



**NCI-FREDERICK  
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes – August 16, 2005  
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:03 p.m. in the Building 549 Executive Boardroom with the following members in attendance:

Dr. Randall Morin, Chair  
Dr. Henry Hearn  
Dr. Melinda Hollingshead  
Dr. David Garfinkel  
Ms. Kitty Nalewaik  
Dr. Dan McVicar

Dr. Stephen Hughes  
Ms. Theresa Duley  
Mr. Lucien Winegar  
Dr. Paul Nisson  
Dr. Jeanne Herring

Members not in attendance: Dr. Michael Baseler, Dr. Stephen Creekmore, Dr. Bruce Crise

Others in attendance: Ms. Cara Leitch, Dr. Scott Keimig, Dr. David Symer, Dr. Ray Harris, Greg Clarke, Samir Shaban, John Appling, and Ms. Mary Carol Fleming

## **INTRODUCTION**

Dr. Morin called the meeting to order.

Dr. Morin asked for comments from the committee on the July meeting minutes. Since the minutes were distributed at today's meeting for review and comment, the committee was asked to review them and comment as appropriate. A final vote by email will be taken by Ms. Leitch.

Ms. Duley introduced the guests in attendance at the meeting, and proceeded to introduce the new business for discussion.

## **PROTOCOL REVIEWS**

### **NEW BUSINESS**

**05-43 (Dr. Symer) – Approved.**

Dr. Garfinkel made a motion to approve this registration based on the fact there are no viruses and no oncogenes involved in this proposal, and appropriate containment measures were addressed. Mr. Winegar seconded and all were in favor.

**05-45 (Dr. Symer) – Approved.**

Dr. Garfinkel made a motion to approve this registration based on the use of “jumping genes” with non-infectious material, which remains inside of an intact cell, and the remote possibility of a recombination event occurring. Dr. McVicar seconded and all were in favor.

**Pathogen (Dr. Jinhua Lu) – Approval pending modifications.**

Ms. Duley introduced this registration request in lieu of Dr. Baseler’s absence. Ms. Duley confirmed that the workspace is in fact a cGMP-validated facility, and validation of equipment and facilities should be completed by the end of August 2005. The issue of potential hazards with needlesticks was raised. It was explained by some of the BDP guests that the Pierce Slide-A-Lyzer Dialysis cassette would be placed in a rack while manipulations such as sample addition and removal are performed. Because the cassette would be in a fixed position and not held in the hand, this would minimize the potential for needlesticks.

- 1) The committee requests confirmation that this procedure will be done inside containment.
- 2) If possible, an 18-gauge syringe needle should be substituted with something less hazardous for this portion of the procedure.
- 3) A riboflavin “run through” should be conducted to test systems virus free before initiating infectious work.

Ms. Duley made a motion to approve with modifications, Mr. Winegar seconded and all were in favor.

**Pathogen (Dr. Reilly) – Approved.**

The Biosafety Office will make sure they are aware of the option to have their material testing for pathogens by LMT.

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

**05-44 (Dr. Tessarollo) – Approved.**

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

**05-41 (Dr. Gamero) – Approval pending modifications.**

- 1) #5 – Answer should be yes since there is a remote possibility that viral vector sequences can recombine to produce new and unpredictable forms of infectious virus. Explain and address the hazards.
- 2) #8c – Provide a detailed description of the human or amphotropic viral vectors that will be utilized.
- 3) #9a and #13 – Specify hazards specific to the retrovirus work to be performed.
- 4) #9c – Confirm that the Ras and cmyc/Raf viruses will be used only in vitro. Specify that the virus will not be used to transfer infected bone marrow to the mice.
- 5) #9d and #14 – Describe the special practices specific to working with retroviruses.

Dr. McVicar made a motion to approve pending modifications, Mr. Winegar seconded, and all were in favor.

