

NATIONAL CANCER INSTITUTE-FREDERICK (NCI-F)
INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES

JULY 16, 2013

CALL TO ORDER / ANNOUNCEMENTS

The NCI-F Institutional Biosafety Committee was convened at 12:06 pm in Building 549 Executive Board Room with the following members in attendance:

Voting (Quorum = 8)

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

Non-Voting

- Walter Hubert
 Kim DiGiandomenico (regrets)

Other

- Karen Barber
 Gail Housaman
 Katalin Baranji
 Enrique Zudaire

Two new IBC members were introduced to the committee – Katalin Baranji, an Assay Validation Scientist from the Vaccine Research Center and Enrique Zudaire from the Mouse Cancer Genetics Program.

APPROVAL OF MINUTES FROM JUNE 18, 2013 MEETING

The minutes from the June 18, 2013 meeting were approved as written. A motion and second were made (For: 9; Against: 0; Abstain: 1)

ACCIDENT REVIEWS

None

REVIEW OF PROTOCOLS

NEW REGISTRATIONS

Jianwei Zhu 13-59 – VRP-TRP2 Vaccine Vialing for a Phase I Clinical Trials The proposed project is to vial clinical grade VRP-TRP2 vaccine for Phase I clinical trials. The reagent VRP-TRP2 will be produced in AlphaVax Inc. and tested for replication competent Venezuelan Equine Encephalitis (VEE) virus (RCV). The bulk drug substance will only be shipped to the BDP following a test to ensure the material is free for RCV. There were some edits to the text and additional clarifications requested by the committee. Eric Freed moved to approve pending clarifications. Randall Morin seconded the motion. For: 8; Against: 0; Abstain: 0

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Andy Stephen (13-60): Antibody binding to intact bacteria using fluorescence correlation spectroscopy The lab plans to use a fluorescently labeled monoclonal antibody to detect the presence of the bacteria Brucella using fluorescence correlation spectroscopy (FCS). The bacteria are either human vaccine strains (B. abortus S19 and RB51) or non-human pathogens (B. canis). The samples will be checked for sterility by the supplying collaborator prior to shipping using their standard protocol for demonstrating sterility in any inactivated bacterial samples prior to shipment to outside collaborators. A memo asserting the results of these sterility checks will be provided by the collaborator prior to beginning any FCS measurements. There were some minor clarifications requested in the paperwork. Dan McVicar moved to approve the registry pending the clarifications. Lucien Winegar seconded the motion. For: 10; Against: 0; Abstain: 0

Kylie Walters (13-61): NMR Structural Studies of Ubiquitin Receptor Protein Complexes This lab is involved in the structural characterization and cellular interactions of ubiquitin receptor protein complexes. This registration is intended to report the recombinant DNA and mammalian cell culture activities that are associated with this project. The committee had minor questions regarding the end result of the experiments (i.e. if they would be used in animals) and where the work would be conducted. Dan McVicar moved to approve the registry pending the aforementioned clarifications. Eric Freed seconded the motion. For: 10; Against: 0; Abstain: 0

Christophe Redon (13-62): Evaluating the role of NOX4 in A-T disease. The goal of this study is to analyze the role of NOX4 enzyme in the mouse model of Ataxia-telangiectasidisease (A-T). The committee requested for the PI to address the use of siRNA's and requested for a complete registry to be filed rather than a breeding only registry. Dan McVicar moved to defer the registry pending submission of the complete registry with expedited review and subsequent approval by himself, Raja Sriperumbudur and Serguei Kozlov. Steve Hughes seconded the motion. For: 10; Against: 0; Abstain: 0

RENEWALS

Giorgio Trinchieri (13-55): Gene expression in human dendritic cells and cytokine signaling in human cells Focus in this lab is to better understand the mechanisms of the programming of mouse and human cells, and their role in the orchestration of immune response in inflammation and cancer. The committee requested better clarification of projects in the SOP, since it was a lab-specific, rather than project specific SOP. Eric Freed moved to approve the registry pending this clarification. Steve Hughes seconded the motion. For: 9; Against: 0; Abstain: 1 (Dan McVicar – His supervisor is Dr. Trinchieri)

Bill Kopp (13-57): Clinical Support Laboratory Operations Conducted Using Biosafety Level-3 Work Practices (BSL 2*) The Clinical Support Laboratory (CSL), Applied/Developmental Research Directorate, provides clinical trial support and core service support to NCI, NIAID and other institutions. The committee requested clarification for the cradle to grave process for use of EBV (how is it stored, in refrigerator, do they use it all or destroy it, etc). Also a statement needs to be made regarding EBV, HCV and SIV being temporally and physically separated. Dan McVicar moved to approve the registry pending clarifications. Steve Hughes seconded the motion. For: 10; Against: 0; Abstain: 0

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Debbie Swing (13-58 (10-39): Generation of Transgenic Mice by Microinjection This renewal is for generating transgenic mice for the Mouse Cancer Genetics Program and other members of the CCR community. Regarding DNA, the committee requested clarification for what is the standard procedure for determining testing. They also requested for the biosafety officer to meet with the PI regarding destination of each entry to this registration. Steve Creekmore moved to approve the registry. Dan McVicar seconded the motion. For: 10; Against: 0; Abstain: 0

AMENDMENTS

Bill Kopp 11-28-A2: Add Vaccinia samples (saliva and urine as well as swabs taken from the vaccination site or from pustules distal (>5cm) from the vaccination site. The lead reviewer requested for this to be evaluated by the full committee since the scope of the samples received has a higher potential for infectious samples (higher titer). Full committee requested a new handling protocol to be developed to include additional information on the handling of the materials and Dan McVicar offered to meet with the PI. Also a question was raised about the vaccination of employees. Are they being vaccinated before working with the material? What if they opt out of being vaccinated? CDC recommends vaccination be done every 3 years. Currently our vaccination schedule is 10 years. Dan McVicar motioned to defer. Steve Hughes seconded the motion. For: 10; Against: 0; Abstain: 0

OUTSTANDING ITEMS

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. A template was provided to the point-of-contact to assist with developing the lab-specific SOP. Lead reviewers requested for the SOP to come back to full committee. After full committee review, the IBC requested EHS and at least one IBC member to visit the lab to discuss the proposed work practices when conducting research with Vaccinia virus. It also was not clear which of the three listed lab spaces was being used for this work. Dan McVicar moved to continue deferral and schedule a lab visit. Steve Hughes seconded the motion. For: 10; Against: 0; Abstain: 0

Miriam Anver 13-40 (09-23): Support Services on the behalf of NCI investigators in PHL (animal) (Kozlov/Hollingshead) A new form was devised and presented to the committee by Dan McVicar. The committee offered edits and Dr. McVicar agreed to assist the PI with modifying the input form. Melinda Hollingshead moved to continue deferral until the form was revised. Dan McVicar seconded the motion. For: 10; Against: 0; Abstain: 0

John Gilly 13-45 (10-16): Use of HEK 293 cells for Alphavirus Vaccine Production Site visit was conducted on July 23, 2013. Follow-up documentation was provided to the PI by Theresa Bell. Dr. Gilly will contact her upon completion of the requested action items.

AMENDMENTS

Eighteen amendments were processed and approved between the June and July IBC meetings.

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OTHER BUSINESS

The IBC web registration system is almost complete. The PDF framework is still being developed.

ADJOURNMENT

The meeting was adjourned at 1:43pm.

Next meetings:

August 20, 2013

September 17, 2013