

**NATIONAL CANCER INSTITUTE AT FREDERICK (NCI@F)**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**MINUTES**  
**APRIL 22, 2014**

**CALL TO ORDER / ANNOUNCEMENTS**

The NCI@F Institutional Biosafety Committee was convened at 12:04 pm in Building 549 Executive Board Room with the following members in attendance:

Voting (Quorum = 8)

- |   |  |
|---|--|
| <input type="checkbox"/> Katalin Baranji (regrets)      | <input type="checkbox"/> Stephen Hughes (regrets)      |
| <input type="checkbox"/> Michael Baseler (regrets)      | <input checked="" type="checkbox"/> Sarah Hooper       |
| <input checked="" type="checkbox"/> Theresa Bell        | <input type="checkbox"/> Serguei Kozlov (regrets)      |
| <input checked="" type="checkbox"/> Rev. David Betzner  | <input checked="" type="checkbox"/> Dan McVicar        |
| <input type="checkbox"/> Stephen Creekmore (regrets)    | <input checked="" type="checkbox"/> Raja Sriperumbudur |
| <input checked="" type="checkbox"/> Bruce Crise         | <input checked="" type="checkbox"/> Lucien Winegar     |
| <input checked="" type="checkbox"/> Eric Freed          | <input checked="" type="checkbox"/> Enrique Zudaire    |
| <input type="checkbox"/> Melinda Hollingshead (regrets) | <input checked="" type="checkbox"/> Sharon Altmann     |

Non-Voting

- |   |  |
|---|--|
| <input checked="" type="checkbox"/> Walter Hubert | <input checked="" type="checkbox"/> Senad Diglesic |
| <input checked="" type="checkbox"/> Karen Barber  | <input checked="" type="checkbox"/> Doug Guam      |
| <input checked="" type="checkbox"/> Sheryl Ruppel | <input checked="" type="checkbox"/> Barbara Brooks |
| <input checked="" type="checkbox"/> Dr. Mann      |  |

**APPROVAL OF MINUTES FROM MARCH 18, 2014 MEETING**

The minutes from the March 18, 2014 meeting were approved as written. A motion and second were made (For: 9; Against: 0; Abstain: 1)

**ACCIDENT REVIEWS** - Mouse bite on pinky finger from a naïve mouse while changing mouse cages. No biologicals. Following up with OBA questions.

**REVIEW OF PROTOCOLS**

***NEW REGISTRATIONS***

Zhi-Ming Zheng – 14-13 – Tumor Virus RNA biology. This study will include experiments with: HPV - Analyzing the HPV gene expression and HPV regulation of host gene expression including non-coding RNAs in HPV-positive cell lines or keratinocytes-derived raft tissues; KSHV - Analyzing KSHV gene expression and KSHV regulation of host gene expression in B lymphocytes with the methods described for HPV study. Future experiments with E71 and ERPV: These two virus stocks will remain in the freezer. They are not going to grow either virus and will not have active projects on either of these viruses in the lab at this time. Employees that are immune compromised or showing signs of upper respiratory symptoms will not be allowed to work on this protocol. The PI will amend this registration when the experiments will begin. Dan McVicar moved to conditionally approve pending clarifications

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regarding the use of the centrifuge, autoclaving waste, cell counter location and clarification of inactivating DNA. Lucien Winegar seconded the motion. For: 8; Against: 0; Abstain: 2

Shuo Gu – 14-14: RNA mediated gene regulation. To study non-coding RNA mediated gene regulation, they need to transfect various human/mouse cell lines with siRNA/shRNA/rDNA. Enrique Zudaire moved to approve the registry. Eric Freed seconded the motion. For: 10; Against: 0; Abstain: 0

