

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

OCTOBER 16, 2012

CALL TO ORDER / ANNOUNCEMENTS

The FNLCR Institutional Biosafety Committee was convened at 12:05 p.m. in Building 549 Executive Board Room with the following members in attendance:

Voting (Quorum = 9)

- | | |
|--|--|
| <input checked="" type="checkbox"/> Michael Baseler | <input type="checkbox"/> Sarah Hooper (regrets) |
| <input checked="" type="checkbox"/> Theresa Bell | <input checked="" type="checkbox"/> Bhargavi Kondragunta |
| <input checked="" type="checkbox"/> Rev. David Betzner | <input checked="" type="checkbox"/> Serguei Kozlov |
| <input type="checkbox"/> Stephen Creekmore (regrets) | <input checked="" type="checkbox"/> Dan McVicar (Chair) |
| <input type="checkbox"/> Bruce Crise (regrets) | <input type="checkbox"/> Randall Morin (regrets) |
| <input checked="" type="checkbox"/> Eric Freed | <input type="checkbox"/> Shalini Oberdoerffer (regrets) |
| <input checked="" type="checkbox"/> Melinda Hollingshead (arrived 12:07pm) | <input checked="" type="checkbox"/> Raja Sriperumbudur |
| <input checked="" type="checkbox"/> Stephen Hughes | <input checked="" type="checkbox"/> Lucien Winegar |

Non-Voting

- Walter Hubert
- Kim DiGiandomenico

Other

Capt. Darrell Laroche
Debbie Schuchardt

APPROVAL OF MINUTES FROM SEPTEMBER 18, 2012 MEETING

The minutes from the September 18, 2012 meeting were approved as written. A motion and second were made. (For: 10; Against: 0; Abstain: 0)

ACCIDENT REVIEWS

There were a few injuries involving sharps; however, none involved the use biological materials.

REVIEW OF PROTOCOLS

NEW REGISTRATIONS

Al Singer 12-74: Retroviral Induced Bone Marrow Radiation Chimeras This group plans to perform experiments using retroviruses to express various genes that are involved in T cell development. All the viral work will be done on the Bethesda and only transduced murine bone marrow cells will be used in animals in Frederick. The committee requested minor changes to the wording regarding the risks of the viral vectors as well as requested added language in Part E regarding necropsies to be done inside a BSC. Melinda Hollingshead motioned to approve the registry pending the aforementioned clarifications. Steve Hughes seconded the motion. For: 11; Against: 0; Abstain: 0

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Jadranka Loncarek 12-76: Mechanisms of Centrosome Reduplication – The PI responded to pre-review questions too late for lead reviewers to review. Based on the nature of questions that were to be addressed, the committee concurred to defer to lead review rather than full committee. Serguei Kozlov motioned to approve the registry pending lead review approval. Steve Hughes seconded the motion. For: 11; Against: 0; Abstain: 0

David Wink / Lisa Ridnour 12-77: Role of Nitric Oxide in Breast Cancer Disease Progression For this new protocol, established cell lines will be exposed to dose response concentrations for times ranging from 0-48 hrs, then harvested. Protein expression and nitric oxide (NO) effects on signaling pathways involved in cancer survival and progression will be evaluated. Human vascular endothelial cells will also be used to examine angiogenic responses induced by NO. All experiments are in vitro only. The only concern the committee expressed was the use of Pasteur pipettes, due to their ease of breaking and introducing a potential route for exposure. Bhargavi Kondragunta motioned to approve the registration pending clarification on the use of Pasteur pipettes. Raja Sriperumbudur seconded the motion. For: 11; Against: 0; Abstain: 0 (Post-IBC meeting, the PI confirmed that only plastic aspiration pipettes would be used.)

RENEWALS

Robert Blumenthal 12-73 (09-51): Radiation Induced and Targeted Chemotherapy This is a renewal registry for Ultrasound induced chemotherapy. Specifically, human tumor cells will be injected into mice, then chemotherapeutic agents will be administered through a nanoemulsion and then the tumors are sonicated. There were some concerns raised during the pre-review about the chemicals being used. Those concerns were forwarded to and addressed by the EHS chemical safety staff. The committee, however, did recommend for disposable microisolator cages to be used in the animal studies as well as a vented BSC or if sterility is not a concern, a necropsy hood for all animal dissections/necropsies/ tissue harvests. Mike Baseler moved to approve the registry with the aforementioned recommendations. Bhargavi Kondragunta seconded the motion. For: 11 Against: 0; Abstain: 0

