

NATIONAL CANCER INSTITUTE AT FREDERICK (NCI@F)
INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES
AUGUST 12, 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)

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

Non-Voting

- Walter Hubert
- Karen Barber

APPROVAL OF MINUTES FROM JUNE 17, 2014 MEETING

The minutes from the July 15, 2014 meeting were approved with one minor change. Dr. Betzner was not in attendance at this meeting. A motion and second were made. (For: 11; Against: 0; Abstain: 1)

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. Moved to approve with the clarification that although there is no safety issues, it seems impossible to attest to the contents of the material. The committee does not want to approve without formal approval by the NCI. Dr. McVicar motioned and Rev. Betzner seconded the motion. For: 12; Against: 0; Abstain: 0

Sivakumarvenkat Vepachedu – 14-27 – PTEN-long - Recombinant human PTEN protein, expressed and purified from bacteria, is commercially available as a reagent for research and development studies. The objectives of this PTEN-long project are; i) conduct analytical assays on PTEN-Long produced in Dr. Parson's lab, ii) R&D production to perform toxicology, PK and PD studies, and iii) medium scale and

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GMP production. A motion to defer to full committee in September for further clarifications. For: 12; Against: 0; Abstain: 0

Vinay Vyas – 14-29 – Process Development and Clinical Manufacture of Mammalian Interleukin 7 -
Interleukin-7 (IL-7) is a multifunctional cytokine with critical and non-redundant roles in T lymphocyte development, hematopoiesis, and post-developmental immune functions. Recombinant human Interleukin 7 (rhIL-7) is being developed as anti-tumor as well as anti-infectious reagent for clinical trials. Recombinant human Interleukin 7 (rhIL-7) has previously been produced at the BDP using an E. coli expression system. The BDP is developing a new mammalian cell based transient expression system for rhIL-7 . Transient expression systems are widely used in industry at the early stage of pre-clinical product development. Advantages of transient expression system use in early product development include low cost, rapid development of a production cell line, and rapid generation of sufficient material for characterization. Dr. McVicar motioned to approve pending clarifications and Dr. Freed second. For: 11; Against: 0; Abstain: 1

RENEWALS

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

AMENDMENTS

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

OTHER BUSINESS

- Discussion on animal caging requirements and if the IBC should create an Institutional Guidance document . A subcommittee will be formed to discuss these requirements.

ADJOURNMENT

The meeting adjourned at 1:50 pm.

Next meetings: September 16, 2014 October 14, 2014