

NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES
DECEMBER 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

- | | |
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| <input type="checkbox"/> Michael Baseler (regrets) | <input checked="" type="checkbox"/> Serguei Kozlov |
| <input checked="" type="checkbox"/> Theresa Bell | <input checked="" type="checkbox"/> Dan McVicar (Chair) |
| <input checked="" type="checkbox"/> Stephen Creekmore | <input checked="" type="checkbox"/> Randall Morin |
| <input type="checkbox"/> Bruce Crise (regrets) | <input checked="" type="checkbox"/> Shalini Oberdoerffer |
| <input checked="" type="checkbox"/> Eric Freed | <input type="checkbox"/> Alberta Peugeot (regrets) |
| <input type="checkbox"/> Melinda Hollingshead (regrets) | <input type="checkbox"/> Raja Sriperumbudur |
| <input checked="" type="checkbox"/> Stephen Hughes | <input checked="" type="checkbox"/> Lucien Winegar |
| <input type="checkbox"/> Scott Jendrek (regrets) | <input checked="" type="checkbox"/> Rev. David Betzner (arrived 12:10pm) |

Non-Voting

- Dianna Conrad
- Kim DiGiandomenico

Other

- Mary Carol Fleming (for Alberta Peugeot)
- Tim Rowe
- Karen Barber
- Robert Thomas

APPROVAL OF MINUTES FROM NOVEMBER 16, 2010 MEETING

The November 16, 2010 meeting minutes were approved as written.
(A motion and second were made. (For: (10) Against: (0) Abstain: (0))

ACCIDENT REVIEWS

In mid-November there was a needlestick involving a minor. The individual was working with inactivated *E. coli* at the time of the incident. Safety is waiting for additional clarification from the PI regarding the incident. A second incident, which was determined to be a non-exposure, involved a long-term FME worker who was transferring contents from one biohazard bag to another. While in the process, contents from the bag dumped onto the floor. The worker attempted to clean the area using bare hands, rather than a brush and dustpan, and cut his hand on broken glass that was located by an adjacent broken glass container. The worker was retrained by the supervisor and safety.

REVIEW OF PROTOCOLS

NEW REGISTRATIONS

Perwez Hussain 10-53: Tumorigenicity of FOXL1 over-expressing Pancreatic Cancer Cell lines The researchers will transfect Panc-1 cells with GFP or FOXL1-GFP and then xenograft them into mice to study tumorigenicity of human cell lines. During the pre-review the PI was asked to expand on what genes were being

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used and potential hazards with them. Lead reviewers were fine with the overall registry and safety aspects addressed by the PI. Dan McVicar moved to approve the registry with some enhanced language regarding sharps safety. Theresa Bell seconded the motion. (For: 11; Against: 0; Abstain: 0)

Diane Palmieri / Stephan Woditschka 10-54: *Effect of DNA Repair Gene BARD1 and RAD51 Overexpression on Brain Metastatic Breast Cancer Progression* This project involves using human breast cancer cell lines transduced with lentiviral vectors and then injecting them into mice to track development of brain tumors. The committee stated that injections should occur in a biological safety cabinet, which was not clearly defined in the LASP SOP that was provided. Additionally, in section A3 of the registry, the committee wanted additional information regarding 15 minutes of scrubbing and an OHS follow-up, should an exposure occur. Additionally, there is no mention of the HIV-based vector in this hazard section, and there should be. Lastly, E6b1 refers to the cells when they come back out of an animal...are they 'infectious'? Eric Freed motioned to approve the registry, pending clarifications to sections A3 and E6b1 as described above. Steve Hughes seconded the motion. (For: 11; Against: 0; Abstain: 0)

Perwez Hussain 10-55: *MicroRNA-based strategies in pre-clinical mouse model for the treatment of pancreatic cancer* This submission involves the use of pre-microRNA and anti-microRNA in mouse models. While the PI addressed safe work practices, there was information lacking in the registry regarding hazards of the materials to be used and specifics for how animals will be manipulated in the studies. The committee requested the following information: LASP SOPs to ensure what the PI is requiring can be met in the animal facilities; further expansion of section A1, hazards of the pre- and anti-microRNA; how dissections will occur; the time that lapses between injection of liposomes and sacrifice, and if enhancements would be needed for standard LASP SOPs to meet the safety needs of the study. Serguei Kozlov moved to conditionally approve the registry with clarifications as mentioned above to lead reviewers. Randall Morin seconded the motion. (For: 11; Against: 0; Abstain: 0)