**05-47 (Dr. Berzofsky) – Approval pending modifications.**

- 1) Certify how the mice were generated (i.e. what methodologies were used to make the mice). Delete the phrase “to my knowledge”.
- 2) Provide the whole list of transgenic strains and knock out strains. Delete the words “include”.

Dr. McVicar made a motion to approve pending modifications, Dr. Garfinkel seconded, and all were in favor.

**05-42 (Dr. Cheng) – Approval pending modifications.**

- 1) #9 – Should be “yes”. Complete all sections of #9.
- 2) #10 – Should be “yes”. What proteins?

Dr. Hughes made and motion to approve pending modifications, Mr. Winegar seconded, and all were in favor.

**05-46 (Dr. Jeang) – Approved.**

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

**Pathogen (Dr. Jiang) – Approval deferred.**

- 1) State how the HBx mutant cell lines are made and where they came from (i.e. what was the starting cell line – fresh human hepatocytes?).

- 2) Provide documentation of pathogen testing. Only mycoplasma testing results are provided.
- 3) Were viral vectors or plasmids used? If so, what are they?
- 4) Is there recombination potential?

Email vote will be taken upon PI's responses to the IBC questions.

## **AMENDMENTS**

### **Pathogen (Dr. Harris) – Approval pending modifications and demonstration**

- 1) A drip tray or pan should be installed at the bottom of the "shower" stall to avoid any splashes from running down the shower walls and outside of the shower stall underneath. Essentially, a mock worst-case scenario of a rupture, leak, or compromise of the containment system was requested by the committee.
- 2) Additional Personal Protective Equipment should be worn. This includes double gloving, covering all exposed skin, head covers, and facemask when procedures are in operation.
- 3) A riboflavin test must be completed. A date and time will be established with interested members of the committee for observation and concurrence prior to initiation of work with virus. Although this cannot be set up in the area in which the work will be done, the "test" space will mimic that of the actual work space when live virus work is done.
- 4) An additional worse case scenario will be imitated by severing the line to determine if the containment is working and appropriate in the event of an unforeseen event.
- 5) A laboratory inspection should be completed by EHS prior to initiation of work with virus.
- 6) The operation shall only take place with a minimum of two personnel present at all times.
- 7) State in the amendment that pressure testing is done, and that pressures established for this operation are set at approximately half of what the system has been verified to handle. If the system exceeds the half way mark, the system will automatically shut down.
- 8) A leak test will be performed to demonstrate that no leaks are present where the connections are made. New tubing will always be used since these operations are performed under GMP requirements.
- 9) It was suggested that heavier grade flexible tubing be used as a secondary layer of protection in case the other tubing would be compromised. If this is going to be done, please clarify in the amendment memorandum.

Dr. Hughes made a motion to approve pending modifications and demonstration, Dr. Garfinkel seconded, and all were in favor.

## **OUTSTANDING ITEMS**

**05-29 (Dr. Rane)** – Approval pending PI response

**05-30 and New Pathogen Registration (Dr. Michiel/Dr. Stoughton)** – Approval pending additional PI responses

**Pathogen (Dr. Dimitrov)** – Responses submitted on 8/15/2005. Will be reviewed at September meeting.

**05-38 (Dr. Stewart)** – PI will resubmit for September meeting.

## **OTHER BUSINESS**

### Proposed Policy Handout

Item #1 – Vaccination Policy – Approved

Item #2 – Validation of Genetic Material Policy – vote by email

Item #3 – Screening Policy – vote by email

Item #4 – Technical Subcommittee Review Policy – Approved

Item #5 – Deadline Change to the first Tuesday of every month - Approved

The meeting was adjourned at 2:10 p.m.  
MINUTES RECORDED BY:

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Theresa Duley, MPH  
IBC Secretary  
Biological Safety Officer, EHS

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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: All Committee Members

Dr. Wiltrout  
Dr. Reynolds  
Mr. Eaton  
Dr. Arthur  
Mr. Bufter  
Dr. Keimig