

**NCI-FREDERICK  
INSTITUTIONAL BIOSAFETY COMMITTEE**

**MINUTES  
DECEMBER 15, 2009**

**CALL TO ORDER / ANNOUNCEMENTS**

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

**Voting**

- |   |   |
|---|---|
| <input type="checkbox"/> Michael Baseler (regrets)            | <input checked="" type="checkbox"/> Scott Jendrek                       |
| <input type="checkbox"/> Theresa Bell (regrets)               | <input checked="" type="checkbox"/> Serguei Kozlov                      |
| <input checked="" type="checkbox"/> Stephen Creekmore         | <input checked="" type="checkbox"/> Dan McVicar (Chair)                 |
| <input checked="" type="checkbox"/> Bruce Crise (left at 2pm) | <input checked="" type="checkbox"/> Randall Morin                       |
| <input checked="" type="checkbox"/> Eric Freed                | <input checked="" type="checkbox"/> Alberta Peugeot                     |
| <input type="checkbox"/> Melinda Hollingshead (regrets)       | <input checked="" type="checkbox"/> Lucien Winegar                      |
| <input checked="" type="checkbox"/> Stephen Hughes            | <input checked="" type="checkbox"/> Rev. David Betzner (left at 2:25pm) |

**Non-Voting**

- Dianna Conrad (regrets)
- Kim DiGiandomenico

**Other**

- Scott Keimig
- Karen Barber
- Bill Brady (regrets)
- Robert Thomas

**MINUTES**

The October 20, 2009 and November 17, 2009 meeting minutes were approved as written. (A motion and 2<sup>nd</sup> were made. (For: (11) Against: (0) Abstain: (0))

**ACCIDENT REVIEWS** – no accidents to report

**REVIEW OF PROTOCOLS**

***NEW REGISTRATIONS***

**09-62 (Laura Schmidt)** *Elucidating FLCN function in an in vivo model through adenoviral expression/knockdown of genes that may interact on the FLCN pathway*

Their research goal is to understand the mechanism by which inactivation of renal cancer susceptibility genes lead to the development of renal tumors through the generation of knockout mice. Both lead reviewers were pleased with the registry and detail regarding safety measures that would be incorporated into lab practices. They noted that viral stocks used in this protocol would be generated at NIH-Bethesda and only the animal studies would be conducted at the NCI-Frederick. Stephen Hughes commented that lab staff who will be performing the animal injections with the Ad-Cre should be aware of the fact that the Cre may not be totally benign should a self-inoculation occur. Serguei Kozlov moved to approve pending completion of Adenoviral training given by Bruce Crise. Dan McVicar 2<sup>nd</sup>.  
FOR: 11 AGAINST: 0 ABSTAIN: 0

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**09-60 (Lino Tessarollo) *No title provided (Botox research)***

Since the previous meeting, this investigator was able to secure the manufacturer diluting the botulinum toxin in smaller aliquots, lowering the number of LD50's to ~7. Stephen Creekmore noted that required PPE when handling the material should also include the use of a face shield. In addition, he requested that an explicit statement noting the number of LD50's in each vial should be incorporated into the registration. Serguei Kozlov added that the main window of concern for exposure is during the first 2 hours of the experiment. Dr. Kozlov also requested confirmation that the toxin would not be under any pressure, such as aspirating waste media. The committee requested for Alberta Peugeot to see if antitoxin would be immediately available, should an exposure occur. She said she would contact Dr. Michael Sauri to determine the availability. Dr. Creekmore moved to approve the registry pending clarification of the aforementioned items in the registry and availability of antitoxin. Dr. Kozlov 2<sup>nd</sup> the motion. FOR: 11 AGAINST: 0 ABSTAIN: 0

**09-61 (Ray Harris) *Development of a neuroattenuated, replication-selective type 1 herpes simplex virus vector, HSV C134, for the treatment of malignant gliomas***

Eric Freed and Bruce Crise commented that this investigator has conducted similar research in the past and noted that the document was well written. Dr. Crise further explained that the PI will be developing a variety of assays in an effort to scale up for larger production. Stephen Hughes noted that the research involved the production of 6L of viral stock, but it was not clear how those 6L were then processed. He requested clarification for this and also for a response plan for the 6L should a spill occur. In addition, Stephen Creekmore requested for the PI to clarify if any of the virus would be under pressure and if so, how it would be managed to reduce the event of an exposure. The committee also indicated that the PI should restrict lab personnel from conducting any of the research under this protocol if the person is taking an anti-herpatic. Dr. Crise motioned to approve the registry once clarifications were received. Dr. Freed 2<sup>nd</sup>. FOR: 9 AGAINST: 0 ABSTAIN: 2 (due to conflict of interest)

**RENEWALS**

**09-45 (Larry Phillips) *Analytical chemistry and Method Development for the Determination of Drug Metabolism and Disposition***

