



**NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes
May 23, 2006
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:05 p.m. in the Building 549 Conference Room with the following members in attendance:

Ms. Alberta Peugeot
Dr. Henry Hearn
Dr. Bruce Crise
Dr. Stephen Creekmore

Ms. Theresa Duley, Secretary
Dr. David Garfinkel
Dr. Melinda Hollingshead
Mr. Lucien Winegar

Members not in attendance: Dr. Randall Morin, Dr. Michael Baseler, Dr. Stephen Hughes, Dr. Dan McVicar, Dr. Jeanne Herring, Dr. Paul Nisson

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

INTRODUCTION

Ms. Duley called the meeting to order.

Ms. Duley requested the IBC members to review the April 2006 meeting minutes. There were no objections to the minutes as written and all were in favor of approval with no further modifications.

PROTOCOL REVIEWS

NEW BUSINESS

06-33 (Dr. Misteli):

This study involves knockout mice, no virus, and minimal risks and hazards are associated with this proposed research.

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

06-47 (Dr. Callahan):

Other than receiving the attachments required in questions A9 and A10, this study involves MMTV and 1 promoter, LTR. The hazards are minimal.

Dr. Hollingshead made a motion to approve the registration, Dr. Crise seconded and all were in favor.

06-13 (Dr. Munroe):

This study involves flu mist, a commercially available vaccine available to the public, which is inherently safe.

The PI takes a reasonable approach in adding a strong DNA denaturant to the Flumist in a BSC and then adding Trisol to isolate the RNA. Potential hazards have been mitigated through appropriate engineering controls and practices.

Dr. Garfinkel recommended approval pending receipt of SOP, Dr. Hollingshead seconded and all were in favor.

06-43 (Dr. Malyguine):

Overall this registration is complete. The extensive SOP states that no work will be conducted with live virus outside of a BSC. There were a few minor typos in the paperwork. There was a question regarding the replication status of the virus in that wild-type adenovirus can be replication competent, particularly Ad-5. However, the transgenes used are not known oncogenes. There are no immunizations or post-exposure prophylaxis recommended for this work other than supportive care in the event of an exposure.

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

06-50 (Dr. Kopp):

This protocol was very well written to cross-reference the collaboration between Dr. Kopp's group and Dr. Malyguine. The committee requested additional clarification regarding the types of cytokine assays to be performed on the "open bench" and a justification for the use of the chemical fume hood as opposed to a BSC regarding aerosol protection. The committee further requested a mock run of the procedures to be performed using riboflavin, and for there to be physical and temporal separation of work.

Dr. Crise made a motion to conditionally approve this protocol pending resolution of the two above noted items. Dr. Hollingshead seconded and all were in favor.

06-45 (Dr. Copeland):

The committee expressed some concern over the sera hazards and the unknown infectious nature of the material to be processed. There was also little information provided on the details for transport procedures to move the material between Bethesda and Frederick. The PI needs to provide specifics on courier transport and material packaging to transfer material between locations. Applicable SOP's pertinent to this work will also need to be included with the final registration document.

Dr. Crise made a motion to conditionally approve with clarification as noted above, Dr. Garfinkel seconded and all were in favor.

06-44 (Dr. Vistica):

This registration is incomplete and requires additional PI responses. A full committee review will be deferred until the June 2006 meeting.

Dr. Crise made a motion to defer until the June IBC meeting, Dr. Hollingshead seconded and all were in favor.

RENEWALS

06-48 (Dr. Hollingshead):

Dr. Creekmore approved this renewal off-line as the designated reviewer but wanted the committee to be made aware of the modifications to this protocol. Dr. Hollingshead explained the changes and updated the IBC on the status of the facility renovations to Building 1023 to accommodate the virus challenge portion of this work. A panic bar exit door has been put in place of the previously existing crash door.

Dr. Creekmore approved this renewal as lead reviewer.

AMENDMENTS

06-32 (Dr. Hartley):

This amendment involves the use of less than 2/3 of the genome and Baculovirus. There are no mammalian genes involved and baculovirus is not likely to infect human cells.

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

06-20 (Dr. Crise):

This amendment requests a modification to permit the use of sharps in combination with infectious material and CsCl gradients. The amendment has been passed to Dr. Stephen Hughes as the lead reviewer and the IBC is awaiting Dr. Hughes' guidance.

OUTSTANDING ITEMS

06-27, 06-23, and 06-22 (Dr. Sei) – PI to address IBC questions.

06-01 (Dr. Poon) - PI to address IBC questions

05-29 (Dr. Rane) – On hold.

06-35 (Dr. Fisher) – PI to address questions.

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

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

06-15 (Dr. Tarr) - PI to address IBC questions

06-16 (Dr. Acharya) - PI to address IBC questions

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

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

06-41 (Dr. Gildersleeve) – PI to address questions

OTHER BUSINESS

The Bloodborne pathogen update reported 94% compliance in the program. Ms. Duley and Ms. Leitch will be diligent in continuing to contact non-compliant personnel to complete their training as soon as possible.

During the meeting Dr. Hollingshead raised some concern over the issue of Bovine Spongiform Encephalopathy risks in association with the use of Bovine Pituitary Extract. A protocol was received by the Animal Care and Use Committee involving these hazards. The IBC will also be asked to review and evaluate the risks associated with this research. A request was made to determine if this material has ever been received here at this campus before and if so, are there procedures already in place or will this be a new process.

There was an update to the committee on the new form to expedite breeding for knockout and/or transgenic mice. A rough draft of the form will be presented to the IBC at the June meeting for review.

Policy & Procedure #604, recently reviewed by the IBC to cover work with infectious material at the NCI was approved.

Two IBC members requested receipt of monthly IBC meeting materials via electronic copies. A web address has been developed so IBC documents may be posted electronically for review by IBC members without making unnecessary paper copies. We will try to provide electronic copies for those interested for the June 2006 meeting.

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