



**NCI-FREDERICK  
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes – September 20, 2005  
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:02 p.m. in the Building 549 Executive Boardroom with the following members in attendance:

Dr. Randall Morin, Chair  
Dr. Henry Hearn  
Mr. Lucien Winegar  
Dr. Paul Nisson  
Dr. Jeanne Herring  
Dr. Stephen Creekmore

Dr. Stephen Hughes  
Ms. Theresa Duley  
Dr. David Garfinkel  
Dr. Bruce Crise  
Dr. Michael Baseler

Members not in attendance: Dr. Dan McVicar, Dr. Melinda Hollingshead

Others in attendance: Ms. Cara Leitch, Dr. Scott Keimig, Mr. Brian Hanshew, Ms. Lois Minchoff, Ms. Barbara Romeka, Dr. Ron Felsted, Dr. Connie Glover, Mr. Samir Shaban, Dr. Jinhua Lu, and Dr. Ray Harris

## **INTRODUCTION**

Dr. Morin called the meeting to order.

Dr. Morin asked for comments from the committee on the August meeting minutes. There were no requested modifications to the minutes as written. Mr. Winegar made a motion to approve the minutes as written, Dr. Hearn seconded and all were in favor. The August minutes were approved as written.

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

## **PROTOCOL REVIEWS**

## **NEW BUSINESS**

**Pathogen (Dr. Glover) - Approved.**

Dr. Glover commented that all those working in and passing through the area allocated for this proposed work are trained and enrolled in the Bloodborne Pathogen Program. Dr. Glover was informed of the opportunity for cell line screening services and the committee recommended this service be used prior to initiating the research.

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

**05-50 (Dr. Keller) – Approved pending modifications.**

The committee recommended a minor correction to the documentation to remove the grammatical error (double negative) in Question # 2, for clarity as follows: "Vectors proposed for use in this registration are non-viral." Furthermore, a statement of how the non-viral work will be kept separate from viral work in the lab was also requested.

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

**Pathogen (Dr. McNeil) – Approved pending modifications.**

The IBC recommended screening services for cell lines to be used in this research protocol. Question #5b in part C of the form requires documentation to be submitted to the committee for review. Handling of mixed waste streams, decontamination methods, and proposed methods for monitoring nanoparticulate counts were discussed.

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

**Pathogen (Dr. Ji Ming Wang) – Approval deferred.**

The IBC would like the following questions addressed:

1. Part B, question #2 - Listeria also infects humans.
2. Where will the mice be held after injection (i.e. will they be kept separate from other mice not infected with Listeria)?
3. What are the waste disposal procedures and husbandry for infected mice and materials they have touched?
4. Will mouse restraints be used when injecting the mice? (we need to address injection hazards with Gene Oliver)

5. Part C#6a states no, but should it be yes, since the agent will be administered to the mice via IP or IV.
6. How will cell lines that are mycoplasma positive be handled differently than cell lines that are not mycoplasma positive?
7. Are there other potential hazards or toxins associated with this strain?
8. Is this lab-acquired infection treatable with antibiotics?
9. Please verify what the animal technicians are injecting.

Dr. Herring made a motion to defer approval, Dr. Hearn seconded and all were in favor.

**05-49 and Pathogen (Dr. Chatterjee/Kaczmarczyk) – Approval deferred.**

The following questions were posed by the IBC:

1. How will the virus be put into the cell (describe the mechanism for virus delivery)?
2. Since the animal study was revised, please include revisions on IBC forms.
3. Once revisions have been made and everyone trained, please check off #15 in the Recombinant DNA form.
4. Is this the best animal model to use for this study?
5. Does virus replicate and infect normally, do you change the receptor, or is it made infectious to cells via tropism?
6. Can the mouse shed virus?

Dr. Creekmore made a motion to defer approval, Dr. Hughes seconded and all were in favor.

**05-51 and Pathogen (Dr. Dimitrov) – Approval deferred.**

After discussion the committee asked the following questions:

- 1) The information in the registration document implies that VSV-G is replication defective. Please clarify.
- 2) Is there any risk of recombination via complementation with CCHFV?
- 3) Is there any homology between the VSV-G expression vector and CCHFV?
- 4) Are you still using the other envelopes you have been previously approved for in other registration or is the only intention here with CCHFV?

Dr. Hughes made a motion to defer approval pending further discussion, Dr. Garfinkel seconded and all were in favor.

**05-48 (Dr. Anderson) – Approved pending modifications.**

The IBC asked the following questions:

- 1) In the registration document, it is stated that there will not be infectious virus made. The packaging systems used will produce infectious Adenovirus. This should be corrected.
- 2) #9d - The virus could recombine with cell lines expressing E1 and E3. How will the lines being used be tested for E1 and E3?
- 3) #13 - Because adenoviral systems can be complimented by virus produced by sick workers, a provision prohibiting virus manipulation by sick workers should be added.

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

## **AMENDMENTS**

### **Pathogen (Dr. Harris) – Approved.**

The IBC requested the BSO to revisit the efficacy of VHP as an appropriate means of decontamination.

Dr. Crise made a motion to approve, Dr. Garfinkel seconded, and all were in favor. Dr. Creekmore abstained from the vote.

## **RENEWALS**

### **Pathogen (Dr. Lu) – Approved pending modifications.**

After discussion the committee asked the following questions:

- 1) Please complete Part C of the form as some of these questions do pertain to the use of animal materials and we simply want to make sure any applicable questions on this part of the form are completed.
- 2) Please make a statement that PAPR's will be made available for use by all those choosing to use them. Furthermore, for those unexpected or unimmunized entrants, a PAPR will be required at times when there is on-going work with Polio in that space.
- 3) Note the contact time for the VHP decontaminations of the room area and that Biological Indicators will be used to verify the decontamination was effective.

Dr. Morin made a motion to approve, Dr. Crise seconded and all were in favor. Dr. Creekmore abstained from the vote.

## **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 and/or transfer of research to another PI.**

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

**Pathogen (Dr. Lu) – Conditional approval pending completion of riboflavin test.**

## **OTHER BUSINESS**

Presentation of IBC on-line registration document by Barbara Romeka and Brian Hanshew.

The meeting was adjourned at 2:20 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. Wiltout  
Dr. Reynolds  
Mr. Eaton  
Dr. Arthur  
Mr. Bufter  
Dr. Keimig