This investigator is processing human and murine blood samples, and on rare occasion, human urine or spinal fluid, in order to develop assays to study the concentration of the chemical (anticancer) agents in the biofluids of living organisms. Knowing how the concentration of the chemical agent varies as a function of time gives an indication of how a living organism absorbs, distributes, metabolizes and eliminates the agent. Since the initial submission of this registration, the committee has been pleased with its development. Stephen Creekmore motioned to approve the registration after the PI clarifies (within the document) how human samples will be chemically denatured. Lucien Winegar 2<sup>nd</sup> the motion. FOR: 11 AGAINST: 0 ABSTAIN: 0

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**AMENDMENTS**

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

**OUTSTANDING ITEMS**

**09-55 (Sandra Ruscetti)** *Development of Animal Models for Xenotropic MuLV-Related Virus (XMRV)*  
Questions that arose at the last IBC meeting were being addressed by the PI. Pending her response and review by lead reviewers, approval can be released. On the day of the December IBC meeting, Mark Shrader contacted Bruce Crise to request a meeting to discuss LASP safety concerns. Dr. Crise brought this to the attention of the committee and a sub-committee consisting of the following members will be convened. As long as sub-committee feels all safety considerations have been addressed, approval will be released: *SUB-COMMITTEE*: Sandra Ruscetti, Bruce Crise, Stephen Hughes, Dan McVicar, Mariam Anver, Mark Shrader, Alberta Peugeot, Scott Keimig, Craig Driver, Kim DiGiandomenico and Karen Barber (if available).

**09-56 (Philipp Oberdoerffer)** *A mechanistic link between DNA damage, chromatin, aging and cancer*  
Questions that arose at the last IBC meeting were being addressed by the PI. In addition, Stephen Hughes requested the most recent registration as the one on SharePoint had been not been updated prior to the meeting. Dan McVicar also requested the PI to provide an SOP describing how the various viral vectors will be segregated to avoid potential intermixing.

**09-58 (Stephen O'Brien)** *Opportunistic collection of animal tissues for genetic, veterinary clinical pathology and histopathologic studies, and feline retrovirus discovery*  
Questions that arose at the last IBC meeting were being addressed by the PI. The PI was also invited to attend the January 2010 meeting to discuss the research in person. In addition, a sub-committee meeting was requested to discuss concerns/issues 'off-line' in an attempt to address all outstanding issues prior to the January 2010 meeting. The meeting date had not been scheduled as of the December IBC meeting. *SUB-COMMITTEE*: Serguei Kozlov, Melinda Hollingshead (if available), Dan McVicar, Lucien Winegar, Alberta Peugeot, Bruce Crise (if available), Raja Sriperumbudur (DEA vet), Robert Werner (new LASP vet), Russ Hanson (lab staff), Melody Reolke-Parker (lab staff), Karen Barber, Scott Keimig and Kim DiGiandomenico.

**09-38 (Stephen O'Brien)** *Human Genetic Analysis*  
Questions that originated by Theresa Bell were sent by Karen Barber to Russ Hanson for clarification. Mr. Hanson responded and these answers were forwarded to Bruce Crise for approval. The registry was also reassigned for 2<sup>nd</sup> lead review on 12/15/09 to Scott Jendrek.

**OTHER BUSINESS**

***VPP Update:*** Bill Brady updated the committee via email regarding the status of the VPP. After speaking to his vendors, he did not expect to receive his tubing and filter assemblies until mid-January. One the upgrades are in place, Mr. Brady will contact the IBC to schedule a visual observation.

***Processing of IBC registrations:*** Dan McVicar and Kim DiGiandomenico have been discussing ways to better process IBC registrations. Dr. McVicar proposed to the committee the following:

- Establish a firm submission deadline for new and renewal registrations – similar to the ACUC and also set a deadline for comment by the IBC lead reviewers
- All questions/comments for the PI would be summarized by the IBC Administrator and sent to the PI for response. The PI would have a minimum of 1 week to respond. All revisions would

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be made directly by the PI within the body of the registration (as a Word document) and emailed back to the IBC Administrator. The PI would also give a point to point summary of the changes that were made within the document, similar to that of a journal review process with which they should be familiar.

- Once the updated document is returned to the IBC Administrator, it would be evaluated for completeness and resent to the lead reviewers for any additional comment.

Dr. McVicar indicated that the committee could test the system internally with select candidates and if it appeared to work more efficiently, it would be incorporated into an IBC policy and notification of the receipt deadline would be communicated to the NCI research community. Dr. McVicar also noted that for now, amendments would be processed on an as needed basis and that he, Theresa Bell and Ms. DiGiandomenico were also discussing the development of a more user-friendly form. Lastly, he requested for the committee to consider the proposal and to provide feedback at upcoming meetings.

**ADJOURNMENT**

The meeting was adjourned at 1:35 pm.

*Next meetings*

*January 19, 2010*

*February 16, 2010*

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Theresa D. Bell, MPH, CBSP  
IBC Secretary  
Biological Safety Officer, EHS

\_\_\_\_\_  
Date

APPROVED:

\_\_\_\_\_  
Dan McVicar, Ph.D.  
Chairman, NCI-Frederick IBC

\_\_\_\_\_  
Date

xc: Dr. Reynolds  
Mr. Wheatley  
Dr. Arthur  
Mr. Bufter