



**NCI-FREDERICK  
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes  
October 28, 2008  
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:02 p.m. in the Building 426 Training Room with the following members in attendance:

Ms. Theresa Bell, Secretary	Dr. Daniel McVicar
Dr. Randall Morin, Chair	Dr. Stephen Creekmore
Dr. Serguei Kozlov	Dr. David Derse
Dr. Bruce Crise	Dr. Eric Freed
Dr. David Garfinkel	Ms. Alberta Peugeot
Mr. Lucien Winegar	Mr. Scott Jendrek

Members not in attendance: Dr. Stephen Hughes, Dr. Melinda Hollingshead, Dr. Michael Baseler, Dr. Henry Hearn, Ms. Dianna Boissey

Others in attendance: Dr. Scott Keimig, Dr. Michael Smith, Dr. Robert J. Thomas, Ms. Kristen Pike, Ms. Cara Leitch

Dr. Morin called the meeting to order. The September minutes were sent out by email for review. A vote will be taken via email in one week.

**LMT Screening Process**

- Dr. Michael Smith and Ms. Kristen Pike from the Laboratory of Molecular Technology (LMT) spoke about the 10-panel human pathogen screening service.
- Questions from the IBC:
  - Is virus in sample a marker for something else that will affect the experiment (is the sample contaminated and with what)?
  - Will that contaminant negatively affect the sample and assays to be performed?
  - How often does LMT see positive results for a contaminant and what are those contaminants?
  - Is there an SOP for positive results?
  - What does the profile look like?
  - Provide a list of all testing and how it's carried out.
  - What about RNA viruses? If a DNA assay is being run, then RNA viruses

would not be detected with this assay; therefore, this assay cannot detect HCV or other RNA viruses.

- Would the LMT consider developing an alternative assay so that RNA viruses could also be part of this screening process? What is the ability to add other viruses to the screening test?

The cost and current customer base was discussed. LMT has determined that other higher priority tasks require current staffing and they are unable to continue the service based on demands and financial considerations. Also, for some of the assays, difficulty in obtaining controls had caused delays. The question was posed regarding the value in conducting the test. The information obtained through the testing results provides assistance in determining if post-exposure prophylaxis is necessary, following an exposure or potential exposure event. The information may also assist in the determination of biocontainment, personal protective equipment, and providing a clearer understanding of what is actually contained in the research materials. The IBC decided to review the list of current pathogens for screening and determine a revised list for screening, and then to pursue alternative means for testing services.

## **NEW BUSINESS**

### **08-63 (Steeq) “Effect of Pigment Epithelium-Derived Factor Expression on Brain Metastatic Breast Cancer”**

- This registration involves the use of mice being injected with brain metastatic human cells with retroviral vectors already in the cells.
- All lead reviewer questions regarding this protocol were answered by the registering PI prior to the IBC meeting.
- Only cells will be shipped, not virus.
- Lentiviral construct is the only virus system used in the lab.
- Supervisor should be updated to reflect a current responsible employee.
- Immunocompromised individuals may be at risk and should have informed consent regarding the risks associated with this project.

*Dr. Kozlov made a motion to approve, Dr. McVicar seconded, and all were in favor.*

### **08-64 (Difilippantonio) “Development of Molecular and Cell Culture based Experimental Approaches Applicable for the Derivation and Analyses of Genetically Engineered Mouse Cancer Models”**

- This study involves the use of genetically engineered mouse models to harvest organs to establish primary cells.
- Part B is difficult to interpret. It would be better to complete Part B by grouping the different research materials by their associated risk.
- Second Part B - B5: This should be checked yes and the sub-questions answered for the use of the CMV promoter

- Part C: This part can be removed from the registration since this section is for potential human pathogens or toxins
- Even though the material is not supposed to be replication competent, the IBC recommends implementing an informed consent for workers who are immunocompromised or pregnant, and discouraging those employees from participating in these research activities.

*Dr. Creekmore made a motion to conditionally approve pending resolution of the above issues, Dr. Derse seconded, and all were in favor.*

**08-65 (Ohler) “Induction of Experimental Carcinogenesis in Genetically Engineered Mouse Models (GEMs) to Evaluate the Efficacy of Novel Anti-Cancer Therapeutics”**

- This registration proposes to use recombinant adenovirus with cre recombinase to infect genetically engineered mice intranasally.
- B5e3: This should be checked "Yes" since the work involves Adeno-cre and then B5e4 should be answered.
- B5c: Should also be checked "Yes" and then the sub-questions answered. Was the material titered for this specific lot of virus, and is the stock titer or the titer of the starting material at  $1 \times 10^9$ ?
- PI should address whether the material been amplified.
- Addendum 1: Please have the listed staff sign the registration document.
- Even though the material is not supposed to be replication competent, the IBC recommends implementing an informed consent for workers handling infectious agents and carcinogens who are immune compromised or pregnant.
- Adenovirus training specific to this registration has been delivered to those involved in the project.
- The material should be considered replication-competent adenovirus if scaled up to a higher concentration in the future.

