

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

JUNE 18, 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)

- Michael Baseler (regrets)
- Theresa Bell
- Rev. David Betzner
- Stephen Creekmore
- Bruce Crise
- Eric Freed
- Melinda Hollingshead
- Stephen Hughes

- Sarah Hooper (regrets)
- Bhargavi Kondragunta
- Serguei Kozlov (regrets)
- Dan McVicar (Chair)
- Randall Morin
- Raja Sriperumbudur (regrets)
- Lucien Winegar (regrets)

Non-Voting

- Walter Hubert
- Kim DiGiandomenico

Other

Margaret Slaughter, RN
WHK summer interns (2)

APPROVAL OF MINUTES FROM MAY 21, 2012 MEETING

The minutes from the May 21, 2012 meeting were approved as written. A motion and second were made (For: 8; Against: 0; Abstain: 0)

ACCIDENT REVIEWS

None

REVIEW OF PROTOCOLS

NEW REGISTRATIONS

Teizo Yoshimura 13-52: Administration of LPS into mice Mice will be injected intraperitoneally by LPS or exposed to LPS aerosol. The reason for IBC review was due to the volume of LPS being used as well as the endotoxin being nebulized for aerosolization challenge into mice. All dosing will be conducted inside an engineering control and adequate protocols are in place for disinfection. Dan McVicar moved to approve the registry. Theresa Bell seconded the motion. For: 8; Against: 0; Abstain: 0

Giorgio Trinchieri 13-56: Transcriptional regulation of differentiation and function of human and mouse immune cells The goal of this study is to investigate the mechanisms involved in differentiation of different immune cells. This research is critical in understanding how to manipulate the processes of inflammation and immunity. The study will be done in vitro using primary human or mouse cells. The committee questioned the selected NIH Classification and asked for the PI to clarify their selection.

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

JUNE 18, 2013

Additionally, it was not clear what the PI meant by using 'virus-like particles' when only the use of lentiviral vectors were proposed in the protocol. Lastly, the committee requested EHS to visit the area to evaluate the biosafety aspects of the lab. Steve Creekmore moved to approve the registry pending the aforementioned clarifications and including a lab visit. Steve Hughes seconded the motion. For: 9; Against: 0; Abstain: 0

RENEWALS

Steve Hughes 13-42 (10-01): Retroviral replication and vector design With this renewal, the lab will continue studies on retroviruses, their components, and their replication, both to be able to generate better retroviral vectors and to develop a better understanding of their replication with the long term goal of trying to develop more effective ways to treat HIV-1 infections. There was some discussion about sharps usage during the meeting, especially for cutting gels. Melinda Hollingshead noted a potential alternative to a straight-edge razor and offered to send additional information to the PI. Dan McVicar moved to approve the registry. Melinda Hollingshead seconded the motion. For: 9; Against: 0; Abstain: 1 (Steve Hughes – PI of registry)

John Gilly 13-45 (10-16): Use of HEK 293 Cells for Alphavirus Vaccine Production The Vaccine Research Center (VRC) is currently developing a process to produce a virus-like particle (VLP) based vaccine against a number of alphaviruses, including Chikungunya virus (ChikV), and three equine encephalitis viruses (WEVEEs). This process involves the transient transfection of VRC293 cells, an HEK 293 cell line derivative, with plasmid DNA (pDNA) encoding the viral capsid protein C, protein 6K, and the three envelope (env) glycoproteins (E1, E2, and E3). The resultant proteins self-assemble to form non-replicating, non-infectious VLPs. The committee requested the batch record to review, as Bhargavi Kondragunta advised that it would give a better idea for the flow of processing the material. After this is reviewed, a site visit will need to be conducted. Eric Freed moved to approve the registry pending review of the batch record and site visit. Steve Hughes seconded the motion. For: 9; Against: 0; Abstain: 1 (Bhargavi Kondragunta – conflict of interest)

