



**NCI-FREDERICK  
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes – June 14, 2005  
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:01 p.m. in the Building 549 Executive Boardroom with the following members in attendance:

Dr. Randall Morin, Chair	Dr. Stephen Hughes
Ms. Carol Ingraham Tobias	Dr. Michael Baseler
Dr. Bruce Crise	Dr. Henry Hearn
Mr. Lucien Winegar, Esq	Ms. Theresa Duley
Dr. Daniel McVicar	Dr. Melinda Hollingshead
Dr. Stephen Creekmore	Dr. Paul Nisson (ex-officio)
Dr. Jeanne Herring	

Members not in attendance: Dr. David Garfinkel

Others in attendance: Dr. Scott Keimig, Ms. Kitty Nalewaik, Ms. Barbara Romeka, Mr. Patrick Moloney, and Ms. Cara Leitch

## **INTRODUCTION**

Dr. Morin called the meeting to order. Dr. Morin announced the departure of Ms. Carol Tobias effective Friday June 17, 2005 and re-introduced Ms. Kitty Nalewaik as the replacement member on behalf of Occupational Health Services. Dr. Morin made a motion to vote Ms. Nalewaik to the committee as a voting member, all members were in favor.

Dr. Morin asked for comments from the committee on the May meeting minutes. Dr. Morin made a motion to approve the minutes with no changes, the committee concurred, and the May minutes were approved as written.

Dr. Morin also introduced Ms. Romeka and Mr. Moloney, who would later be discussing the progress of the on-line IBC registration form.

## **OUTSTANDING ITEMS**

**05-10 (Dr. Schmidt) – Approved pending sequencing**

**05-03 (Dr. Young) – Approved pending PI response**

**04-20 Amendment (Dr. Young) – Approved pending PI response**

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

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

**02-24 (Dr. Tessarollo) Amendment - PI to submit new paperwork**

**05-13 (Dr. Waugh) – Pending PI responses**

**Pathogen Registration (Dr. Lifson) – Pending agreement for shared equipment and facilities**

## **NEW BUSINESS**

### **PROTOCOL REVIEWS**

**New Pathogen Registration (Dr. Phang) – Approval pending PI response**

- 1) Please clarify the relationship between Dr. Phang's recombinant DNA registration and Dr. Diwan's Animal Study Proposal.
- 2) Please provide a list of names of the animal facility staff who will be involved with this research effort.
- 3) Please discuss further the potential for recombination and/or replacement, regarding the use of infectious adenovirus cells, and if the virus is mobilizable and/or replication competent? Item #8C states that the virus is not replication competent because the virus requires cells to express various genes lending to replication. However, mammalian cell lines are being used for this study. Please further explain if and why these are an exception.
- 4) Identify any unknown potential hazards that may result from this experiment (especially if infectious adeno cells are injected into mice) and identify any mitigation measures implemented to resolve these issues.
- 5) Specify (including attachment of an SOP) how live infectious items will be transported from one location to another.
- 6) If an ABSL-2 environment is used to conduct animal studies and a safetygram describing such procedures is attached to your submission, please identify special practices (i.e.-use of microisolator cages, autoclaving wastes, etc) particular to the animal facility work.
- 7) Item #16 states that animal studies do not included adenoviral work; however, if the proline oxidase may or may not express cells which are potentially infectious with adenovirus, then why does animal work not include adenovirus? Please explain.

- 8) In Item #9C, it asks if infectious virus will be produced during this work. Explain why your answer is "None" if cells are infected with adenovirus which may replicate and
- 9) Are the mammalian cells being used in this study permissive to adenovirus infection?

## **RENEWALS**

### **T190601JOA02 (Dr. Ortaldo) – Approved pending PI response**

- 1) Item #7: are the volumes specified for each of the two identified agents or is the volume total for both?
- 2) Item #6b: Please verify the amount of toxin and if this amount is being used all at once or in increments?

### **05-31 (Dr. Oppenheim) – Defer approval**

- 1) Item #8 vector list is incomplete.
- 2) Item #13, further identify potential hazards and mitigation measures.
- 3) Item #9D should be "Yes" and please further explain potential recombination with endogenous viruses and amphotropic abilities.
- 4) Item #9C should be "Yes", and please specify potential products, associated hazards and how they will be addressed.
- 5) Please specify if this work is on-going or is this a new research study?
- 6) Please further identify how this renewal is different to currently approved registrations.
- 7) Please state that the HIV envelope will not be obtained throughout the course of this work.
- 8) Dr. McVicar, the designated reviewer, will work with Zack Howard to clarify research purposes and procedures and will re-submit renewal registration for approval at the July meeting.

## **AMENDMENTS**

### **P141097SFB03 (Dr. Hornung) – Approved.**

## **OTHER BUSINESS**

### **DRAFT IBC FORMS**

Ms. Romeka and Mr. Moloney gave a brief demonstration on how to access and complete on-line IBC registrations using the form in development. Revisions continue and the committee will be updated as progress is made.

## **DRAFT VACCINATION POLICY**

Comments were collected from participating IBC members and discussions continued. It was decided that a policy should be drafted and voted on by the committee stating that the need for vaccinations will be reviewed on a case by case basis, and the need for determining vaccination status will be based on a risk assessment for safety and health hazards, relating to the research proposed. A draft policy will be submitted to the committee for review during the July meeting.

## **ANIMAL STUDY PROPOSALS AND TECHNICAL REVIEW SUBCOMMITTEE DRAFT**

Comments are being collected from participating IBC members. A policy summarizing requirements for a technical subcommittee, to include members, quorum, and responsibilities will be drafted and submitted to the committee for review and comment. A vote on this subject matter will be taken at the July meeting.

## **SEQUENCING POLICY**

A draft policy regarding sequencing of virus and cell lines for human pathogens will be proposed at the July meeting.

The meeting was adjourned at 2:00 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. Wilttrout  
Dr. Reynolds  
Mr. Eaton  
Dr. Arthur  
Mr. Bufter  
Dr. Keimig