*Dr. Creekmore made a motion to conditionally approve pending resolution of the above issues, Dr. Crise seconded, and all were in favor.*

**RENEWALS**

**08-61 (Hatfield) “Prevention of Mammary Cancers with Selenoproteins in Knockout and Transgenic Mice”**

- This protocol investigates the role of selenium-containing proteins in preventing breast cancer and studies the effect of targeted Sec tRNA disruption on tumor formation induced by DMBA.
- No virus or viral vectors are produced.
- The IBC asked how the cre recombinase will be expressed/delivered.
- Lab personnel should be especially cautious when working with DMBA.
- No exogenous viral infection is mentioned.

*Dr. Garfinkel made a motion to conditionally approve pending resolution of the above issues, Dr. Freed seconded, and all were in favor.*

**08-60 (Phang) “The Proline Metabolism in Cancer and other Diseases”**

- This study involves the use of human and mouse cell lines as well as transgenic and knockout mouse models.
- A3: PI should clarify statement regarding needles – are needles used in conjunction with adenovirus work?
- Has testing been done for RCA?
- Even though the material is not supposed to be replication competent, the IBC recommends implementing an informed consent for workers handling infectious agents
- D5a: B16F10 mouse cell line statement must be clarified. It states that the B16F10 mouse cell line is not intended for use for another six months.
- Part C must be completed since work with adenovirus is being conducted.
- Chemical fume hood was indicated. Ensure that work with infectious material does not occur at any time in the CFH but only in the BSC (biological safety cabinet).
- Standard BSL-2 containment, practices and procedures are required.

*Mr. Jendrek made a motion to conditionally approve pending resolution of the above issues, Dr. Crise seconded, and all were in favor.*

**AMENDMENTS**

**06-78 (Anver) “Support Services on the Behalf of NCI Investigators in PHL”**

- This is a support service registration that provides investigators with histology and veterinary pathology services.
- This group should implement a service request form that addresses the nature of the material they are receiving, the hazards associated with the material, and what precautions should be taken when handling the materials.
- The form can be modeled after other service request forms that various groups use.

*Dr. McVicar made a motion to defer approval pending resolution of the above issues, Ms. Bell seconded, and all were in favor.*

**06-66 (St. Croix) “Targeting New Tumor Endothelial Markers”**

- This amendment was reviewed and approved prior to the IBC meeting.
- Sharps SOP was checked and verified.
- Irradiator usage will be checked for appropriate authorization.

*Dr. Kozlov moved to approve and all were in favor.*

**06-70 (Wiltrout) “Immunomodulation and Immunotherapy of Tumors in Mice”**

- The IBC will defer approval to the lead reviewer who is absent from the meeting.

### **OUTSTANDING ITEMS**

- Amendment of 07-09 (Wolff): Subcommittee to meet with PI
- 07-70 (Trinchieri): EHS/OHS to conduct training session when lab is ready
- 08-31 (Whitby): Revised submission out with lead reviewer for final approval
- 08-53 (Wang): EHS/OHS to conduct training session when lab is ready
- 08-57 (Ruscetti): Subcommittee to meet with PI

### **OTHER BUSINESS**

- The Bloodborne Pathogen Program is 98.3% compliant.
- OHS reported one potential biological exposure incident this month.
- HIV Surveillance was discussed for those groups working with unscreened samples of clinical materials. This surveillance program should only be offered to those working with known HIV infected materials and all unknown material/diagnostic samples should be treated as if potentially infectious.
- Eye protection usage in a BSL2 lab is decided on by the PI or supervisor, unless the IBC specifically requests eye protection to be worn under certain circumstances.
- Dr. O'Brien has received a request for an IBC renewal based on recent information regarding changes in work scope and additional research activities requiring IBC review and approval. The IBC renewal document should be forthcoming in the next few months.

The meeting ended at 2:05 p.m.

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Theresa D. Bell, MPH, CBSP  
IBC Secretary  
Biological Safety Officer, EHS

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Ms. Cara Leitch  
IBC Coordinator  
Sr. Safety Specialist, EHS

APPROVED:

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Randall S. Morin, Dr. P.H.  
Chairman, NCI-Frederick IBC  
Director, EHS

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Date

xc: Dr. Reynolds  
Mr. Wheatley  
Dr. Arthur  
Mr. Bufter