Ralph Parchment 12-75 (07-63): Specimens for Pharmacologic and Toxicologic Assessment For this IBC renewal, the laboratory will continue the development of quantitative assays for new oncology drugs and their actual or predicted effects in animal and human patients using healthy tissues and cells, malignant tissues and cells, and body fluids. During the pre-review, there were some minor concerns that were addressed regarding the SOP and decontamination; however, overall the PI addressed the primary hazards with the work and how risks with manipulating the materials would be mitigated. Melinda Hollingshead motioned to approve the registry after confirming all pre-review questions regarding the SOP were addressed. Theresa Bell seconded the motion. For: 11 Against: 0 Abstain: 0

OUTSTANDING ITEMS

Ji Ming Wang 12-30: Use of normal human blood cells for studies of inflammation and cancer in vitro Even though the submission for 12-30 was withdrawn by PI; the IBC still requested follow-up actions regarding safe lab practices. In September, a memo was distributed by the IBC chair to Dr. Craig Reynolds and the PI's supervisors outlining the safety concerns and action items the

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committee requested of the PI. The PI addressed the concerns by the October IBC meeting and invited assistance from IBC and EHS with laboratory training sessions. Dan McVicar motioned for the laboratory re-training to be completed within 90-days and sessions should involve the biological safety officer. Theresa Bell seconded the motion. For: 11; Against: 0; Abstain: 0

Andy Hurwitz 12-60 (08-37): Chronic Prostatitis as a Model for Prostate Carcinogenesis Deferred at July meeting for more comprehensive SOP regarding the use of E. coli 1677; Per request by PI and concurrence with BSO and IBC Chair, response will be provided for review at October 16, 2012 meeting. PI provided the requested agent-specific SOP. Steve Hughes moved to approve the registration with mock observation prior once staffing has been determined. Dan McVicar seconded the motion. For: 11; Against: 0; Abstain: 0

John Gilly 12-67: Production of chimpanzee adenoviral vectors for use as HIV vaccines) Deferred at September meeting for further clarification on the adenoviral vector being used and support for the claim that it does not recombine, a description of the assay used to test for RCA and to what titer, clarification on how the virus stock is concentrated, where the QC testing is being done and why closed containment devices are not being used. Additional questions arose at the October meeting, as it was still unclear if chimp adenovirus could be complimented by human adenovirus and if the PPE/containment proposed by the PI would be sufficient to adequately protect. Dan McVicar moved to defer for further clarification. Steve Hughes seconded the motion. For: 10; Against: 0; Abstain: 1 (Bhargavi Kondragunta – works at VPP) (Post-IBC note: Theresa Bell met with Dr. Peter Alexander to discuss revisions and IBC questions and revised paperwork would be provided for the November IBC meeting)

Dennis Klinman 12-71 (09-54): Infectious Pathogens used in the study of vaccines, adjuvants, and modulators of the innate immune system Deferred at September meeting due to lack of response to pre-review questions. PI responded to lead review questions; however still did not provide a laboratory SOP. Additionally the committee requested clarification on if infected animals would be brought back to the main lab for necropsy/tissue harvest as well as acknowledgement that passing these materials (infectious pathogens as referenced in the title) through mice can actually make these pathogens more infectious. Dan McVicar motioned to defer the registry until clarifications and SOP are received. Theresa Bell seconded the motion. For: 11; Against: 0; Abstain: 0

AMENDMENTS

Seventeen amendments were processed and approved between the September and October IBC meetings, while one remained outstanding.

OTHER BUSINESS

- Internal Policy: final version of the Joint IBC/ACUC/EHS sub-committee for enforcement actions regarding Government employees was distributed to appropriate IBC, ACUC and EHS personnel.
- Revisions to FNL IBC Charter-Charter was provided to NCI Office of Scientific Operations (OSO) and Management Operations and Support Branch (MOSB) for review and signatures.
- Membership – Dr. Jianwei Zhu; Director, Early Process Sciences-Biopharmaceutical Development Program (BDP)-not discussed

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- Changes to NIH Guidelines for Synthetic Nucleic Acid Molecules - effective date March 2013- Committee members were provided with the new changes to the NIH Guidelines for review and discussion at the November meeting.

ADJOURNMENT

The meeting adjourned at 1:50 pm.

Next meetings:

November 20, 2012

December 18, 2012