



**NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes – May 17, 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)

Members not in attendance: Dr. Jeanne Herring, Dr. David Garfinkel

Others in attendance: Dr. Scott Keimig, Lt Col Janice Rusnak, Dr. Michael Parker, Dr. Judy Poiley-Nelson, Mr. Trevor Broadt, Dr. Dennis Michiel, Mr. Charles Trubey, Ms. Kitty Nalewaik, and Ms. Cara Leitch

INTRODUCTION

Dr. Morin called the meeting to order. Dr. Morin officially welcomed Dr. Parker for his presentation on NIH Guideline interpretation for Biosafety Level 4 recombinant research requirements.

Following discussions and recommendations from the committee with Dr. Parker, Dr. Morin introduced Lt Col Janice Rusnak from the United States Army Medical Research Institute of Infectious Diseases, sitting in on the committee to observe as a potential future member.

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

OUTSTANDING ITEMS

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

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

04-03 Amendment (Dr. Schmidt) – Approved pending PI responses

04-20 Amendment (Dr. Young) – Approved pending submitting committee questions

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

05-31 and New Pathogen Registration (Dr. Michiel/Dr. Stoughton) – Approved pending modifications

NEW BUSINESS

PROTOCOL REVIEWS

05-30 (Dr. Michiel) – Approved pending modifications

1. Provide an SOP specific to the recombinant DNA work and molecular procedures. Have the staff sign off that they have read and understand the procedures.
2. Provide a statement that no more than 10L will be used and if research exceeds volumes of 10 Liters at some point, seek IBC approval first.
3. Provide classification according to the NIH Guidelines. (Ms. Duley and Ms. Leitch).

New Pathogen Registration (Dr. Poiley-Nelson) – Approval deferred

1. Determine level of attenuation and provide more information on specific strain.
2. Each individual must have a titer done with OHS to work on the project.
3. How are aerosolizations avoided?
4. Define and address potential hazards with the standard operating procedures to include handling techniques.
5. What is the source of the Rhesus red blood cells?
6. Is there a less virulent strain that can be used in this study?

New Pathogen Registration (Dr. Lifson) – Approval deferred

1. #10 should answer "yes" instead of "no".
2. Contact Dr. Pavlakis and Dr. Lifson about sharing the flow cytometer and address the hazards (Ms. Duley and Ms. Leitch).
3. Research plexiglass HEPA-filtered containment for the flow cytometer (Ms. Duley and Ms. Leitch).

05-34 (Mr. Broadt) – Approved pending modifications

1. Provide a statement that the proposed registration is a service to BDP.
2. Provide assurance that you will take responsibility for providing assurance that the virus is not mobilizable.

05-32 (Dr. Muegge) - Approval deferred

1. Give a description of your project in lay language.
2. #3b is not consistent with #7e.
3. Define associated hazards from genes in mice and how they will be mitigated.
4. What volume of virus will you be using?
5. How will the cells be screened/sorted?
6. Describe risks, main issues, perceptions, and actions
7. Where is the virus inherently safe?
8. Identify safety features of virus system and why does this make it safe?

New Pathogen Registrations (Dr. Jin) - Approval deferred

1. Confirm that the mice mentioned in the registration are not located at NCI-Frederick.
2. Clarify that E. Coli manipulations are done in the biological safety cabinet (BSC).
3. Use plastic flasks.
4. Have the cell lines sequenced at LMT (Laboratory of Molecular Technology).
5. Will cells being propagated have virus in them?
6. Clarify SOP for working with E0157, describing spill cleanup procedures, transport of containers.

05-33 (Dr. Roberts) – Approved pending modifications.

1. What are the potential hazards associated with manipulation of the lung and tumor after they have been removed from the mouse?
2. Is there a possibility that a murine retrovirus can be produced?

05-35 (Dr. Bennett) – Approved.

AMENDMENTS

02-24 (Dr. Tessarollo) – Approval deferred pending PI submission of new registration.

04-27 (Dr. Perkins) – Approved by designated reviewer Dr. Crise on May 10, 2005.

RENEWALS

05-13 (Dr. Waugh) – Approval deferred pending PI response to committee questions as follows:

1. Rewrite the registration as if Yersinia Pestis (protein) is not a Select Agent. It reads as if it is, but since only a protein is being used, it is exempt from the Select Agent rule.
2. Provide a more specific SOP that addresses safety issues related to this particular study.
3. Clarify the BSL where work will be conducted. It should be a BSL 2 across the board, not changing from a BSL1 to a BSL2 and vice versa.
4. Where will production occur?
5. What is the scale of work? less than 10 L or more than 10L?
6. Specify which proteins will be produced from genomic DNA.
7. Explain what won't be done in this registration. (ie. will not recombine separate proteins in E. coli)

A technical subcommittee consisting of Drs. Baseler, Morin, Hughes, and Crise, Ms. Duley, and Ms. Leitch will continue to address these questions with the PI.

05-12 (Dr. Waugh) – Approved by designated reviewer Dr. Baseler on 05/13/2005.

05-11 (Dr. Waugh) – Approved by designated reviewer Dr. Baseler on 05/13/2005.

OTHER BUSINESS:

DRAFT IBC FORMS

New draft forms for rDNA registrations and pathogen registrations will be available June 1, 2005 on line for use and further comment. 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.

The meeting was adjourned at 3:10 p.m.
MINUTES RECORDED BY:

Theresa Duley, MPH
IBC Secretary
Biological Safety Officer, EHS

Cara Leitch
IBC Coordinator
Sr. Safety Specialist, EHS

APPROVED

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

DATE

xc: All Committee Members
Dr. Wilttrout
Dr. Reynolds
Mr. Eaton
Dr. Arthur
Mr. Bufter
Dr. Keimig