

**NCI-FREDERICK  
INSTITUTIONAL BIOSAFETY COMMITTEE  
MINUTES**

**NOVEMBER 15, 2011**

**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 (Quorum = 8)

- |   |  |
|---|--|
| <input checked="" type="checkbox"/> Michael Baseler                     | <input checked="" type="checkbox"/> Sarah Hooper                       |
| <input checked="" type="checkbox"/> Theresa Bell                        | <input checked="" type="checkbox"/> Serguei Kozlov (arrived at 1:10pm) |
| <input checked="" type="checkbox"/> Rev. David Betzner (left at 2:30pm) | <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 type="checkbox"/> Shalini Oberdoerffer (regrets)                |
| <input checked="" type="checkbox"/> Eric Freed                          | <input type="checkbox"/> Raja Sriperumbudur (regrets)                  |
| <input checked="" type="checkbox"/> Melinda Hollingshead                | <input checked="" type="checkbox"/> Lucien Winegar (left at 1:45pm)    |
| <input checked="" type="checkbox"/> Stephen Hughes                      |  |

Non-Voting

- Walter Hubert
- Kim DiGiandomenico

Other

- Dr. Rob Gorelick (left at 1:45pm)
- Dr. Stephan Mann (arrived at 1:00; left at 1:45pm)

**APPROVAL OF MINUTES FROM SEPTEMBER 20, 2011 AND OCTOBER 18, 2011 MEETINGS**

The September 20, 2011 and October 18, 2011 meeting minutes were approved as written. (A motion and second were made. (For: (12) Against: (0) Abstain: (0))

**ACCIDENT REVIEWS**

There were no accidents to report.

**REVIEW OF PROTOCOLS**

**NEW REGISTRATIONS**

Andre Nussenzweig 11-60: *Role of DNA repair in tumorigenesis* - BREEDING ONLY **Notification to committee**

Richard Hodes 11-63: *Breeding and Maintenance of mice at FCRF* - BREEDING ONLY **Notification to committee**

**RENEWALS**

Jonathan Keller 11-57 (08-67): *Transduction of human hematopoietic cells and cell lines with replication incompetent retroviral vectors* (Hollingshead / Creekmore) The goal is to continue to

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investigate the effects of candidate genes whose expression levels change during early hematopoietic development using both in vitro (transfection into cell lines and primary mouse and human cells) and in vivo (transgenic and knock-out mouse) models. Their goal is to identify them as molecular targets for the development of new chemotherapies. During committee review, several members felt that there was a lack of consistency related to the use of 'ecotropic' and 'amphotropic' in the registry. Parts of the registry refer to virus as infecting people when it is an ecotropic virus, etc, which led to concerns about the investigators knowing what they're really working with. Given the tricky inserts being employed in the research, it is important that the document shows they really know what is going on. The committee has requested for them to evaluate the document for consistency and resubmit for committee review. Dan McVicar motioned to defer the registry review and approval back to lead reviewers, himself and Steve Hughes once the revisions are made. Steve Hughes seconded the motion. For: 12 Against: 0 Abstain: 0

Jonathan Keller 11-58 (08-72): Hematopoietic Stem and Leukemic Gene Investigation (General Cloning-no viral vectors) This group has previously identified candidate genes whose expression levels are altered during early blood cell development. They would like to continue to investigate the effects of these genes on hematopoietic cell growth and maturation using both in vitro and in vivo models, with the goal of identifying them as molecular targets for anti-cancer agents, or for therapies to treat anemia. During the pre-review it was confirmed that no viral vectors will be used with this project and primary human cells were no longer used. Transcription factors are cloned using standard cloning techniques and then expressed in immortalized cells. When the registry was reviewed by full committee, there was still some reference to primary human cells. Dan McVicar moved to approve the registry once the primary human cell references were removed. Lucien Winegar seconded the motion. For: 12 Against: 0 Abstain: 0

**OUTSTANDING ITEMS**

R. Gorelick 11-03-A1 – Hepatitis C Virus work – The PI attended the meeting to address questions that the committee had regarding the research. Prior to the next meeting, the committee requested the following:

1. The SOP(s) need revamped to specifically include what PPE will be used (over and beyond BSL2), how samples will be received, what to do in the event of an accident, how to decon cabinet, etc.
2. Theresa Bell will confirm with Dave McGivern on how the samples are packaged by his group at UNC and how they will be received here (NCI-F).
3. Some of the chemistry steps involved with the procedure were discussed by the PI. It was mentioned that an anhydride step may be added which hasn't been done in the past. The committee requested for the PI to provide confirmation that the samples after this step of the procedure would be non-infectious.
4. Sarah Hooper (OHS) will investigate any investigational drugs which may be available in the event of an exposure. (The CDC was noted as a resource, but the committee asked for the PI to see if his collaborators already have information on hand that they could supply.)
5. Set up a demo using fluorescein dye prior to the next IBC (December 20).