Yinling Hu – 14-15 – The study of Kras G12D in production of Adenocarcinoma formation. To study the effect of IKK $\alpha$  in Kras G12D-driven lung carcinogenesis. This is the intratracheal animal injection work. The primary concern that arose during the pre-review, and which was subsequently addressed, was how the virus titer was determined and decontamination time. Raja Sriperumbudur motioned to approve. Theresa Bell seconded. For: 10; Against: 0; Abstain: 0

***RENEWALS***

Vinay Vyas/George Mitra – 14-12 (06-29): Production of recombinant human IL-15 for Research and Cancer Clinical Trials. This study involves GMP fermentation (up to 500 L scale), purification, lyophilization, and fill/finish of rhIL-15. The primary concern that arose during the pre-review, which was subsequently addressed, was the manual fill procedures and the potential for contamination of the vials and the potential for aerosolization. Once the vials are lyophilized, if there is any contamination on the outside of the vial, you will see a white spec. The vials are individually wiped with a sterile wipe, regardless of a visual spill. If any disinfectant is left, the vials are wiped with alcohol. Regarding aerosolization if there is a spill in the pan: when this material is lyophilized, the powder cannot aerosolize due to a crust on the powder. The pan is wiped with a sterile wipe. Dan McVicar motioned to approve and Bruce Crise seconded. For: 10; Against: 0; Abstain: 0

***OUTSTANDING ITEMS***

Yinling Hu – 14-01(09-12) Role of IKK $\alpha$  in Cancer and Inflammation. IKK $\alpha$  has been found to be important for the development of squamous cell carcinomas in humans and mice and for inflammation and immune function. A better understanding of the mechanism of how IKK $\alpha$  is involved in these aspects will provide the insight into therapeutic targets for preventing or treating these diseases. The primary concern that arose during the pre-review, which was subsequently addressed, was if the KHSV cultures produce low levels of virus and if the cells are removed from the BSC; inactivation procedures for both KHSV and HPV; infection of raft cultures; centrifugation procedures; employees that are immune compromised or showing signs of upper respiratory symptoms will not be allowed to work on this protocol. Conditional approval motioned by Eric Freed. Enrique Zudaire seconded the motion. For: 10; Against: 0; Abstain: 0

John Gilly 14-06 (10-16) – Use of HEK 293 cells for alphavirus vaccine production. Use of HEK 293 cells for Alphavirus Vaccine Production: The primary concern that arose during the pre-review, which was subsequently addressed, was clarifications regarding the hazards of the pump if it failed and the decontamination procedures for manual filling needed to be clarified. The filling process is 100% manually inspected. Once the vials are lyophilized, if there is any contamination on the outside of the

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vial, you will see a white spec. The vials are individually wiped with bleach, regardless of visual contamination. If any disinfectant is left, the vials are wiped with alcohol. Regarding the pump pressure issue, the group tested the pump, several times, with pressure regulators on each end of the tube to measure the pressure. The pressure never reached higher than 62 PSI. The tubing rating is 1300 PSI. Dan McVicar motioned approve. Bruce Crise seconded. For: 10; Against: 0; Abstain: 0

Dimiter Dimitrov 13-38 (04-04, 08-20): Developing anti-viral vaccines and human antibodies against infectious diseases and cancer antigens by using recombinant membrane proteins of HIV, Nipah, Hendra, Dengue viruses and cancer antigens. Committee requested additional clarifications and a Vaccinia-specific SOP as well as a lab visit. Post-meeting, Theresa Bell learned that the lab was relocating and suggested that the space that will be used for the Vaccinia work should not be evaluated until the move has been completed. No Vaccinia work is being performed at this time. **Continue deferral until lab move and observation is completed.** For: 8; Against: 0; Abstain: 0

**AMENDMENTS**

Nineteen amendments were processed and approved between March and April IBC meetings.

**OTHER BUSINESS**

Immunization requirements

Launch of the new online IBC registration submittal.

Clorox concentration change and dilution requirements.

**ADJOURNMENT**

The meeting adjourned at 2:00 pm.

***Next meetings:***

***May 20, 2014***

***June 17, 2014***