



**NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes – November 15, 2005
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:05 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. Michael Baseler
Dr. Stephen Creekmore

Ms. Alberta Peugeot
Ms. Theresa Duley, Secretary
Dr. David Garfinkel
Dr. Dan McVicar

Members not in attendance: Dr. Paul Nisson, Dr. Bruce Crise, Dr. Stephen Hughes, Dr. Jeanne Herring, Dr. Melinda Hollingshead

Others in attendance: Ms. Cara Leitch

INTRODUCTION

Dr. Morin called the meeting to order. Dr. Morin requested that the IBC members review the October meeting minutes and to email any comments to Ms. Duley or Ms. Leitch. A vote for October meeting minutes approval will be taken by email.

The Committee also reviewed a final draft of the proposed IBC policies regarding Validation and Screening. It was stated that clinical samples should be the noted exception with regard to these policies, provided there is no informed consent signed by the donor providing the clinical specimen. A full committee vote was taken and the Validation and Screening policies were approved with modifications as discussed. A final revised document of these two policies will be posted to the IBC webpage.

The IBC Coordinator had not obtained a quorum vote on the September minutes prior to this meeting, so comments were requested. No modifications were recommended, and the September meeting minutes were approved as written.

PROTOCOL REVIEWS

NEW BUSINESS

05-39, 05-39 Amendment; and 05-40 (Dr. Green) - Approved

The lead reviewer introduced these two submissions, noting that the systems being used in the studies are safe and well practiced. At this time, the lead reviewer also discussed the Amendment submitted for 05-39, received after the original submission of 05-39, but before it's initial approval. The importance of obtaining all signatures and a complete SOP from the animal facility manager prior to initiating work was reiterated. Approval was recommended.

Dr. Morin made a motion to approve, all were in favor.

05-54 (Dr. Green/Dr. Hatfield) - Approved

The lead reviewer stated that there are only small portions of virus being used in this study 05-54, posing minimal hazards. A member of the committee noted that the person preparing the documents did a good job of summarizing the study in "lay language".

Dr. Morin made a motion to approve the protocol as written, Dr. Garfinkel seconded, and all were in favor.

05-48 (Dr. Anderson) - Approved

The IBC was updated on the status of Dr. Anderson's registration 05-48. This registration was conditionally approved at the October IBC meeting. Dr. Anderson provided the requested cell line screening information and all outstanding items were resolved.

Dr. Morin made a motion to approve as written, Dr. McVicar seconded and all were in favor.

AMENDMENTS

P150205SSA01 (Dr. Sei) - Approved

This proposed amendment explained that the lab would simply be using a different strain of virus. The lab has been previously approved for work involving vaccinia, and the necessary individuals have been immunized. SOP's to restrict work area and personnel involved with this work are also applicable. It was further requested that those not willing or medically able to take the vaccinia immunization should sign a declination statement for documentation in their medical records with OHS. The IBC should also document which individuals have been immunized and are cleared for working with this virus. This has already been done.

Dr. Morin made a motion to approve as written, Dr. McVicar seconded and all were in favor.

05-41 (Dr. Gamero) - Approval Deferred

The lead reviewer for this amendment incurred a short notice schedule change and was unable to attend the meeting. One member stated they didn't think the amendment had anything to do with the original registration. The discussion on the amendment was deferred until feedback from the lead reviewer could be obtained.

T240304AHA01 (Dr. Hurwitz) - Approval Deferred

This work involves a strain of E. coli, which is a potential human pathogen. Questions were raised regarding the potential for passing this or other pathogens along to mice, in addition to the potential for human hazards associated with possible repercussions of this proposed work. Micro isolator caging systems will be used to house affected animals, animal care staff will be properly trained with accurate documentation, and the IBC will need to further review this proposed registration in conjunction with the Animal Study Proposal. Upon further review, the determination will be made if an amendment is sufficient to accommodate the proposed modifications in this work.

Dr. Garfinkel made a motion to defer approval, all were in favor.

RENEWALS

None

OUTSTANDING ITEMS

05-29 (Dr. Rane) - On hold.

05-52 (Dr. Michiel/Dr. Stoughton) – Approval pending additional PI responses and/or transfer of research to another PI.

05-38 (Dr. Stewart) – PI to answer designated review questions.

Pathogen (Dr. Wang) – Waiting for PI responses-out of the country.

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

Pathogen (Dr. Yoshimura) – Waiting for PI responses.

OTHER BUSINESS

- 1) Ms. Cara Leitch provided an update on the compliance status of the Bloodborne Pathogen Training Program. The IBC members offered up assistance and support in encouraging compliance in the research environment and suggested using different, more direct methods to contact non-compliant employees, and include their supervisors in the initial notification. Also, the IBC recommended shorter windows of time between notifications and after 60 days of non-compliance, the IBC Chair and EHS Director should become involved to help support compliance efforts.
- 2) The committee discussed the Highly Pathogen Avian Influenza and Dr. Morin mentioned the idea of potential future studies on clinical samples coming to the NCI-Frederick campus. It was determined that there are limited facilities that could possibly accommodate this work, but that no projects are slated for initiation at the present time.
- 3) Ms. Duley and Ms. Leitch stated they continue to work on updating the Policy and Procedure #604 to include all pathogenic material used at the NCI, to eliminate the restrictions of the document to only HIV work.

The meeting was adjourned at 1:25 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. Wiltrout
Dr. Reynolds
Mr. Eaton
Dr. Arthur
Mr. Bufter
Dr. Keimig