



**NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes March 22, 2006, 2006
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:03 p.m. in the Building 549 Executive Board Room with the following members in attendance:

Dr. Randall Morin, Chair
Dr. Henry Hearn
Dr. David Garfinkel
Dr. Michael Baseler
Dr. Bruce Crise

Ms. Alberta Peugeot
Ms. Theresa Duley, Secretary
Dr. Paul Nisson
Dr. Stephen Hughes
Dr. Stephen Creekmore

Members not in attendance: Dr. Melinda Hollingshead, Dr. Dan McVicar, Mr. Lucien Winegar, and Dr. Jeanne Herring

Others in attendance: Ms. Cara Leitch, Dr. Scott Keimig, Dr. Jianwei Zhu, Dr. Vinay Vyas, Dr. Yueqing Xie, Mr. Andrew Burnette, Dr. Barry O'Keefe, and Dr. Jim McMahan.

INTRODUCTION

Dr. Morin called the meeting to order.

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

Dr. Morin asked for a final vote on the Policy and Procedure #604 so this document could be forwarded to the government for further review. The committee was in favor of approving the document as written.

PROTOCOL REVIEWS

NEW BUSINESS

06-09 (Dr. Tessarollo):

The significant hazard present within this registration request involves the handling of mice. It was noted that there is a portion of text missing from the SOP#1.003 on pages 1 and 2. Signatures are still needed for final approval.

Dr. Creekmore made a motion to approve with the above noted minor modifications, Dr. Crise seconded and all were in favor.

06-17 Dr. Thorgeirsson:

This proposal is complete as written and only requires appropriate signatures for final approval. Dr. Creekmore made a motion to approve the registration, Dr. Hughes seconded and all were in favor.

06-27 (Dr. Sei):

The committee requested the following modifications:

- 1) Define the methods of physical and temporal separation to ensure safety in work practices and procedures and how all potentially hazardous materials will be kept separated to avoid the possibility of cross-contamination. Please clarify a statement reflecting the manipulation methods to be used. On the second page of the memo where it states "assigned separate BSC whenever possible"- assure the IBC with a statement that the materials in the lab will be kept separate at all times and how that will be done.
- 2) Please clarify in a statement the methods for transport of hazardous materials on campus. Item A2: Transport from BDP to 431 is not clear and consistent with response in item A6 where a "NO" is indicated. Indicate containers to be used to transport material safely across campus since transport will be occurring.
- 3) B5 is "YES" but B6 is "NO"-this is not correct. Human material (i.e.- hepatocytes) should be noted here and throughout the document, since they are also considered to be biohazardous material (noted in A2). Please answer B6a-B6c as applicable.
- 4) Item B9-what safety practices are put in place to address the enhanced tropism and please identify any information known with respect to these enhanced tropisms.
- 5) Clarify in a statement the precise experiments to be performed and the procedures and practices associated with each experiment protocol. How will the toxicity in the hepatocytes be measured?
- 6) Verify this work is only a cell toxicity assay and that there will be no growth of material. Specify the volumes to be used as well.

Dr, Hughes made a motion to defer approval pending receipt of modifications, Dr. Crise seconded and all were in favor.

06-29, 06-25, 06-26 (Dr. Zhu):

Please provide a summary statement to address the following concerns:

- 1) Further define the actual procedures to be used.
- 2) Centrifugation and lysis can create aerosols, how will the potential for aerosolization be mitigated? Please document methods.
- 3) Confirm the 100ug/ml dilution will take place in a closed container.
- 4) Give a brief description of how the work will be contained. The email response provided prior to the meeting is acceptable but please attach to registration documents and SOP's.
- 5) How will personal contact with material be avoided, what personal protective equipment will be worn?
- 6) Clarify that no large-scale work will be conducted under this registration submittal.
- 7) Please provide a flow chart to document procedures to be used.
- 8) Define disinfectants to be used and if they are verified to be efficacious against the infectious agents in use.
- 9) 80L of viable HA-22 virus can be used at one time
- 10) EHS will schedule a lab inspection prior to approval of your protocol.

Pending receipt of a statement to address the remaining issues outlined above, Dr. Hughes made a motion for conditional approval, Dr. Crise seconded and all were in favor. Dr. Creekmore abstained from the vote.

06-24 (Dr. Pinto):

The committee requested the following clarification:

- 1) Clarify how the cholera toxin in a powder form will be reconstituted. To avoid the potential for aerosolization of the powder, reconstitution should take place in a closed system via septum in a Biological Safety Cabinet. This process should also be clarified and referenced in the applicable SOP.

Dr. Crise made a motion to approve the research protocol pending receipt of the statement of assurance regarding reconstitution of the cholera toxin powder. Dr. Hughes seconded and all were in favor.

