



**NCI-FREDERICK  
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes  
January 20, 2009  
NCI-Frederick

**INTRODUCTION**

The NCI-Frederick Institutional Biosafety Committee was convened at 12:27 p.m. in the Building 549 Board Room, immediately following President Barack Obama's inaugural speech, with the following members in attendance:

Dr. Randall Morin, Chair	Dr. Dan McVicar
Dr. Bruce Crise	Ms. Alberta Peugeot
Ms. Renee Kahn, IBC Administrator	Dr. Michael Baseler
Ms. Theresa Bell, Secretary and Biosafety Officer	
Dr. David Garfinkel	Mr. Lucien Winegar
Mr. Scott Jendrek	Dr. David Derse
Dr. Stephen Hughes	Ms. Dianna Conrad
Dr. Hollingshead	Dr. Serguei Kozlov
Dr. Stephen Creekmore	

Members not in attendance: Dr. Henry Hearn, Dr. Eric Freed.

Others in attendance: Dr. Scott Keimig

**MINUTES**

-November 2008 minutes were posted to the sharepoint IBC website for review. Dr. Hollingshead made a motion to approve the minutes as written, Dr. Derse seconded and all were in favor.

-December 2008 minutes will be distributed for review and approval via email.

**REVIEW OF PROTOCOLS**

**NEW IBC REGISTRATIONS**

**(08-84) (Drs. Tarr/Alexander): Vero Cell Line Cell Banking and Growth Studies**

There were no comments or questions outstanding on this registration.

*Dr. Baseler made a motion to approve as written, Dr. Derse seconded and all were in favor.*

**(08-78) (Dr. Carrington): Work with Human Blood Samples and Cell Lines**

- Verify the location is appropriate.
- The SOP should clearly refer employees to OHS should they have open wounds or other health concerns prior to beginning their work.
- Bleach solutions should be changed weekly.
- PPE donning and doffing requirements have been clearly stated and are acceptable.
- Submit A2 collaborator list as attachment.
- A3 acknowledge there may be other potentially infectious materials present even if the samples are HIV-free.
- Verify all employees are on BBP medical surveillance.
- C10b: they need to verify they will maintain a 2\* operation with BSL-3 practices and procedures.
- It was verified that no flow cytometry work will be done.

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

**(08-80) (Dr. Giaccone): Development of New Brain Metastasis Models of Lung Carcinoma**

- Is EGFP in the cell line
- Clarify the connection between this proposed research and the research reference in the first few paragraphs...will these cell lines be transfected with recombinant material? (there is no Part B completed at this time to register recombinant work).
- How will injections to the animals be performed safely (please provide documentation of tech training and experience and SOP's, animal restraints, anesthesia, etc.)

*Dr. Hughes made a motion to defer approval, pending receipt of the above information, Dr. Creekmore seconded and all were in favor.*

**08-73 (Dr. Kurdziel): Evaluation of multimodality imaging parameter correlation in a human MNNG/HOS-LUC osteosarcoma metastatic lung tumor mouse model**

- Part B should be completed to discuss the details of the recombinant material being used (even if it is from another source)

- Why is the luc necessary in this case (if we can eliminate this hazard that would be good)
- Try to write out acronyms for those not familiar with the details
- The issue of mobilization is not clear because of the murine stem cell virus promoter and what affect this could possibly have with endogenous virus in the mouse.
- How will injections with the MMNG-HOS be done safely (technician proficiency and SOP)

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

**08-87 (Dr. Thorgeirsson) Generation of mice hemizygous for MxCre transgene and homozygous for TGF-beta type ii receptor (TBIIR) or c-met floxed allele”**

There are no comments for this protocol.

*Dr. Hughes made a motion to approve, Dr. Creekmore seconded and all were in favor.*

**08-75 (Dr. Steeg) Human ErbB2 in brain human breast cancer cells**

- How will needlesticks be avoided to minimize the hazards and risks? (Dedicated LASP personnel trained with demonstrated proficiency will be performing this technique. The SOP for the injection will also be obtained.

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

\*\*A lead reviewer expressed the concern (not only related to this IBC) that there needs to be clarification on all IBC documents regarding the use of sharps in conjunction with recombinant, infectious or other potentially infectious material when performing work with animals and documenting technician proficiency in performing injections. A statement or document from the technician or LASP documenting proficiency would help to alleviate this concern from the IBC.

**08-77 (Dr. Sterneck) Lentiviral vector mediated expression or silencing of C/EBPdelta**

- How will the virus preps be transported from Dr. Conde’s lab to this lab (provide transport SOP)
- Be sure all containers are labeled and hand-carried, and they must all be opened and closed inside the BSC

*Dr. Hughes made a motion to approve, Dr. Hollingshead seconded and all were in favor.*

**RENEWALS**

### **08-79 (Dr. Hughes/Dr. Kearney) Core Facilities Studies**

- B3 responses were confirmed
- D5b should be clearer regarding screening results. This answer was provided based on knowing samples are HIV-positive so they are also assumed positive for other pathogens too. However, the procedures used to inactivate the HIV would also inactivate other pathogens if present, through the use of guanidinium salts.

