

NATIONAL CANCER INSTITUTE AT FREDERICK (NCI@F)
INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES
OCTOBER 21, 2014

CALL TO ORDER / ANNOUNCEMENTS

The NCI @ F Institutional Biosafety Committee was convened at 12:10 pm in Building 427 Conference Room with the following members in attendance:

Voting (Quorum = 8)

- | | |
|--|--|
| <input checked="" type="checkbox"/> Katalin Baranji | <input type="checkbox"/> Stephen Hughes (<i>regrets</i>) |
| <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 type="checkbox"/> Raja Sriperumbudur (<i>regrets</i>) |
| <input checked="" type="checkbox"/> Bruce Crise | <input checked="" type="checkbox"/> Lucien Winegar |
| <input type="checkbox"/> Eric Freed (<i>regrets</i>) | <input checked="" type="checkbox"/> Enrique Zudaire |
| <input type="checkbox"/> Melinda Hollingshead (<i>regrets</i>) | <input checked="" type="checkbox"/> Sharon Altmann |

Non-Voting

- Walter Hubert (*regrets*)
- Karen Barber
- Matthew Nawn

APPROVAL OF MINUTES FROM SEPTEMBER 16 MEETING

The minutes from the September 16, 2014 meeting were approved with one minor change. A motion and second were made. (For: 11; Against: 0; Abstain: 0)

ACCIDENT REVIEWS : None

REVIEW OF PROTOCOLS

NEW REGISTRATIONS

- ❖ Gordon Whiteley – 14-35 – Cell Surface Mapping of KRAS cancers – KRAS mutations are the leading cause of pancreatic, lung and colorectal cancers. The experiments we are planning involve several cell lines. These have been obtained from human samples and have been grown in tissue culture. While these experiments can provide some information, it is a fact that tissue cultured cells are not the same as cells that are obtained from animals. The in vivo cells can have differences and this may be reflected in the cell surface. It is our intent to confirm or reject our findings in cells that have been grown in tissue culture through the growth of these cells in mice. Theresa Bell motioned to approve with changes and David Betzner seconded. (For: 11; Against: 0; Abstain: 0)

NATIONAL CANCER INSTITUTE AT FREDERICK (NCI@F)
INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES
OCTOBER 21, 2014

- ❖ Donald Court – 14-36 – Engineering a Multivalent, Lytic Bacteriophage Platform Targeting Carbapenemase-Producing Klebsiella pneumonia to reduce resistance and enhance clinical efficacy. The purpose of our research is to engineer bacteriophages specific to KPC+ Klebsiella pneumonia for use in phage therapy approaches. This project will generate much-needed therapeutic approaches for combating a pathogen that has become resistant to all available clinically used antibiotics. Conditional approval was motioned by Dan McVicar with additional documentation to be added and Theresa Bell seconded. (For: 11; Against: 0; Abstain: 0)
- ❖ Beverly Keseling – 14-38 – Measles Viru-NIS for Multiple Myleoma, Technology Transfer and Process Optimization– Measles virus MV-NIS is an attenuated, oncolytic measles virus genetically engineered to express the human thyroidal sodium iodide symporter (NIS). The Biopharmaceutical Develop Program (BDP) has received a request through the NCI Next program to further optimize the production and purification of the virus to provide at least enough to complete a Phase II clinical trial. With the present production methods and resource limitations at the Mayo Clinic Viral Vector Production Laboratory, this cannot be accomplished. Bruce Crise motioned to approve and Lucien Winegar seconded. (For: 11; Against: 0; Abstain: 0)
- ❖ John Gilly – 14-39 – Chinese Hamster Ovary Cell Line, Cell Banking, Growth Studies and 2000L scale production – The purpose of this project is to produce sufficient quantities of an anti-HIV monoclonal antibody for GLP preclinical studies and production of GMP quantities to support human clinical trials under US FDA IND. Steve Creekmore motioned to approve and Dan McVicar seconded. (For: 11; Against: 0; Abstain: 0)
- ❖ Robert Gorelick – 14-32 – Structure-function studies of retroviral proteins, retroviral assembly, and immunological control of retroviruses – Retroviruses and specific proteins from these including mainly HIV-1, HIV-2, SIV, HTLV-1, HTLV-2, MuLV, RSV, MMTV, and EIAV will be studied, examining properties and requirements of viral and cellular proteins, and RNA genomes in viral replication. Under no circumstances are animals directly inoculated/injected with recombinant DNA or vector viruses. Recombinant DNA is used to generate viruses and vectors in cell culture. The viruses and vectors or cells infected with viruses or vectors are generated in cell culture and are then used in animal studies. Cell lines developed from primary non-human primate cells will be expanded and transferred into recipient animals. These experiments will be performed both at FNL (mouse studies under FNL-ASP and IBC jurisdiction) and at the NIH-Bethesda animal facility. NHP studies under separate IBC registries and ASPs, not associated with FNL. Steve Creekmore motioned to approve with minor edits and Serguei Kozlov seconded. (For: 11; Against: 0; Abstain: 0)
- ❖ **RENEWAL REGISTRATIONS**
 - ❖ James McMahon – 14-24 (P191187JMA) – Whole Cell Anti-HIV Screening Assay. The general assay involves the infection of CEM-SS cells with HIV-1 in the presence of the test compound. A subm-assay involves the infection of H9 cells with HIV-1. This is necessary to resupply our virus stock

NATIONAL CANCER INSTITUTE AT FREDERICK (NCI@F)
INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES
OCTOBER 21, 2014

used in the anti-HIV whole-cell assay. (Sriperumburdur/Kozlov) Deferred to full committee in August. Received additional documentation. Is ready for full committee.

OUTSTANDING ITEMS

Peter Gorelick – 14-26 (08-27). Serological diagnostic testing of non-human primates for the presence of potentially adventitious viruses - Diagnostic serological testing for routine health monitoring of NHPs. (Bell) Deferred to full committee in August. Awaiting additional documentation.

Stephen Lockett – 14-22 (08-46) – 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. (Zudaire/Hughes/Altmann) Deferred to full committee in August. Awaiting additional documentation.
ON HOLD. WAITING ON CHANGES IN THE DEPARTMENT BEFORE SUBMITTING. As of October 14, 2014, no updates have been made.

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

Twenty four amendments were processed and approved between August and September IBC meetings.

OTHER BUSINESS

- BSL-0 designation from Bethesda IBC
- Introduction of the new medical consultant: Dr. Anusha Belani

ADJOURNMENT

The meeting adjourned at 1:45 pm.

Next meetings:

November 18, 2014

December 23, 2014