



**NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes
August 15, 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:

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|------------------------------|--------------------------|
| Dr. Randall Morin | Dr. Michael Baseler |
| Ms. Theresa Duley, Secretary | Dr. Melinda Hollingshead |
| Dr. Henry Hearn | Dr. Bruce Crise |
| Dr. Stephen Creekmore | Ms. Alberta Peugeot |
| Dr. Paul Nisson | Dr. David Garfinkel |

Members not in attendance: Dr. Dan McVicar, Mr. Lucien Winegar, Dr. Jeanne Herring, Dr. Stephen Hughes

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

INTRODUCTION

Dr. Morin called the meeting to order.

Dr. Morin requested a vote be taken for final approval of the June 2006 meeting minutes. All members were in favor of approving the June minutes as written.

PROTOCOL REVIEWS

NEW BUSINESS

06-74 (Horak):

There were no additional comments on this registration.

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

06-55 (Dr. Green):

Ms. Duley reviewed comments from the Lead Reviewer since they were unable to attend the meeting.

- The client (University of MO) does all the MAP testing.
- No material will be transferred from Building 41 (NIH) to NCI-Frederick without MAP testing and appropriate results accompanying the material (the MAP testing is the responsibility of the PI in conjunction with the ACUC).
- No specific SOP is attached.
- Are there any concerns regarding post-exposure prophylaxis?
- There is little chance of emergence of virus, since there are no cells shedding virus due to the deletion in the HIV genome. Only cell lines will be handled in this research. Where does our jurisdiction lie?
- Are there HIV glycoproteins present in the lab where the work with HIV-1 and HIV-2 will occur?
- B5d: thymidine kinase hazards need to be addressed.
- B5k: the response to address potential aerosols is sufficient.
- B6a: mitigation measures are correct. An entire piece is missing from the transfection.
- E10: Clarify what material is actually coming to NCI-Frederick, and what will be done with it. The materials and procedures pertinent only to NIH need not be included in this registration. Provide the validation method used to verify the piece of information missing from the transfection.

Dr. Crise made a motion to defer approval, Dr. Creekmore seconded and all were in favor.

06-56 (Dr. Green):

- The MAP test does not test for MMTV.
- The LTR MMTV is only used at NCI-Frederick, and there is no virus present.
- Clarify that the mice are made at NCI-Frederick and then moved to NIH.
- Verify the employees working on the Frederick research activities so medical surveillance issues may be properly addressed.
- D8: Is this work done at NIH or at NCI-Frederick?

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

06-71 (Dr. Green):

- Provide clarification of what the replication defective material is and why it is replication defective.

Dr. Crise made a motion to approve pending receipt of a sufficient response to the question noted above, Dr. Hollingshead seconded and all were in favor.

06-72 (Dr. Dimitrov):

- D3 should be changed to “Yes”
- D5: MCF 7 cells from the DCTD Tumor Repository have been screened for human pathogens by LMT’s PCR assays as well as by MAP testing for rodent pathogens.
- The PI needs to sign the registration.

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

06-77 (Dr. LeGrice):

- Provide a statement that there will be no resheathing of needles. The only exception would be a one-handed recapping method.

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

06-78 (Dr. Rogers):

- Clarify the sharps safety question under Item A4a.

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

RENEWALS

06-76 (Dr. Hughes):

- This laboratory has expensive expertise with viral propagation, vector design, and rDNA techniques. This renewal outline 28 projects and their associated risks. Several projects have risks that have yet to be fully defined.
- Project 12: New ENV genes (that are not of avian origin) cloned into ALV vectors may expand the tropism or pathogenecity of the virus. This should be carefully considered before introduction of the new viruses in vivo.
- Project 15: New ENV genes will be cloned into HIV-1. As described, this work will be limited to ENV genes that don’t support replication in human cells. ENV genes with potential for replication in human cells should require further IBC review.
- Project 27: The laboratory will start using adenoviral vector derived materials. Adenoviruses are considerably more stable in the environment than retroviruses. Additionally, different means to decontaminant adenoviruses than retroviruses may be required. This should be considered by the lab staff using adenovirus vector material.
- Project 28: Cloning of the Ebola Gp gene into the RCAS system will disable one of the two biological controls of the system. Special care should be exercised when using RCAS-Ebola/Gp recombinants.

- Post Exposure Prophylaxis is recommended for some of these projects. These should be addressed within OHS.

Dr. Crise made a motion to approved pending response to the statements above, Dr. Garfinkel seconded and all were in favor.

06-70 (Dr. Wiltrout):

- Describe what and how the work is conducted with the mice and the virus.
- What will be done with pox virus?
- A3 and the reference to chicken pox is confusing. Clarify the relevance of the chicken pox virus in relation to vaccinia virus.
- B2b: 293 human cell lines are referenced. If passages are done with these cells it may be possible to get hot virus back. Are volume and passage limits established?
- Is there a certification for the virus material to be used?
- Minimal vector information is provided.
- How will materials be physically and temporally separated?
- No unnecessary vaccines should be given to personnel. No boosters and no chicken pox vaccination should be required.
- Address any variations in strains.
- Reconsider the experimental design so the objectives and goals of the research are more clear.

Dr. Creekmore made a motion to defer approval, Ms. Duley seconded and all were in favor.

AMENDMENTS

05-41 (Dr. Gamero):

No further items were discussed regarding this amendment.

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

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.

06-16 (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

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

06-69 (formerly 06-41) (Dr. Gildersleeve) – PI to address questions

06-49 (Dr. Young) – PI to address questions

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

06-52, 06-62, 06-63, 06-64 (Dr. Melillo) – PI to address questions

OTHER BUSINESS

The P&P 604 title was changed to remove the word “acquisition” so the P&P would not be incorrectly associated with the Acquisition and Logistical Services Department. The new title of P&P 604 is *Research Material Handling and Use Policy*.

Confidential Disclosure Agreements must be signed by all community members and other attendants who participate in the IBC meetings.

The IBC Charter is due for the annual update and submission to the Office of Biotechnology Activities in October 2006.

The IBC was approached by a researcher to perform work with oligonucleotides and zebrafish. It was determined that a registration document is not needed at the present time.

The Bloodborne pathogen program is currently 97.5 % compliant. Drs. Crise and Morin will assist the biosafety staff with tracking non-compliant personnel within the training program for both SAIC and the NCI, respectively. Ms. Duley and Ms. Leitch will be diligent in continuing to contact non-compliant personnel to complete their training as soon as possible.

The IBC continues to receive comments on the proposed IBC short form for breeding activities. There is some redundancy between IBC and ACUC forms simply because the pertinent details must be addressed separately in each individual document for purposes of compliance and clarity.

All new work will require a full committee review, even if approval is recommended by the lead reviewer(s) prior to the meeting.

With the new paperless system in place and in use, the IBC coordinator will continue to use the secure IBC website to post IBC registrations. Lead reviewers will continue to receive a hard copy for all registrations requiring review.

Registrations will be posted separate from Animal Study Proposals and other related attachments on the website to ease the review process for larger documents.

The Material Transfer Agreement question is being reviewed by the Technology Transfer Branch and will be revised to identify and protect confidential material.

The meeting was adjourned at 2:10 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