*Dr. McVicar made a motion to approve, Dr. Baseler seconded and all were in favor. Dr. Hughes abstained from the vote.*

### **08-81 (Dr. Harris) Production of non-pathological oncolytic poliovirus chimera for the treatment of brain tumor**

- Remove Dr. Khare as PI
- Verify immunizations are in place for polio
- C5a needs clarified

*Dr. Derse made a motion to approve, Dr. Hollingshead seconded and all were in favor. Dr. Creekmore and Mr. Jendrek abstained from the vote.*

### **08-82 (Dr. Zhang) TGF-beta/Smad signaling**

This protocol involves breeding only and is straightforward.

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

### **08-83 (Dr. Zhang) Role in Smurf in TGF-beta/SMAD signaling**

- D3: are these cells human or murine?
- A better description of the packaging systems is needed
- What are the safeguards for injections to avoid needlesticks (technician proficiency and SOP\_
- Will histopathology services be performed and if so, how will the mice be transported?
- How will this research be temporally and physically kept separate from other research in the lab?
- pBABE has gag - replication competent recombinants which are an issue that needs addressed
- Are these eco or amphotropic?
- The IBC document does not appear to complement the salient points in the ASP document, clarify this issue.

*Dr. McVicar made a motion to defer approval, Dr. Hollingshead seconded and all were in favor.*

**08-85 (Dr. Kopp) Cell processing and Immunologic monitoring of clinical material obtained from patients with HIV including samples from patients co-infected with Hepatitis C or mycobacterium tuberculosis**

-Ensure that glass from sample containers are kept inside of and disposed into a sharps container within the BSC prior to final disposal for autoclaving (in other words, do not pull untreated waste out of the BSC to dispose of).

*Dr. Garfinkel made a motion to approve, Mr. Jendrek seconded and all were in favor.*

**08-86 (Dr. Kopp) Cell processing and immunologic monitoring of material obtained from Non human primates infected with Simian Immunodeficiency Virus (SIV)**

No comments.

*Dr. Garfinkel made a motion to approve, Mr. Jendrek seconded and all were in favor.*

**AMENDMENTS**

All amendments resolved outside of full committee meeting.

**OUTSTANDING ITEMS**

- Amendment of 07-09 (Dr. Wolff): Waiting on responses from PI.
- 08-68 (Dr. Hu): With PI for more clarifications.
- 08-31 (Dr. Whitby): With lead reviewers for review and comment.
- 08-57 (Dr. S. Ruscetti): PI still working with subcommittee for approval. Another meeting is to be scheduled.
- 08-71 (Dr. Jin and Dr. Wang): Working with PI to make changes on IBC documents.
- Amendment of 06-78 (Williams/Anver): Approval on this amendment has been retracted by registering PI with modifications to be submitted pending meeting with LASP Director.
- Amendment of 06-107 (Dr. Wakefield): PI to submit clarifications as requested.

**OTHER BUSINESS**

**BBP Compliance: 9/1077 = 99.99 % (through 12/31/08)**

**Human Pathogen Screening:**

The following pathogens are being considered by the IBC to be required for screening:

HIV-1, HIV-2, EBV, Cytomegalovirus, HTLV-1/2, Hepatitis A, Hepatitis B, Hepatitis C, Herpes Simplex Virus, Adenovirus, Vaccinia, HHV 6, HHV 8, and Herpes B Virus.

The committee will look to outsource this screening to a private company, but will also pursue internal options within the NCI as well. Assay development, feasibility, and costs will be assessed and updated to the IBC as information becomes available.

**Informed consent:**

This document will change names to an Acknowledgement of Risk/Risk Communication and is being discussed with legal and human resources.

**OHS Accident Update:**

Nothing to report this month.

**Lead Reviewer Assignments:**

The committee discussed if one or two lead reviewers was necessary for new and renewal registrations. It was decided to leave the reviewer assignment procedure as it is currently, assigning two lead reviewers for each registration. Amendments can continue to be reviewed by one lead reviewer, and be recommended for full committee when the lead reviewers deem it appropriate.

**Outside IBC Member:**

The IBC currently has two community members and had decided to pursue a third outside community member. This will help to ensure that we ensure attendance of community members at every meeting. Suggestions for outside members are being collected by the Chair, Dr. Morin at this time. Candidates will be further discussed at the February 2009 meeting.

**Meeting was adjourned at 2:45 p.m.**

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

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Ren'ee Kahn  
IBC Administrator  
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. Butfer