

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

**SEPTEMBER 18, 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 type="checkbox"/> Michael Baseler (regrets)                         | <input checked="" type="checkbox"/> Sarah Hooper                                  |
| <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 (arrived 12:10pm, left 1:05pm) |
| <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                                 |
| <input type="checkbox"/> Eric Freed (regrets)                              | <input type="checkbox"/> Shalini Oberdoerffer (regrets)                           |
| <input checked="" type="checkbox"/> Melinda Hollingshead (arrived 12:35pm) | <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  
Jianwei Zhu

**APPROVAL OF MINUTES FROM AUGUST 21, 2012 MEETING**

The minutes from the August 21, 2012 meeting were approved as written. A motion and second were made. (For: 10; Against: 0; Abstain: 1 - Lucien Winegar, as he was not at the August meeting)

**ACCIDENT REVIEWS**

None to report

**REVIEW OF PROTOCOLS**

***NEW REGISTRATIONS***

John Gilly 12-67: Production of chimpanzee adenoviral vectors for use as HIV vaccines The purpose of this project is to manufacture adenoviral vectors derived from chimpanzees used to boost the immune response in the prime-boost strategy. The product consists of two different adenoviral vectors which encode the EnvA (gp140, clade A) and EnvC (gp140 clade C) HIV proteins. The vectors are non-replication competent meaning that they can not reproduce unless they are in the expression cell line used for manufacturing. The committee had several concerns regarding the research which required additional clarification including: 1. A3 – states “The chimp adenovectors that will be produced by this process are replication incompetent in normal cells and are incapable of producing replication competent recombinants.” This statement was questioned by the committee. With most adenoviral vectors, recombination can occur when the modified 293 cells (producer cells) are transfected. Adenoviral vectors are notorious for picking up (missing) complementing parts in the

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producer cells. The committee requested clarification and support for the claim that the vector system used does not recombine; 2. What assay is used to test for RCA and to what titer (relative to the defective virus titer) is replication competent Adenovirus tested; 3. How will the virus stock be concentrated (include safety aspects of the process); 4. Where is the QC testing done (inside a BSC) and lastly, 5. Why are the closed containment devices (plexiglass-boxes) NOT being used - or is this inferred in the reference to IBC 07-60 in A2? If the latter, the committee requests more detail provided in this registry since it is a stand-alone document from the other Adeno-research. Theresa Bell moved to defer the registry back to full committee pending responses to the questions above. Steve Hughes seconded the motion. For: 10; Against: 0; Abstain: 1 (Bhargavi Kondragunta – conflict of interest)

Ji Ming Wang 12-72: The role of the G protein-coupled chemoattractant receptor mFPR2 in the recruitment of bone marrow mesenchymal stem cells and myeloid cells in cancer The objective of this study is to evaluate the role of a chemoattractant receptor mFPR2 in mouse resistance to cancer. Only murine cell lines will be used. The committee requested for the PI to complete Part E8 and E9 of the form as it was incomplete. Theresa Bell moved to approve the registry pending the completion of Parts E8 and E9. Raja Sriperumbudur seconded the motion. For: 11; Against: 0; Abstain: 0

#### RENEWALS

Doug Kuhns 12-56 (09-59): Laboratory Operations of the Neutrophil Monitoring Laboratory This is a renewal registry for the Neutrophil Monitoring Laboratory (NML), Applied/Developmental Research Directorate, which provides clinical trials support to NIAID. The primary function of NML is to receive, process, and perform functional assays on clinical specimens from patients with chronic granulomatous disease, mycobacterial infections, Job's syndrome or other primary immunodeficiency diseases. The NML also monitors the percent of cells that produce normal levels of reactive oxygen species from transplant patient. There were minimal concerns and comments during the pre-review. The PI sufficiently addressed the hazards involved with the research materials, however, the committee wanted the PI to clarify that cells are fixed first and then imaged and also requested a statement in the registry that immunosuppressed employees should not be permitted to handle the *S. aureus* assays. Dan McVicar moved to approve the registry with minor clarifications. Steve Creekmore seconded the motion. For: 12; Against: 0 Abstain: 0

Ying Zhang 12-64 (08-82): TGF-beta/Smad signaling Breeding only protocol - *Notification to committee*