Shyam Sharan 13-48 (10-11): Functional Analysis of Breast Cancer Susceptibility Genes This renewal is to continue studies on the BRCA1 and BRCA2 genes. The research involves the creation of shRNAs and introducing them into mouse embryonic stem cells using viral vectors. The research also involves the creation of transgenic mice. The committee noted a few contradictory statements in the paperwork that needed fixed, but otherwise had no additional concerns with the safety aspects of the research. Dan McVicar moved to approve the registry with the modifications to the paperwork. Steve Creekmore seconded the motion. For: 10; Against: 0; Abstain: 0

Joel Schneider 13-51 (10-02): Antibacterial Assessment of Peptide Hydrogels This group is continuing their work from 2010 with developing hydrogels with antibacterial properties. The hydrogels are challenged with various pathogens to determine the antimicrobial activity of the gel surface. No new pathogens have been added to this work. Bhargavi Kondragunta moved to approve the renewal registry. Bruce Crise seconded the motion. For: 10; Against: 0; Abstain: 0

Janelle Cortner / Sarah Hooper 13-53 (07-44): Research Donor Program Blood Collection This renewal registration is for the Research Donor Program (RDP) to collect human samples. The RDP serves as a central repository for the collection and distribution of whole blood samples from healthy volunteers to the Frederick National Lab Investigators for *in vitro* research use. The

NATIONAL CANCER INSTITUTE-FREDERICK (NCI-F)

INSTITUTIONAL BIOSAFETY COMMITTEE

MINUTES

JUNE 18, 2013

program is administered by Occupational Health Services. The committee had no additional safety concerns during their review. Dan McVicar moved to approve the renewal. Bhargavi Kondragunta seconded the motion. For: 10; Against: 0; Abstain: 0

Jianwei Zhu 13-54 (08-81): Production of non-pathological oncolytic polio virus chimera for the treatment of brain tumor This registration covers the production of cGMP grade clinical lot of PVS-RIPO (a non-pathogenic poliovirus/rhinovirus chimeric oncolytic virus) for FDA required toxicology/neuro-virulence studies and Phase II clinical trial using a procedure previously approved by the IBC. There were some minor clarifications for locations of instruments needed in the SOP, as there was still reference to building 459, which is no longer used for this work. In addition, the IBC requested for EHS to revisit the lab space once all the instruments have been relocated and installed prior to initiation of the research. Dan McVicar moved to approve the registry with no work commencing until instruments have been relocated and EHS has revisited the space. Steve Hughes seconded the motion. For: 9; Against: 0; Abstain: 1 (Steve Creekmore- conflict of interest)

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. 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) The observation of laboratory procedures, particularly the tissue trimming, for PHL was conducted by EHS and an IBC representative on June 3, 2013. A razor blade holder with a side-handle or using a hot knife were recommended for trimming embedded blocks. A few additional minor suggestions were provided regarding placement of the sharps container and for re-sheathing a disposable scalpel. The committee still had concerns with the current input request form used. The IBC chairman offered to speak with the PI to further clarify the committee's concerns with the lack of requested information on the current form. Melinda Hollingshead moved to continue deferral until the form was revised. Theresa Bell seconded the motion. For: 10; Against: 0; Abstain: 0

AMENDMENTS

Fifteen amendments were processed and approved between the May and June IBC meetings.

OTHER BUSINESS

The IBC web registration system is almost complete. DMS will finish some additional edits and turn it over to EHS/IBC to test functionality on June 19th with one week to test and provide feedback. The

NATIONAL CANCER INSTITUTE-FREDERICK (NCI-F)

INSTITUTIONAL BIOSAFETY COMMITTEE

MINUTES

JUNE 18, 2013

PDF framework is still being developed. Pilot testing will begin on July 1 for one month with the expectation of roll-out in August.

ADJOURNMENT

The meeting was adjourned at 1:43pm.

Next meetings:

July 16, 2013

August 20, 2013