06-28 (Dr. McMahon):

The following points were noted as needing further clarification.

- 1) The paperwork currently reflects inconsistent information to effectively describe the material to be manipulated as heat-killed, attenuated, or live virus. Please clarify the exact nature of the material to be shipped.
- 2) Specify methods used by shipper to inactivate live or attenuated virus. Obtaining an SOP from the shipper is also requested. Boiling of virus should be done with a complete immersion boiling bath for a duration of at least 60 minutes, to ensure any potentially contaminated material in the threads of the container are also killed.
- 3) Describe validation assay used by the shipper to verify material to be shipped is in fact inactivated prior to shipment. The committee would recommend and request the shipper provide documentation of methods prior to shipment. The shipper should assure that the readout methods are sufficient to provide reliable data and relative assurance of the inactivity of the material.
- 4) The Biological Safety Officer (BSO) at the NCI-Frederick will work with the shipper's BSO to verify paperwork and assure that the shipment is acceptable and in compliance with all applicable regulatory requirements.
- 5) The shipper is responsible for shipping the material as a diagnostic specimen per DOT and IATA requirements.
- 6) The IBC recommended that the consignee Dr. O'Keefe, upon receipt of the material, boil the material again for a determined amount of time to ensure the material received is in fact rendered inactive.
- 7) Please clarify the nomenclature for the specific samples to be shipped. As they are written now they are incomplete.
- 8) Verify if an MTA (Material Transfer Agreement) is needed to transfer this material.
- 9) Clarify what you will not be doing with this material (i.e.-no working with cultures and no growing of virus, etc)
- 10) If the material will be received killed or inactivated, and the material is to be boiled again upon arrival, BSL2 containment facilities are sufficient for handling material. Provide the rationale for this downgrade in containment level based on the viability (or lack thereof) of the material, once the material has been received and boiled. Please provide a revised SOP to reflect all of these noted changes in procedures.
- 11) Clarify that once material received has been boiled again, gels and blots and other procedures do not need to be performed in a BSC, since at this point the material has been verified killed and only work with the protein will be conducted.
- 12) For all future work varying from this current protocol, an amendment to the IBC for review will be required.
- 13) OHS recommended a flu immunization.

Dr. Baseler made a motion to defer approval pending modifications noted above and obtaining all necessary permits and documents for transport. Dr. Crise seconded and all were in favor.

06-04 (Dr. Chatterjee):

The committee requested the following two clarifications be made for approval.

- 1) Verify what genes exactly will be cloned and how this may or may not related to the on-going E.coli work.
- 2) Clearly state that there will not be any pathogenic or toxic material produced as a result of this work.

Dr. Garfinkel made a motion for conditional approval pending sufficient responses to the items above, Dr. Crise seconded and all were in favor.

06-18 (Dr. Malyguine):

The committee requested the following additional information prior to final approval:

- 1) Because it is difficult to keep AAV separate from Adenovirus, please further clarify how the AAV will be handled to avoid any potential for cross-contamination with other lab materials.
- 2) The committee recommended treating the lab as if it contains Adenovirus for extra safety precautions.
- 3) EHS will provide those working on this registration with AAV and Adenovirus specific training prior to initiation of work. EHS will work with IBC members and BDP staff to assist with this training effort.
- 4) Ensure that the hazards pertinent to handling macaque materials are recognized and addressed in the SOP.

Ms. Duley made a motion to conditionally approve this registration and pending receipt of these final requests and EHS inspecting the laboratory facilities, a full committee vote will be obtained by email. Dr. Crise seconded and all were in favor.

RENEWALS

06-22 and 06-23 (Dr. Sei):

The committee requested the following clarification:

- 1) Please clarify that the viruses have temporal and physical separation at all times to include storage, culturing, and all other manipulation procedures to prevent cross-contamination.

Ms. Duley made a motion to conditionally approve these two registrations pending receipt of a sufficient summary statement to address the above noted concerns. Dr. Crise seconded and all were in favor.

AMENDMENTS

None.

OUTSTANDING ITEMS

05-29 (Dr. Rane) – On hold.

05-52 (Dr. Xie) – April IBC meeting.

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

06-01 and 06-02 (Dr. Poon) - PI to address IBC questions.

05-60 (Dr. Kopp) - PI to provide additional information.

06-18 (Dr. Malyguine) – March IBC

OTHER BUSINESS

An update on the compliance status of the Bloodborne Pathogen Training Program was given by Ms. Cara Leitch. The compliance status has increased to 98%.

The meeting was adjourned at 2:45 pm.

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. Butfer
Dr. Keimig