

**FREDERICK NATIONAL LABORATORY FOR CANCER RESEARCH (FNLCR)
INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES**

JULY 17, 2012

CALL TO ORDER / ANNOUNCEMENTS

The FNLCR Institutional Biosafety Committee was convened at 12:03 p.m. in Building 549 Executive Board Room with the following members in attendance:

Voting (Quorum = 9)

- | | |
|---|--|
| <input checked="" type="checkbox"/> Michael Baseler (left at 1:30 pm) | <input checked="" type="checkbox"/> Sarah Hooper (arrived at 12:30pm) |
| <input checked="" type="checkbox"/> Theresa Bell | <input checked="" type="checkbox"/> Bhargavi Kondragunta |
| <input type="checkbox"/> Rev. David Betzner (regrets) | <input checked="" type="checkbox"/> Serguei Kozlov |
| <input checked="" type="checkbox"/> Stephen Creekmore | <input checked="" type="checkbox"/> Dan McVicar (Chair) |
| <input type="checkbox"/> Bruce Crise (regrets) | <input checked="" type="checkbox"/> Randall Morin (arrived at 12:30pm) |
| <input type="checkbox"/> Eric Freed (regrets) | <input checked="" type="checkbox"/> Shalini Oberdoerffer |
| <input type="checkbox"/> Melinda Hollingshead (regrets) | <input checked="" type="checkbox"/> Raja Sriperumbudur |
| <input checked="" type="checkbox"/> Stephen Hughes | <input checked="" type="checkbox"/> Lucien Winegar |

Non-Voting

- Walter Hubert
- Kim DiGiandomenico

APPROVAL OF MINUTES FROM JUNE 19, 2012 MEETING

The minutes from the June 19, 2012 meeting were approved as written. A motion and second were made. (For: 12; Against: 0; Abstain: 0)

ACCIDENT REVIEWS

Two accidents were reported at the July meeting. The first was an SAIC-LASP employee from the Bethesda campus. The individual was training investigators on how to perform a tail vein injection and was using a murine cell that had been transduced with a 3rd generation lentiviral vector. The needle was not secured properly to the syringe and when the individual dispensed the material during injection, it squirted from the syringe onto the individuals face. The work was being done on the open bench and no face or eye protection was being worn at the time the incident occurred. This was an NIH-OBA reportable event; however, since the research fell under an NIH-Bethesda IBC protocol, NIH-Bethesda was to report the incident.

The second accident occurred with a minor. The student was observing the supervisor conduct a necropsy on an un-infected transgenic wild-type mouse when peritoneal fluid splashed into the eye. No eye protection was being worn during the observation. The individual was seen by OHS, the parents were notified, and the individual was released back to work. This was also an NIH-OBA reportable event since a transgenic mouse was involved. The IBC had asked if the mouse was made using Adeno-Cre and EHS indicated that they would inquire (*Post-note: Mouse strain was not made with Adeno-Cre*).

FREDERICK NATIONAL LABORATORY FOR CANCER RESEARCH (FNLCR)

INSTITUTIONAL BIOSAFETY COMMITTEE

MINUTES

JULY 17, 2012

REVIEW OF PROTOCOLS

NEW REGISTRATIONS - none

RENEWALS

Ligia Pinto 12-33 (P181200MBA01): Cellular Immunity Studies using Human Mononuclear Cells originated from Blood or Bone Marrow The purpose of this renewal is to continue research for evaluating cellular immune responses to various stimuli (mitogens and antigens) in mononuclear cells from a variety of cohorts, including Human Papillomavirus (HPV) vaccine recipients and patients with cervical HPV infection. The antigens to be studied include the HPV vaccine (non-infectious HPV L1 virus like particle antigens), as well as tetanus toxoid and the Influenza A virus. The antigens listed will be used as a recall antigen to assess the immune responses in vitro of subjects enrolled in HPV vaccination studies or in HPV natural history studies. There was discussion regarding handling of human materials that have been unscreened for pathogens, waste flow and personal protective equipment worn while manipulating such samples. Kim DiGiandomenico confirmed that waste is double bagged prior to disposal and the autoclave is down the hall from the laboratory. Eric Freed motioned to approve the registry with the following recommendations: DTap and seasonal influenza vaccination are strongly recommended; eye protection and double gloves (when working inside the BSC) are strongly recommended; and disposable, impermeable lab coats or wrap-around gowns are recommended over reusable lab coats. Melinda Hollingshead seconded the motion. For: 13 Against: 0 Abstain: 0