Ji Ming Wang 11-43 (08-53): The role of mouse G protein receptor FPR2 in infection, inflammation and cancer (Hollingshead/Freed) Deferred and project suspended in September 2011; On November 1, 2011, Dan McVicar, Theresa Bell and Melinda Hollingshead observed the laboratory techniques for handling and aliquotting *Listeria*. Ms. Bell and Dr. Hollingshead then went with the research fellow and PI to the 571 animal facility to observe the animal handling and injection techniques. On November 4,

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2011, Ms. Bell and Dr. Hollingshead observed organ harvest by the research fellow in the animal facility and then transport of materials back to the laboratory in 560 for processing.

Ms. Bell and Dr. Hollingshead observed several improper techniques that could lead to contamination of the procedure rooms with *Listeria*. The observations with recommendations will be supplied to the PI and research fellow for follow-up action.

Additional concerns were noted during the mock observation in the animal facility such as the lack of documented procedures and practices for what is referred to as the pathogen challenge room and lack of training for users of what is referred to as the pathogen challenge room. After much discussion, Dan McVicar made the following motions:

1. The safety concerns with the layout and operational practices and procedures of what is referred to as the pathogen challenge room will be brought to the attention of Dr. Lionel Feigenbaum for immediate action.
2. Regarding the practices of the research fellow with handling the *Listeria*, the following will occur:
  - The fellow and PI will be provided a list of the observations and recommended remediation actions;
  - The PI will re-write the SOP to incorporate these recommendations into the standard practice for manipulating *Listeria* and will train the research fellow on proper handling, disposal and disinfection technique;
  - Another mock observation of the experiment will then be conducted by Ms. Bell and Dr. Hollingshead.
  - If the revised safe handling practices/procedures are not exercised by the research fellow then the fellow will no longer be permitted to work with the agent to ensure the safety of the LASP and laboratory staff.
3. The *Listeria* research continues to be suspended until the aforementioned list of concerns is adequately addressed.

Theresa Bell seconded the motion. For: 12; Against: 0; Abstain: 0

Trinchieri/Noer – IBC 11-66 (formerly 10-60) Flow cytometry core lab: The PI had provided revisions to the IBC registration, but had not provided the revised request form or newly designed matrix for classifying samples and handling procedures. The review of the document was tabled until the December meeting due to lack of time and the aforementioned support documents.

#### **AMENDMENTS**

Twenty-seven amendments were processed between the October and November meetings. Two remained outstanding as of the meeting date, while twenty-five were approved.

#### **OTHER BUSINESS**

- During the review of one of the registrations, there were concerns expressed about how many laboratory staff do not know the proper use or function of a biological safety cabinet (BSC). It was asked what type of formal training lab staff receive upon their hire. At new employee safety orientation, there is a portion during the blood borne pathogen training that touches on the use of a BSC; however, there is no formal hands-on or BSC-only training. Some committee members felt that BSC training should be part of the IBC renewal process, while others added that not only should staff be trained, but they should also be subject to random post-approval monitoring to determine the effectiveness of the training.

Steve Hughes made the following motions:

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1. *Recommended action items from the IBC to EHS*

- a. EHS will create a training module with a hands-on demonstration for proper use and function of a BSC. This module will be made available to all incoming employees who work in a laboratory (primary post-docs).
- b. Once training has been completed and documented, EHS will conduct post-training monitoring to determine the value and impact of the module. The control will be to visit laboratories who have not yet received the training and determine if there is a difference in practices when using a BSC.

2. *Action item for the IBC:* At the time of renewal or when amendments involving a higher work hazard are submitted, the PI and his/her staff are expected to demonstrate minimum competency with the use of a BSC.

3. A copy of this motion would be provided to Craig Reynolds through the IBC Chairman, Dan McVicar.

Dan McVicar seconded the motion. For: 12 Against: 0 Abstain: 0

- *Discussion of changes to HIV and Hepatitis C surveillances* – For informational purposes, Sarah Hooper briefed the committee on a meeting regarding the current HIV and proposed new Hepatitis C Virus (HCV) medical surveillance programs. Although the NIH has dissolved their HIV surveillance program, the NCI-F Occupational Health Clinic will continue to offer it. The ‘training’ component to this surveillance will also go away and will be provided through a formal ‘offer’ letter to persons who are identified as working with the material. The HCV program would be offered the same way and at this time would only be applicable to individuals working with high titers of HCV. Dr. Stephan Mann added that a big concern of the group was people becoming complacent because of the surveillance availability; thus, leading to under-reporting of incidents/near misses or not reporting at all. Ms. Hooper will take the lead role in the revisions, development and implementation of these programs.
- *Membership appointment policy (tabled due to time)*
- *Medical surveillance and monitoring for EBV, CMV, XMRV (tabled due to time)*

**ADJOURNMENT**

The meeting was adjourned at 2:50pm.

*Next meetings:*

*December 20, 2011*

*January 17, 2012*