



**NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes – April 19, 2005
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:06 p.m. in the Building 549 Executive Boardroom with the following members in attendance:

Dr. Randall Morin, Chair
Dr. Jeanne Herring
Dr. Bruce Crise
Dr. Henry Hearn
Ms. Theresa Duley

Dr. David Garfinkel
Ms. Carol Ingraham Tobias
Dr. Stephen Hughes
Mr. Lucien Winegar, Esq
Dr. Daniel McVicar

Members not in attendance: Dr. Michael Baseler, Dr. Melinda Hollingshead, Dr. Stephen Creekmore, Dr. Paul Nisson (ex-officio)

Others in attendance: Dr. Scott Keimig, Dr. Lionel Feigenbaum, Dr. Daniel Stoughton, Dr. Dennis Michiel, and Ms. Cara Leitch

INTRODUCTION

Dr. Morin called the meeting to order. Dr. Morin officially welcomed Dr. McVicar as a new IBC Member by casting a vote. All were in favor.

The March IBC minutes were approved with no changes.

OUTSTANDING ITEMS

05-18 (Dr. Awasthi and Dr. Feigenbaum) - Approved

Dr. Feigenbaum addressed the IBC in response to the questions posed during the March IBC meeting.

Ms. Duley made a motion to approve 05-18, all committee members were in favor, and 05-18 was approved.

05-10 (Dr. Schmidt) – Approval Pending Sequencing

05-03 (Dr. Young) – Approval Pending PI Response

NEW BUSINESS

PROTOCOL REVIEWS

05-31 and New Pathogen Registration (Dr. Michiel/Dr. Stoughton) – Approved Pending Modifications:

- 1) Consider using bleach to decon waste products rather than NaOH.
- 2) Show that potentially infectious DNA is not longer infectious.
- 3) BSO will identify any mixed waste issues.
- 4) Perform a dry run with riboflavin before using virus.

Dr. Crise made a motion to approve 05-31 and the Pathogen Registration, Ms. Duley seconded, all committee members were in favor, and both registrations were approved with noted modifications.

05-28 (Dr. Yeh) – Approved

Dr. Crise made a motion to approve 05-28, all committee members were in favor, and 05-28 was approved.

05-29 (Dr. Rane) – Approval Pending

- 1) Confirm that no virus is being used.
- 2) Define the transgene.
- 3) Further define the nature of the mouse knock out, and differentiate the knock out and the transgene.
- 3) Confirm scope of work to be performed in Frederick.
- 4) Further define the promoter for the overexpressor used in the recombinant sequences.
- 5) Further define the experimental variations of the two strains indicated.

05-27 (Dr. Perry) - Approved

It was noted there is a need for IACUC permission to perform the work. It was also noted that some of the responses in the IBC protocol and the ASP did not match.

Dr. Hughes made a motion to approve 05-27, with pending ACUC permission and ASP modifications, all committee members were in favor, and 05-27 was approved.

05-22 (Dr. Anderson) – Approval Pending

- 1) Clarify the new strains to be created.
- 2) Be more explicit with the methods to be implemented with the new strains.
- 3) Some of the responses in the ACUC ASP and the IBC protocol do not match. Please clarify.

05-09 (Dr. Waugh) – Approved

Dr. Hughes made a motion to approve 05-09, all committee members were in favor, and 05-09 was approved.

AMENDMENTS

04-20 (Dr. Young) – Approval Pending further committee review of PI responses.

04-03 (Dr. Schmidt) – Approval Pending committee review of PI responses to questions.

Amendment of multiple registrations (Mr. Broadt) – Resubmit protocols to IBC for review.

- 1) Develop a stand-alone protocol reflecting PI in charge of the research.
- 2) Clearly state the use of non-infectious forms of DNA and less than two thirds of the genome.
- 3) Specify RNA work with Hepatitis C.

P150403DPA01 (Dr. Harris) – Approved by designated reviewer Dr. Crise on 4/18/05.

Amendment of multiple registrations (Dr. Poiley-Nelson) – Resubmit protocols to IBC for review.

- 1) Develop a stand-alone protocol reflecting PI in charge of the research.
- 2) Clarify measles vaccination requirements and associated laboratory safety practices and procedures.

RENEWALS

05-13 (Dr. Waugh) – Review deferred to May meeting.

05-12 (Dr. Waugh) – Review deferred to May meeting.

05-11 (Dr. Waugh) – Review deferred to May meeting

P301193NCA03 (Dr. Colburn) – Approved by designated reviewer Ms. Tobias on 4/18/05.

05-24 (Dr. Colburn) – Approved by designated reviewer Ms. Tobias on 4/18/05.

05-25 (Dr. Colburn) – Approved by designated reviewer Ms. Tobias on 4/18/05.

05-23 (Dr. Colburn) – Approved by designated reviewer Ms. Tobias on 4/18/05.

05-21 (Dr. Wang) – Approved by designated reviewer Dr. Hollingshead on 4/15/05.

P150102TIA02 (Dr. Imamichi) – Approved by designated reviewer Dr. Garfinkel on 4/19/05.

P150102TIB02 (Dr. Imamichi) – Approved by designated reviewer Dr. Garfinkel on 4/19/05.

P300697NBB02 (Dr. Bhat) – Approved by designated reviewer Dr. Crise on 4/18/05.

05-26 (Dr. Ruscetti) – Approval pending committee review of PI responses to questions.

05-20 (Dr. Wang) - Approved by designated reviewers Drs. Hollingshead on 4/22/05.

OTHER BUSINESS:

DEADLINES

The committee voted to review only protocol submissions received by the IBC Administrator no later than the second Monday of the month prior to that month's meeting. All protocols received after this 8 day deadline will be reviewed at the following month's meeting.

DRAFT IBC FORMS

Comments were collected from participating IBC members, and a draft form will be posted for applicant use on or about the May IBC meeting.

DRAFT VACCINATION POLICY

Comments were collected from participating IBC members, and a decision on the need for a vaccination policy will be discussed at the May meeting.

ANIMAL STUDY PROPOSALS AND TECHNICAL REVIEW SUBCOMMITTEE DRAFT

Comments are being collected from participating IBC members, and a vote on this subject matter will be taken at the May meeting.

The meeting was adjourned at 2:08 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. Buffer
Dr. Keimig