Susan Mackem 12-44 (09-16): Analysis of developmental regulators controlling vertebrate morphogenesis The objective of this registry is to understand mechanisms and regulatory cascades leading to morphogenesis--how cells are instructed to adopt different fates and make complex tissues and organs, using genetic approaches in mice and in chick embryos, and cell biological studies in tissue culture, and in vitro biochemical experiments. Experiments in mice will employ genetically engineered animals detailed in a separate registry (12-43) for breeding transgenic and KO animals. This PI employs the use of avian retroviral vectors and in the context of their use in this IBC, they cannot replicate in mammalian cells. There is minimal chance of aerosol hazards and the viruses are not very stable in the environment. There were some questions regarding the content of the SOP regarding waste handling that EHS would address. Steve Hughes motioned to approve the renewal registry pending the findings from EHS. Shalini Oberdoerffer seconded the motion. For: 14; Against: 0; Abstain: 0 (Post-meeting note: SOP was checked against EHS website regarding waste handling and material was accurate.)

Zoe Ohler 12-50 (08-65): Induction of experimental carcinogenesis in genetically engineered mouse models (GEMs) to evaluate the efficacy of novel anti-cancer therapeutics The goal for the Center for Advanced Preclinical Research (CAPR) is the preclinical evaluation of experimental candidate cancer drug compounds in a spectrum of genetically engineered mouse lines prone to tumor development either spontaneously or in an inducible manner. The current proposal delineates several tumor induction procedures that were established in this laboratory; potential hazards and risks were listed and evaluated for each of the routes and possible mitigation strategies were suggested. Since the GEM mice used in this IBC are covered under a separate IBC 'breeding only' registry, the PI had requested that those mouse lines be deemed approved for procedures covered in this IBC. The IBC indicated that they would concur with the request as long as the GEMs were not made with mobilizable retroviral elements. If they are, then it would warrant additional discussion, at a minimum, by lead reviewer. Steve Creekmore moved to approve the renewal with the stipulation regarding GEMs noted above. Bruce Crise seconded the motion. For: 14; Against: 0; Abstain: 0

FREDERICK NATIONAL LABORATORY FOR CANCER RESEARCH (FNLCR)

INSTITUTIONAL BIOSAFETY COMMITTEE

MINUTES

JULY 17, 2012

John Gilly 12-59 (05-57): Plasmid DNA Vaccine Production The Vaccine Pilot Plant (VPP) is a government owned contractor-operated facility, which manufactures investigational vaccine candidates for use in human clinical trials, under the strict quality and regulatory guidelines set forth by the U.S. Food and Drug Administration (FDA). The committee felt this renewal was well written and updated the goals of the project appropriately. They requested confirmation that there is no intent of transfecting any of the listed plasmids in combination resulting in all elements ending up in the same cell (in particular the HIV). In addition, they also wanted the quarterly update table to list serotypes of the insert entries to ensure that none of the inserts are the full length. Bruce Crise moved to approve the renewal with the aforementioned clarifications. Theresa Bell seconded the motion. For: 14; Against: 0; Abstain: 0

