



**NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes
September 19, 2006
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:10 p.m. in the Building 549 Executive Board Room with the following members in attendance:

Dr. Randall Morin	Dr. Michael Baseler
Ms. Theresa Duley, Secretary	Dr. Jeanne Herring
Dr. Henry Hearn	Dr. Bruce Crise
Ms. Alberta Peugeot	
Dr. Stephen Hughes	
Dr. David Garfinkel	

Members not in attendance: Dr. Dan McVicar, Mr. Lucien Winegar, Dr. Melinda Hollingshead, Dr. Paul Nisson, Dr. Stephen Creekmore

Others in attendance: Ms. Cara Leitch, Dr. Scott Keimig, Dr. Robert Thomas

INTRODUCTION

Dr. Morin called the meeting to order.

The July 2006 meeting minutes were distributed for review prior to today's meeting. All members are requested to review the minutes, submit changes and modifications to Ms. Leitch, and a final vote for approval of the minutes will be obtained through email.

The August 2006 meeting minutes will also be distributed through email for review and approval after an approval is reached for the July minutes.

PROTOCOL REVIEWS

NEW BUSINESS

06-79(Dr. Whiteley)

- The overall process should be described in section A of the IBC form, from sample receipt through when the samples have been processed and disposed (including how the samples are prepared prior to loading the machines and then how are they removed from the robotics prior to disposal).
- Address any potential aerosols that may result during the entire sample receipt, processing, and disposal process.
- Provide any additional information regarding the source of the material - is it serum, whole blood, or both, and how will it be received?
- What volumes of material will be used?

Ms. Duley made a motion to conditionally approve this registration, pending a sufficient response to the above questions, Dr. Crise seconded and all were in favor.

06-80 (Dr. Diwan)

- There were no further discussions on this protocol.

Dr. Crise made a motion to approve this protocol as written, Dr. Baseler seconded and all were in favor.

06-81 (Ms. Williams)

- In Item A2, the term “mostly” transgenic and knockout mice will need to be clarified.
- The committee requested that if any other strains are added other than those specifically identified in the Part E forms submitted as part of this initial registration, they be amended to this registration.
- The IBC requested that if there is knowledge or any presumptions that any animals coming in or any animal work may involve potentially mobilizable elements, that additional safety hazards and appropriate mitigation measures be identified to the committee prior to the initiation of work.

Dr. Hughes made a motion to conditionally approve this registration pending receipt of a statement from the PI concurring with the above request. Dr. Crise seconded and all were in favor.

06-82 (Dr. Imamichi)

- The committee would like to know who actually performs the blood draws and where this occurs.
- An IBC member noted the systems used for the Flow Cytometry are completely closed systems, minimizing the potential for aerosol production and dispersion.
- All employees included on this registration are already enrolled in the Bloodborne Pathogen Program.

Pending the receipt of any comments or questions identified by the lead reviewer not present in the meeting, Dr. Garfinkel made a motion to approve, Dr. Baseler seconded and all were in favor.

06-83 (Dr. Sterneck)

- In A3, “there are no known hazards” should be removed. The committee would like consideration to be given to the reasons why standard Biosafety Level 2 precautions, laboratory practices and procedures are required.
- The potential hazards for someone who may have an allergy to doxycycline should be considered. There are risks that need to be identified along with an appropriate mitigation measure.
- Since there is a tet regulator present, which is under the control of the MMTV LTR, it would be necessary to acknowledge the possibility of potentially mobilizable elements and to describe why this material in use is not dangerous to the employees working with it.
- The committee asked for clarification regarding if mice will be imported or if they will be made here at the NCI-Frederick.

Dr. Baseler made a motion to conditionally approve pending receipt of sufficient responses to the issues addressed above, Dr. Hughes seconded and all were in favor.

06-84 (Dr. Camphausen)

- The IBC requested that Section A1 be revised to include a summary describing the injection of human cell lines, and to reference the cell line screening results in Question D5.

Pending the receipt of any comments or questions identified by the lead reviewer not present in the meeting, Ms. Duley made a motion to conditionally approve pending receipt of the requested modifications, Dr. Crise seconded and all were in favor.

RENEWALS

NONE

AMENDMENTS

NONE

OUTSTANDING ITEMS

05-29 (Dr. Rane) – On hold.

06-36 and 06-37 (Dr. Schneider) – PI to address questions.

05-49 and Pathogen (Dr. Chatterjee) – On hold.

06-11 and 06-12 (Dr. Moschel) - PI to address IBC questions

06-39 (Dr. Kopp) – Pending riboflavin run

06-13 (Dr. Munroe) – Pending receipt of SOP

06-51 and 06-38 (Dr. Keller) – PI to address questions

06-70 (Dr. Wiltrout) – PI to resubmit revised registration

OTHER BUSINESS

The Bloodborne pathogen update reported 94.6% compliance in the program. Ms. Leitch will continue to notify program members of their requirement to complete this annual training.

Ms. Leitch and Ms. Duley will continue working with the ACUC Administrator to collaborate activities and procedures to streamline the committees and their operations.

The committee discussed the upcoming IBC and ACUC registrations from Dr. Dennis Klinman. Dr. Klinman is expected to begin operations here at the NCI-Frederick later in October and November of 2006. Dr. Klinman will be requesting to register some pathogenic strains of bacteria, which have not been previously manipulated here at the NCI. The materials require Biosafety Level 2 laboratory facilities and practices. There will be a subcommittee formed of about 10 members, both from the ACUC and the IBC, to discuss potential questions and issues of concern regarding Personal Protective Equipment, animal housing, husbandry practices, immunizations, post-exposure prophylaxis, and other pertinent safety issues regarding laboratory and animal facility workers.

Some particular questions raised included if virulent strains will be present in the laboratory, are there quality testing systems in place to verify the integrity of the material(s) used, will vaccination and challenge occur at the same site, will animals be housed in PIV or microisolator cages, will animal room exhaust be placed under negative pressure with HEPA filtered exhaust and will employees be offered PAPR's? A sub-committee will be meeting to address these concerns prior to Dr. Klinman's arrival and initiation of research activities.

Dr. Hearn asked a question about how research projects are determined, awarded, and funded. Dr. Baseler described some limited detail regarding the yellow tasking system.

No other issues were raised to the committee's attention and the meeting was adjourned at 1:20 pm.

MINUTES RECORDED BY:

Theresa Duley, MPH, CBSP
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. Reynolds
Mr. Wheatley
Dr. Arthur
Mr. Bufter
Dr. Keimig