

**NATIONAL CANCER INSTITUTE AT FREDERICK (NCI@F)**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**MINUTES**  
**JULY 15, 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 ( <i>regrets</i> ) | <input checked="" type="checkbox"/> Stephen Hughes     |
| <input type="checkbox"/> Michael Baseler ( <i>regrets</i> ) | <input checked="" type="checkbox"/> Sarah Hooper       |
| <input checked="" type="checkbox"/> Theresa Bell            | <input checked="" type="checkbox"/> Serguei Kozlov     |
| <input checked="" type="checkbox"/> Rev. David Betzner      | <input checked="" type="checkbox"/> Dan McVicar        |
| <input checked="" type="checkbox"/> Stephen Creekmore       | <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 checked="" type="checkbox"/> Melinda Hollingshead    | <input checked="" type="checkbox"/> Sharon Altmann     |

Non-Voting

- Walter Hubert
- Karen Barber

**APPROVAL OF MINUTES FROM JUNE 17, 2014 MEETING**

The minutes from the June 17, 2014 meeting were approved as written. A motion and second were made (For: 14; Against: 0; Abstain: 0)

**ACCIDENT REVIEWS** : None

**REVIEW OF PROTOCOLS**

***NEW REGISTRATIONS***

John Gilly – 14-23 – Storage of BARDA Vaccine Materials. (McVicar/Creekmore). The purpose of this project is solely to store materials that were generated by MedImmune for the development of pandemic influenza live attenuated vaccines for BARDA/HHS. Concerns with the “unlabeled vials” on the list of material being stored. Deferred until new ruling by NIH on “unlabeled vials” is determined. Clarification needed on type of disinfectant being used and a risk based appraisal of their procedures. Confirmation of how they receive and document the packages. Deferred to full committee in August. Dr. Creekmore motioned and Dr. McVicar seconded the motion. For: 14; Against: 0; Abstain: 0

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John Gilly – 14-25 – (Freed/Crise) - Production of Hemagglutinin-Ferritin nanoparticle (HA-FN) by HEK293 cell line. The work described in this registration applies to the use of HEK293 cells to produce a recombinant protein comprised of a fusion between the hemagglutinin (HA) protein of influenza virus and Helicobacter pylori ferritin protein. This registration did not have many issues. Dr. Freed motioned to approve; Dr. Crise second the motion. For: 14; Against: 0; Abstain: 0

***RENEWALS***

Stephen Lockett – 14-22 (08-46) – (Zudaire/Hughes/Altmann) - Ras project 3 and CCR support. Discovery methods to directly target oncogenic Ras protein, and live and fixed cell fluorescence labeling in support of CCR research. *This was not reviewed at this meeting. Awaiting further documentation from the PI.*

James McMahon – 14-24 (P191187JMA) – (Kozlov/Sriperumbudur) - MTL Antiviral Screening Group. The testing of compounds for anti-HIV activity in a live virus, cell-based assay. The PI was notified, prior to this meeting, that an extensive re-work of this registration was needed. Clarifications of live virus vs. defective; mitigation of all the risks when using the replication competent virus; how are the plates read (how and what instrument is it performed in); the committee felt that the registration did not give enough information on working with a live virus. Recommendation was made to ask the PI to voluntarily stop all work on this project until the registration has been approved. A motion to defer this registration was made by Dr. McVicar and Dr. Creekmore seconded. For: 13; Against: 0; Abstain: 1

Peter Gorelick – 14-26 (08-27). (Bell) - Serological diagnostic testing of non-human primates for the presence of potentially adventitious viruses - Diagnostic serological testing for routine health monitoring of NHPs. *This was not reviewed at this meeting. Awaiting further documentation from the PI.*

***OUTSTANDING ITEMS***

Dimitar 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

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**AMENDMENTS**

Thirty six amendments were processed and approved between June and July IBC meetings.

**OTHER BUSINESS**

- Update on Dr. Pavlakis registration (13-80). A dedicated room has been created for this work for the duration of the study. A list of employees has been identified to be evaluated for the Vaccinia vaccination. Clarification of the type of cages being used and negative air pressure within the lab.
- Laboratory Safety Manual (aka SOP) – A laboratory Safety Manual guidance document was created to assist Principal Investigators in developing their lab specific laboratory operating procedures.

**ADJOURNMENT**

The meeting adjourned at 1:10 pm.

*Next meetings:*

*August 19, 2014*

*August 16, 2014*