Andy Hurwitz 12-60 (08-37): Chronic Prostatitis as a Model for Prostate Carcinogenesis The goal of the project outlined in this IBC renewal is to test whether chronic inflammation of the prostate predisposes to the development of prostate cancer. An infectious approach will be used where mice are infected with a urotropic strain of *E. coli*. The committee concurred that a more lab- and agent-specific SOP must be provided by the PI and the research must be conducted in a BSC. They also requested a mock observation to be completed by EHS. Steve Hughes motioned to defer the renewal back to full committee pending responses to the aforementioned committee concerns. Theresa Bell seconded the motion. For: 14 Against: 0 Abstain: 0

Stephen Yoo 12-61 (09-27): The effects of irradiation along, targeted agents alone, and irradiation and targeted agents in combination to inhibit the growth of human tumor lines The goal of the Molecular Radiation Therapeutics Branch (MRTB) is to extend initial tissue culture results that illustrate promising radiation/drug interactions by studying the effect of these agents on cell cycle, DNA damage response, DNA repair, tumor metabolism, hypoxia and other tumor specific vulnerabilities. Positive findings over the past five years have encouraged the MRTB s to move on to evaluate specific inhibitors of other cellular processes. These studies of novel investigational agents will require testing in several specialized cell lines. There were some concerns with how the paperwork was presented due to a transduced cell line that was being acquired from a PI on the Bethesda campus. Melinda Hollingshead moved to defer the registry back to lead review once the minor paperwork clarifications are fixed. Bhargavi Kondragunta seconded the motion. For: 14 Against: 0 Abstain: 0

OUTSTANDING ITEMS

Ligia Pinto 12-34 (06-101): HPV Antibody Assays for serum, saliva and cervical secretions This renewal had been deferred at the June meeting. The PI sufficiently addressed concerns with handling human samples and the flow of materials through the lab. Steve Hughes moved to approve the registry with the recommendation to wear double gloves while working in the BSC. Shalini Oberdoerffer seconded the motion. For: 12; Against: 0; Abstain: 0

Trinchieri/Noer – IBC 12-62 (formerly 11-66 (10-60 (07-25))) Flow cytometry core lab: Final versions of IBC paperwork sent to Kathleen Noer for review to ensure all aspects of the operations were properly captured. Approval will be released once signed PI Acknowledgement and employee rosters are received.

Ding Jin 12-17 (09-25): Transcription Regulation in *E. coli* (K12) and *H. pylori* The PI revised his registry to remove the affiliation with any animal work, as previously submitted. The committee requested minor modifications to include use of double gloves, disposable, impermeable lab gowns, face/eye protection and confirmation that Cavicide was an appropriate disinfectant. Dan McVicar moved to approve the registry

FREDERICK NATIONAL LABORATORY FOR CANCER RESEARCH (FNLCR)

INSTITUTIONAL BIOSAFETY COMMITTEE

MINUTES

JULY 17, 2012

with the aforementioned clarifications. Steve Creekmore seconded the motion. For: 11; Against: 0; Abstain: 0

Ji Ming Wang 12-30: Use of normal human blood cells for studies of inflammation and cancer in vitro
Deferred to full committee at March 2012 meeting. At the June 2012 meeting, a revised SOP had been submitted. The committee requested for a sub-committee to evaluate staff training, techniques and proficiency against the SOP prior to the July IBC meeting. Evaluation occurred on July 3, 2012 and was shared with the committee. The sub-committee was concerned with the PI's defensive and hostile attitude toward the hazards being manipulated in the laboratory, especially since he had prior IBC assistance with another registration only a few months prior. The committee concurred that the lack of attention to safety and prior assistance from the IBC should be escalated to Dr. Craig Reynolds and the PI's immediate supervisors. A memo outlining the re-occurring violations will be circulated via email for full committee concurrence prior to submission by the IBC chairman to Dr. Reynolds.

AMENDMENTS

Twenty-seven amendments were processed and approved between the June and July IBC meetings, while one remained outstanding.

OTHER BUSINESS

Pathogen challenge room – Sub-committee-Discussions tabled until August

ADJOURNMENT

The meeting was adjourned at 2:55 pm.

Next meetings:

August 21, 2012

September 18, 2012