

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

**DECEMBER 18, 2012**

**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 = 9)

- |  |  |
|--|--|
| <input checked="" type="checkbox"/> Michael Baseler      | <input checked="" type="checkbox"/> Sarah Hooper         |
| <input type="checkbox"/> Theresa Bell (regrets)          | <input checked="" type="checkbox"/> Bhargavi Kondragunta |
| <input checked="" type="checkbox"/> Rev. David Betzner   | <input type="checkbox"/> Serguei Kozlov (regrets)        |
| <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 type="checkbox"/> Stephen Hughes (regrets)        |  |

Non-Voting

- Walter Hubert
- Kim DiGiandomenico

Other

CAPT Darrell LaRoche

**APPROVAL OF MINUTES FROM NOVEMBER 20, 2012 MEETING**

The minutes from the November 20, 2012 meeting were approved as written. A motion and second were made. (For: 11; Against: 0; Abstain: 0)

**ACCIDENT REVIEWS**

There was one accident reported that occurred in the Laboratory of Human Retrovirology. It occurred on a Sunday while the staff member was removing a biohazard bag from a waste container. A pipette tip punctured the bag and the employee thought he was stuck on his right hand thumb; however, the tip had only been used for RNA work. No other lab members had conducted any HIV work over the weekend after trash had been disposed on Friday evening. The staff member reported to Occupational Health for follow-up.

**REVIEW OF PROTOCOLS**

***NEW REGISTRATIONS***

Jianwei Zhu 12-85: Manufacturing of a VRP-TRP2 Vaccine for a Phase I Clinical Trials This submission will be reviewed by the Federal select agent program technical advisory group on December 20, 2012, as there are some reports of reversion with the replicon RNA-based strains. The Ag Select Agent Program requested more detailed information concerning the strain, specifically, any data that

**FREDERICK NATIONAL LABORATORY FOR CANCER RESEARCH (FNLCR)**

**INSTITUTIONAL BIOSAFETY COMMITTEE**

**MINUTES**

**DECEMBER 18, 2012**

demonstrates the TRP2VRP vaccine strain is attenuated or avirulent. No further IBC discussions will occur until the biosafety officer is notified of the advisory group's decision.

Robert Wiltout 12-79: Infection of mice with Encephalomyocarditis virus (EMCV) At the November meeting, the IBC chairman informed the committee that this registration had been put on hold. The lab notified the IBC Administrator that the registry has been withdrawn and thanked the committee for their input.

**RENEWALS**

Ron Hornung 12-84 (08-23): Isolation of blood products from Vaccinia vaccinated volunteers and the study of the induction of cytokines post Vaccinia Vaccine inoculation The purpose of this (renewal) project is to see if persons who are inoculated with the Vaccinia vaccine produce an immune response as measured by cytokine production and to correlate these findings with symptoms of the vaccination. The lab will obtain blood samples from NIH volunteers who have been inoculated with the Vaccinia vaccine at the Bethesda campus and delivered to the IML by SAIC couriers. The IML will cryopreserve these blood products for input into the NCI-Frederick repository facility. Upon request, cryopreserved samples will be forwarded to NIH collaborators in Bethesda.

The IBC conditionally approved this renewal pending some clarifications. In the paperwork, A3 states that "Due to the controversy as to whether a Vaccinia viremia occurs within four weeks...those contraindicated for vaccine due to family restrictions will not be allowed to work with blood..." and will be kept out of the area where the work is being conducted. The IBC requested for this statement to be revised so that *anyone* who is contraindicated for the vaccine (the individual or due to family restrictions) will not be allowed to conduct the research. The committee also requested for the PI to identify who will be conducting the research so that EHS can obtain concurrence with Occupational Health that the individual(s) are cleared for the work. Also, the committee wanted to know if the gauze used to open the Vacutainer tubes is wetted with disinfectant prior to using it to open the tubes. Lastly, since the SOP is lab-, rather than protocol-specific, the committee requested a 'special considerations' section for each of the agents that may be in the samples received. For instance, a sign should be posted in the BSL2\* lab when the Vaccinia work is being done so no one else enters the lab; there should be specific mention that gauze is whetted prior to opening tubes, etc. The committee agreed that an observation should be conducted of staff involved in the research. Steve Creekmore moved to conditionally approve the renewal pending clarifications above. Melinda Hollingshead seconded the motion. For: 11; Against: 0; Abstain: 0

Dan Soppet 12-86 (08-43): Genetic Analysis of RNA and DNA from clinical patients and research models This lab will be identifying DNA sequences and RNA expression profiles for a variety of research and clinical materials to identify genetic differences relevant to disease diagnosis and treatment. The primary work will involve enzymatic modification or amplification of nucleic acids from fixed tissues or purified DNA and should pose a very low level of risk to lab workers. The lab has no intention to work on pathogenic materials however there may be occasion to work on cell lines, blood, or unfixed tissue from animal models and some cell lines which may contain recombinant genetic material. During the pre-review, the PI was asked for their DNA extraction SOP, which once provided, cleared up any additional concerns the reviewers had. Mike Baseler moved to approve the registration. Bhargavi Kondragunta seconded the motion. For: 11; Against: 0; Abstain: 0

**OUTSTANDING ITEMS**

Dennis Klinman 12-71 (09-54): Infectious Pathogens used in the study of vaccines, adjuvants, and modulators of the innate immune system The registration was conditionally approved at the

**FREDERICK NATIONAL LABORATORY FOR CANCER RESEARCH (FNLCR)**

**INSTITUTIONAL BIOSAFETY COMMITTEE**

**MINUTES**

**DECEMBER 18, 2012**

November meeting, pending clarifications to the SOP and agents being administered to animals. The clarifications were received the day of the IBC meeting and were pending final review and approval.

Ralph Parchment 12-75 (07-63): Specimens for Pharmacologic and Toxicologic Assessment Due to lack of signature sheets, the IBC administrator has not been able to release the approval. Dr. Mike Baseler offered to meet with the PI to obtain what was required for the approval.

**AMENDMENTS**

Twelve amendments were processed and approved between the October and November IBC meetings.

**OTHER BUSINESS**

- Dan McVicar notified the committee that Dr. Shalini Oberdoerffer would no longer be serving on the FNL IBC. Her lab is being relocated to the Bethesda campus.
- The committee was reminded of the beta-testing period for the IBC web-to-database registration system and to provide feedback to Kim DiGiandomenico by February 28, 2013.
- Changes to NIH Guidelines for Synthetic Nucleic Acid Molecules - effective date March 2013 – tabled

**ADJOURNMENT**

The meeting was adjourned at 12:50 pm.

***Next meetings:***

***January 15, 2013***

***February 19, 2013***