

**NCI-FREDERICK**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**MINUTES**  
**JULY 19, 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

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

Non-Voting

- Walter Hubert
- Kim DiGiandomenico

Prior to the meeting, Steve Hughes was asked by Dan McVicar to stand in as acting chair in his absence.

**APPROVAL OF MINUTES FROM JUNE 21, 2011 MEETING**

The June 21, 2011 meeting minutes were approved as written. It was suggested that in the future, the minutes also capture why individuals abstain from a vote and to document any training or additional activities that the IBC conducts for a registry, such as a site visit or viral vector safety training. (A motion and second were made. (For: (11) Against: (0) Abstain: (0))

**ACCIDENT REVIEWS**

Two accidents were reported to the committee. One involved a laceration to a finger when the individual was using a scalpel to cut centrifuge tubes. The second incident involved a CRTA/Special Volunteer who was freezing samples from animals on dry ice and ethanol splashed onto the face. No safety glasses/goggles were worn at the time of the incident.

**NEW REGISTRATIONS**

Glenn Merlino 11-34: *Breeding of Transgenic Mice* BREEDING ONLY *Notification to committee*

**RENEWALS**

Howard Young 11-21 (06-06): *Work with Immortalized Human / Mouse Lymphoid Cell Lines Previously deferred* The PI revised his registration to make the separation of the two projects more clear. Upon further discussion; however, the committee wanted the PI to acknowledge the following within the registry: Whenever murine vectors are introduced into murine cells or the vectors are introduced into a human cell line and then a mouse, it should be acknowledged that endogenous mouse virus could compliment the vector and mobilize a defective vector. Some endogenous mouse viruses can infect, and replicate in, human cells; for these reasons using murine vectors that carry "hot" oncogenes in murine cells is a concern. Also, the committee requested additional text added to A3 regarding how cells with the known uncharacterized virus in it is kept separate from uninfected cells. Scott Jendrek motioned to defer the vote pending the PI's response to these additional concerns. The responses must be sent back to full committee for email vote for final release of approval. (For: 11; Against: 0; Abstain: 0)

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Tomozumi Imamichi 11-30 (P150102TIA02): *Laboratory Operations of the Laboratory of Human Retrovirology* The continuing research of this group consists of two primary functions: (1) to evaluate the potency and efficacy of anti-viral materials or co-infection of non-HIV virus in HIV or SHIV infection and replication using *in vitro* culture systems; and (2) to investigate the mechanisms by which HIV/SHIV infection activates the innate immune response in the presence/absence of the materials. No animal research is involved with this protocol. All work is conducted at BSL2\* and the practices were well defined in the PI's SOP. The committee requested the following clarifications prior to releasing approval: Confirm that autoclaving of wastes is done by the lab staff, as described in the SOP, rather than placed in a red cart for autoclaving, as seen in the registry; for work with the Adenoviral vectors, no Cavicide should be used – Wescodyne or a phenolic would be suitable; How are materials segregated to ensure no 'mixing and matching' of various viral systems; How is the Sendai virus propagated and stored – clarify how the lab ensures inactivation of the virus upon receipt; what markers (proteins) do the CMV vectors express; and request for samples received from the Bethesda campus to be placed in plastic containers rather than glass. Eric Freed moved to approve the registry pending the aforementioned concerns. Bruce Crise seconded the motion. (For: 11; Against: 0 Abstain: 0)

Thomas Sayers 11-35 (08-36): *Modification of tumor antigenicity and cell death in vitro & in vivo* Steve Hughes motioned to table the review until the August meeting because both primary reviewers were not present at the meeting nor did they provide their review comments prior to the meeting. Theresa Bell seconded the motion. (For: 11; Against: 0; Abstain: 0)

#### **OUTSTANDING ITEMS**

Robert Blumenthal 11-23 (P110797RBA03): *Mechanism of viral entry and pathogenesis and*  
Robert Blumenthal 11-24 (P180897RBA01): *Working with Vaccinia recombinants for protein expression and the study of viral entry* Theresa Bell, Dan McVicar and Serguei Kozlov conducted a second site visit per the IBC to observe the actual procedures that were being conducted for these experiments. The summary document of these observations was provided to the laboratory as well as the full committee for review and comment. There was concern expressed by the committee regarding the recommendations being upheld once the approval was released. Theresa Bell volunteered to follow-up in 6 weeks to ensure that the recommendations were implemented and motioned to approve the registries with the enhanced safety practices incorporated into the registry. Serguei Kozlov seconded the motion. (For: 11; Against: 0; Abstain: 0)

Trinchieri/Noer – IBC 10-60 *Flow cytometry core lab* No updates to report; still waiting for information from the PI regarding SOPs

#### **AMENDMENTS**

Eighteen amendments were processed and approved between the June and July meetings.

#### **OTHER BUSINESS**

**The draft NIH Policy for Cell Sorters** was reviewed and discussed by the committee. Theresa Bell informed the committee that she collected an inventory from the property database of all instruments that may meet the definition of a cell sorter. Michael Baseler offered staff support to Ms. Bell to help her review the inventory to determine what is / is not a cell sorter. Narrowing the numbers from the inventory will help determine how many are currently compliant with the draft policy and what may be needed to bring current systems into compliance if the draft policy is accepted. Ms. Bell was also instructed to ask the owners of the cell sorters if they were using them for sorting or if they were only using them as analyzers.

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If the former, the owner of the instrument would need to demonstrate that the aerosol capture device is functioning properly (as described in the draft policy). The IBC was concerned about the policy being overly restrictive regarding the requirement for containment of sorting non-infectious murine cells. As a result, the group requested if Kevin Holmes and Steve Perfetto could be invited to the August IBC meeting to discuss the policy and how the specific requirements arose. Ms. Bell asked for a vote for who felt the policy was good and applicable to the NCI-F (i.e. that everything should be performed in containment). Ten members disagreed with the policy as currently written and one community member abstained as he felt he did not have the expertise to comment.

**Viral Vector Safety Training** was conducted on July 15, 2011 by Bruce Crise and Serguei Kozlov with 10 attendees. The group was comprised of staff from Occupational Health Services, IBC 11-18, IBC 08-41 (interns) and IBC 11-35 (one being the PI).

**ADJOURNMENT**

The meeting was adjourned at 1:20pm.

*Next meetings:*

*August 16, 2011*

*September 20, 2011*