RENEWALS

Perwez Hussain 10-51 (07-47): *Role of Nitric oxide and miRNA in the development of lung cancer in LSL-k-rasG12D mice (CONFIDENTIAL)* For this renewal, the PI will continue administering an Adeno-Cre construct into LSL-K-ras-G12D mice. The committee requested the following clarifications: LASP SOPs to ensure what the PI is requiring can be met in the animal facilities; further expansion of sections A1 and A3; and more information regarding viral titer and experiment endpoints. Serguei Kozlov moved to conditionally approve the registry pending lead approval of the clarifications listed above. Theresa Bell seconded the motion. (For: 11; Against: 0; Abstain: 0)

Lionel Feigenbaum 10-52 (02-19): *Production of Genetically Engineered Mice* --- Breeding only- with notification to committee

Teizo Yoshimura 10-56 (07-62): *Breeding of formyl peptide receptor (FPR) 1 and 2 double KO mice* --- Breeding only- with notification to committee

Patricia Steeg / Jean-Claude Marshall 10-57 (07-45): *Metastasis suppression function of NM23-H1 in an animal model of breast cancer* This renewal was for the continued study of 4T1 mouse model system to determine the in vivo role that NM23, a metastatic suppressor gene, plays in determining metastatic progression. Lead reviewers and the committee found no additional safety hazards with the renewed materials. Serguei Kozlov moved to approve the registry. Steve Hughes seconded the motion. (For: 11; Against: 0; Abstain: 0)

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George Pavlakis / Barbara Felber 10-58 (06-88): *Gene Transfer and Expression of Cellular DNAs* This was a renewal for a continuing project that focuses on the identification of mechanisms controlling gene expression and the role of molecular adjuvants in optimization of DNA vaccines. This PI also has other IBC approved protocols that pertain to the use of viral vectors and the lead reviewers requested clarification from the PI for how the non-human primate materials in this renewal would be segregated from the viral vectors. The committee requested enhanced language in the SOP regarding the heat inactivation of materials. Even if heat inactivated, materials should not be considered 'non-infectious' and the PIs should recognize this in their registry. Steve Hughes moved to approve the registry with the added language and lead review approval. Theresa Bell seconded the motion. (For: 11; Against: 0; Abstain: 0)

Robert Fisher 10-59 (06-35): *Measurement of antibody levels for HA22 immunotoxins in a limited section of patient samples from a study conducted by Dr. Ira Pastan of the NCI* This renewal was to continue the study to measure antibody level for HA22 immunotoxins in a limited selection of patient samples from a study conducted by Dr. Ira Pastan of the NCI. The antibodies will be delivered at the lab in Bethesda and only quantification will be conducted at the NCI-F using a Proteon XPR36 protein interaction array system. No splashes or aerosols are expected to be generated by this system and all waste will be collected in bleach. Shalini Oberdoerffer moved to approve the renewal. David Betzner seconded the motion. (For: 11; Against: 0; Abstain: 0)

Giorgio Trinchieri / Kathleen Noer 10-60 (07-25): *Flow Cytometer Core Service Study* This renewal is for the flow cytometry core facility for cell sorting and analysis. There was discussion about what materials are fixed and which ones are not and a few members were not convinced that the laboratory knew what they are receiving before sorting. There was also concern expressed regarding how much time passes between an 'infectious' sort versus a 'non-infectious' sort; how the room is decontaminated after an infectious cell sort and the difference between a sort operator and an analyzer operator. Steve Hughes motioned to defer the renewal until further information was provided by the PI. Specifically, the motion was that the IBC would provide guidance for a triage list (for sorting) – lead by Dan McVicar and Shalini Oberdoerffer; the PI/lab manager would explore the possibility of putting the cell sorters into a containment device – Theresa Bell offered to research some options for the PI as well; and the lab must agree to uphold, at a minimum, BSL2 practices at all times (including when accessing the cell sorting suite). Lucien Winegar seconded the motion. (For: 10 Against: 0 Abstain: 1)

OUTSTANDING ITEMS - none

AMENDMENTS

Twenty-five amendments were processed and approved between the November and December meetings.

OTHER BUSINESS - none

ADJOURNMENT

The meeting was adjourned at 2:00pm.

Next meetings:

January 18, 2011 (549 EBR)

February 15, 2011 (549 EBR)