Sheue-yann Cheng 12-66 (09-30): Role of mutant thyroid hormone receptor in thyroid cancer Breeding only protocol - *Notification to committee*

Rosi Salcedo / Giorgio Trinchieri 12-68 (09-48): Role of Inflammation on carcinogenesis By utilizing several models of carcinogen and inflammation-associated carcinogenesis, this lab will continue to investigate the roles of inflammatory mediators in cancer promotion and progression in their IBC renewal. During IBC discussion, the committee requested further clarification on the following: A1 /D1 - provide more detail on how the virus will be purified for sequencing and how will this be done safely; A3 /B6a / B10a / E9 – Regarding the hydrodynamic injections, there is still danger involved with autoinoculation of oncogenes regardless of the number of hits. Technicians injecting these materials should be cognizant of this; C9a – Clarify the concentration of the dose of LPS that is administered to mice; the Dual Use Questionnaire (Part F) must be completed and signed; What is Addendum #5 (SOP) as it was not provided; and in the SOP specific rules: *Gloves, lab coat and face protection when conducting experiments outside a BSC* should be used, not just gloves. Dan McVicar motioned to defer the

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registry back to lead reviewers for approval pending the aforementioned clarifications. Serguei Kozlov seconded the motion. For: 12; Against: 0 Abstain: 0

Melinda Hollingshead 12-69 (09-36): In vitro and in vivo Drug Development This renewal is aimed at the development of preclinical evidence of antitumor activity of new chemotypes undergoing development to treat human cancers. New to the registry are patient derived samples that will be put into mice. The goal is to grow tumors and characterize DNA cell lines to determine if drug resistance is innate in the tumor if drugs make the tumors resistant to the treatment. All work will be performed according to BSL2 practices. All pre-review questions were sufficiently addressed. Theresa Bell moved to approve the registry. Steve Creekmore seconded the motion. For: 10; Against: 0; Abstain: 2 – Melinda Hollingshead (she is the PI for the registry) and Serguei Kozlov (left for another meeting)

Perwez Hussain 12-70 (09-02): Development and Cross-breeding of Genetically Altered Mouse Strains and Study of Tumorigenesis Breeding only protocol - *Notification to committee*

Dennis Klinman 12-71 (09-54): Infectious Pathogens used in the study of vaccines, adjuvants, and modulators of the innate immune system Deferred to October meeting. PI had not addressed pre-review questions as of the September IBC meeting.

#### OUTSTANDING ITEMS

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.

Ji Ming Wang 12-30: Use of normal human blood cells for studies of inflammation and cancer in vitro Registry has been deferred since March 2012 meeting. After EHS Director contacted PI with deficiencies found in the laboratory, the PI responded that the chemotaxis work was being discontinued due to a change in the research direction and resource constraints (August 18, 2012). In lieu of this, the IBC still wanted to respond to the observations noted in the July visit by IBC members to his lab. The memo was distributed by the IBC Chair for committee comment and vote at the September meeting. With minor modifications, Dan McVicar motioned to accept the memo for distribution. Lucien Winegar seconded the motion. For: 10; Against: 0; Abstain: 0

#### AMENDMENTS

Twenty-six amendments were processed and approved between the August and September IBC meetings, while one remained outstanding.

#### OTHER BUSINESS

- *Internal Policy: Joint IBC/ACUC/EHS Sub-committee for Advisory Actions Regarding Government Employees* The IBC Chair distributed the final iteration to the committee for discussion and formal vote. Minor modifications were suggested with some of the language as well as changing the title to reflect that this is not an enforcement committee, but rather an advisory committee. Dan McVicar motioned to adopt the internal policy with the noted changes. Theresa Bell seconded the motion. For: 11; Against: 0; Abstain: 0

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- *Revisions to FNL IBC Charter* were posted to SharePoint for review by committee prior to presentation to Dr. Craig Reynolds. Dan McVicar motioned to adopt the changes to reflect the new 'Frederick National Laboratory (FNL)' name as well as incorporate Dual Use into the scope of IBC review. Theresa Bell seconded the motion. For: 11; Against: 0; Abstain: 0

**ADJOURNMENT**

The meeting adjourned at 2:10 pm.

***Next meetings:***

***October 16, 2012***

***November 20, 2012***