

**FREDERICK NATIONAL LABORATORY FOR CANCER RESEARCH (FNLCR)  
INSTITUTIONAL BIOSAFETY COMMITTEE  
MINUTES**

**JANUARY 15, 2013**

**CALL TO ORDER / ANNOUNCEMENTS**

The FNLCR 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"/> Bhargavi Kondragunta |
| <input checked="" type="checkbox"/> Rev. David Betzner   | <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          | <input checked="" type="checkbox"/> Randall Morin        |
| <input checked="" type="checkbox"/> Eric Freed           | <input checked="" type="checkbox"/> Raja Sriperumbudur   |
| <input checked="" type="checkbox"/> Melinda Hollingshead | <input type="checkbox"/> Lucien Winegar (regrets)        |
| <input checked="" type="checkbox"/> Stephen Hughes       |  |

Non-Voting

- Walter Hubert
- Kim DiGiandomenico

Other

CAPT Darrell LaRoche  
Grace Baskerville, RN

**APPROVAL OF MINUTES FROM DECEMBER 18, 2012 MEETING**

The minutes from the December 18, 2012 meeting were approved as written. A motion and second were made. (For: 14; Against: 0; Abstain: 0)

**ACCIDENT REVIEWS**

An employee noticed clear liquid on her hand upon removing her gloves after cleaning a centrifuge bucket. The bucket had been wetted for 30 minutes with Cavicide and appeared to have dried material around the threads of the cap. The employee was scratching off the material with a paper towel and her fingernail and thought she may have broken through her glove. Upon scrubbing for 15 minutes with disinfectant, she reported to Occupational Health for evaluation/consult. It was determined that there was no exposure to the materials that may have been on the centrifuge.

**REVIEW OF PROTOCOLS**

***NEW REGISTRATIONS***

Jianwei Zhu 12-85: Manufacturing of a VRP-TRP2 Vaccine for a Phase I Clinical Trials As of January IBC meeting, Theresa Bell was still awaiting response from the technical advisory group for the Federal select agent program. The group was scheduled to meet on December 20, 2012.

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**RENEWALS**

Ron Hornung 13-01 (07-34): HSV family protocols: Human cytokine polymorphism study, HSV-2 infection in an immune compromised patient study, Human HSV-2 vaccine study and the RhCMV vaccine study For this renewal, the IML will isolate PBMCs and plasma from clinical samples known or unknown to be infected with HSV, and the Laboratory of Clinical Investigation will prepare DNA and determine the sequence of different portions of cytokine genes from the isolated cells. The IML will isolate serum, plasma and PBMCs from each sample, store the samples in the Central repository and return the samples to the Center for Human Immunology Institute. There the serum and plasma samples will be tested for cytokine activity, and the PBMCs tested for cell surface markers and microchip arrays. The IML will also process samples from rhesus monkeys immunized with RhCMV glycoprotein L particles, replication deficient RhCMV virus or RhCMV virus deleted of invasive genes which down regulate MHC I and II. Eight weeks after the last immunization the monkeys will be challenged with wild type RhCMV. Blood and throat wash specimens will be harvested weekly after the challenge.

The committee requested clarification for where these samples are processed (BSL2\* lab?), and strongly suggested that a flow chart be devised and posted so there is no confusion as to what gets processed where. They have also strongly suggested that Dispatch or Bleach, rather than Cavicide, be used due to the fact that many of the samples are coming from severely immunocompromised patients (which are notorious for harboring other pathogens due to the patients' immune status). Melinda Hollingshead moved to approve the renewal with the suggestions. Steve Creekmore seconded the motion. For: 13; Against: 0; Abstain: 1 (Mike Baseler – PI is a direct report)

Ron Hornung 13-02 (07-33): Chronic Lyme Disease Protocol The purpose of this renewal is to assemble a well-characterized cohort of patients with presumed chronic Lyme disease and relevant controls that will yield a prospective database upon which stringent diagnostic criteria can be established and future therapeutic trials can be designed. The committee requested clarification for what samples are processed in the BSL2\* lab and which ones are processed in the other labs, and strongly suggested that a flow chart be devised and posted so there is no confusion as to what gets processed where. They have also strongly suggested that Dispatch or Bleach, rather than Cavicide, be used due to the fact that many of the samples are coming from severely immunocompromised patients (which are notorious for harboring other pathogens due to the patients' immune status). Lastly, they wanted the removal of the implication in A3 that no hazards exist. Steve Creekmore moved to approve the renewal with the suggestions. Melinda Hollingshead seconded the motion. For: 13; Against: 0; Abstain: 1 (Mike Baseler – PI is a direct report)

Scott McNeil 13-03 (09-44): NCL In vitro and In vivo Characterization Assays The Nanotechnology Characterization Laboratory (NCL) performs and standardizes the pre-clinical characterization of nanomaterials intended as cancer therapeutics and/or diagnostics developed by researchers from academia, government, and industry. These characterizations include not only physical/chemical characterization, but also in vitro and in vivo characterization assays.

During the pre-review process, it was confirmed that the cell lines would not be transduced by the NCL lab, but rather by the investigators who were supplying them. The PI also provided a nice grid in Part D to depict which cell lines would be used and how / where they would be used. The committee did request clarification for if any of the cell lines were transduced with pBabe and if so,

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were these cells being used in *in vivo* studies. Eric Freed moved to approve pending the aforementioned clarification. Serguei Kozlov seconded the motion. For: 14; Against: 0; Abstain: 0

Esta Sterneck 13-04 (09-52): Analysis of CEBPD functions by RNA interference in tumor cell lines To analyze the role of CEBPD at different stages of tumor progression, and to identify the cell-type specific functions of CEBPD, this lab generated sub-lines of tumor cell lines with stable silencing of CEBPD expression and respective control cell lines. These cell lines are being characterized molecularly in cell culture assays. As part of this renewal, they also plan to inject the cell lines into host mice to compare tumor growth, metastasis to the lungs, macrophage infiltration, and gene/protein expression. There was some committee discussion regarding the MMTV transgenes; however, the committee felt there was low risk for them to mobilize and transmit to humans based on how they were made and used. The committee did request a revision to the text provided in E11 regarding accidental injection of modified cells into the animal handler to actually state, that any potential exposure to the skin should be scrubbed for 15 minutes and then the individual should report to Occupational Health for additional evaluation. The incident should also be reported to the immediate supervisor. Steve Hughes motioned to approve the renewal with the modification to the text. Melinda Hollingshead seconded the motion. For: 14; Against: 0 Abstain: 0

**OUTSTANDING ITEMS** - None

**AMENDMENTS**

Seven amendments were processed and approved between the December 2012 and January 2013 meetings.

**OTHER BUSINESS**

- The committee was reminded of the changes that will take effect in March to NIH Guidelines for Synthetic Nucleic Acid Molecules.
- Dan McVicar reminded the members to log-into the IBC web registration. The beta-testing period will run through February 28, 2013.

**ADJOURNMENT**

The meeting was adjourned at 1:03pm.

***Next meetings:***

***February 19, 2013***

***March 19, 2013***