of cell surface markers, internal cellular markers such as cytokines, and cell cycle analysis. The Lymphokine Testing Section performs a wide range of assays for cytokines, chemokines, soluble receptors, and other serum factors with the primary testing platforms being commercial ELISA and electrochemiluminescence kits. In addition to routine testing, there are several special projects involving either recombinant agents or pathogens performed by the laboratory or under approved requests to be performed by the laboratory. The PI provided a very comprehensive SOP to outline the various hazards and handling practices with the agents they receive. The chain of custody of materials was questioned. Michael Baseler described the various checks and balances in place when samples are received and processed. Bruce Crise moved to approve the registry. Eric Freed seconded the motion. (For: 12 Against: 0 Abstain: 0)

Dianne Newton 11-29 (05-17): *Drug Mechanism Group* The Drug Mechanism Group is responsible for determining the mechanism of action and identifying potential surrogate markers of drug activity for a select number of compounds slated for preclinical development using microarray- and proteomic-based platforms. Inclusive in the proteomics technology is quantitative, subcellular, chemical, and 2D PAGE proteomics. Validation technology is extensive. The PI addressed all safety concerns during the lead review. Eric Freed moved to approve the registry. Bruce Crise seconded the motion. (For: 12 Against: 0 Abstain: 0)

OUTSTANDING ITEMS

Patricia Steeg / Joji Nakayama 11-02: *Examination of effects of loss of LPA1 mediated signal in MDA-MB-231T xenograft model* – PI terminated registration on 05/02/11.

Trinchieri/Noer – IBC 10-60 *Flow cytometry core lab* – No new updates to provide as of the May meeting.

AMENDMENTS

Eleven amendments were processed and approved between the April and May meetings.

OTHER BUSINESS

The Biosafety office will be developing BioMaterial Fact Sheets for laboratory and animal care staff as a means to communicate hazards and minimum handling requirements of specific agents. The first draft, Adenovirus and Adenoviral Vectors, was distributed to the Committee for comment. Dan McVicar indicated that these would be well received by the research community.

ADJOURNMENT

The meeting was adjourned at 1:30pm.

Next meetings:

June 21, 2011 (549 EBR)

July 19, 2011