



**NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes
July 18, 2006
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:11 p.m. in the Building 549 Executive Board Room with the following members in attendance:

Dr. Randall Morin
Ms. Theresa Duley, Secretary
Dr. Henry Hearn
Dr. Stephen Creekmore
Dr. Stephen Hughes

Dr. Michael Baseler
Dr. Jeanne Herring
Dr. Bruce Crise
Ms. Alberta Peugeot
Dr. Paul Nisson

Members not in attendance: Dr. Dan McVicar, Mr. Lucien Winegar, Dr. Melinda Hollingshead, Dr. David Garfinkel

Others in attendance: Ms. Cara Leitch, Dr. Frank Maldarelli, Dr. Robert Thomas

INTRODUCTION

Dr. Morin called the meeting to order.

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

A vote will be obtained through email following distribution of the June minutes after today's meeting.

Ms. Alberta Peugeot, Manager, Occupational Health Services (OHS) introduced two guests attending today's meeting: Dr. Frank Maldarelli from the NIH, Bethesda, and Dr. Robert Thomas, the OHS Physician on staff.

The meeting opened with a discussion on Post-Exposure Prophylaxis (PEP) for those individuals working with lentiviral and retroviral vectors, among other significant unknown hazards at the National Cancer Institute-Frederick.

Additional administrative functions such as identifying an on-call individual tasked with responding around the clock are being considered.

A list of all potential vectors in use for research purposes at the NCI was requested so that “dedicated” PEP’s can be recommended specific to the individuals and the hazards of their research. Recommendations from the Centers for Disease Control and Prevention although generic and limited to more common laboratory exposures such as HIV and HBV exposures, should still be deferred to as the guideline to follow.

Questions included the necessity of keeping drugs on hand within the OHS clinic to be prepared to treat a potentially exposed or exposed individual within the shortest time possible following the incident, ideally within a two-hour timeframe. Another question asked was where does the patient go for treatment and follow-up after the exposure occurs, Frederick Memorial Hospital or Shady Grove, which would be dependent upon who would be the attending physician for the individual.

Ideally when protocols come to the IBC for review, a PEP should be considered and if necessary, identified and discussed at the time the registration is considered for approval.

Ms. Peugeot will form a sub-committee to include Drs. Maldarelli and Thomas among others to determine a path forward on this issue. A protocol may be developed to outline the procedures once a local standard of practice has been established. Ms. Peugeot will update the IBC as more information becomes available.

PROTOCOL REVIEWS

NEW BUSINESS

06-41 and 06-42 (Dr. Fisher):

- The remaining issues include more detail on how the virus was inactivated and what quality control procedures are in place to ensure that the material is in fact inactivated and how that may be validated.
- The SOP established for this work is good
- A Biosafety Cabinet will be borrowed from another laboratory
- Separation of work and people is an issue—PI will need to ensure that others working in the lab are not unnecessarily exposed to hazards and work will need to be limited to the BSC to avoid the potential for cross-contamination.
- The IBC will work with Dr. Fisher to assist him in obtaining a BSC dedicated to his lab for his research purposes. This will be a requirement for Dr. Fisher’s lab should he decide to work with additional viruses or if this work transitions to more long-term projects.

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

06-36 (Dr. Schneider):

- There are still some minor items to address in this registration.
- The response to the IBC's question for C8 is for a working volume of 1.5 ml and a max volume of 10 ml. These changes were reflected in C8, however, C11 still states that 0.1-2 L will be cultured. Should this change also?
- C13 - Will a chemical fume hood be used in this project, or is it just checked off because it is available?
- C12 - Is the centrifuge a containment centrifuge? In the SOP, it states that the rotor will be loaded in a BSC, but most importantly, will it be unloaded in the BSC after the run? After centrifugation, the IBC strongly recommends waiting until potential aerosols have settled prior to opening the centrifuge lid and removing the rotor. If checking for spills, it should be done in a BSC.
- What volume of bleach is added to acquire the 1:10 dilution for treatment of the liquid waste?

Dr. Crise made a motion to conditionally approve this protocol pending the final modifications requested above. Defer approval on both protocols. Dr. Creekmore seconded and all were in favor.

06-37 (Dr. Schneider):

- A more extensive and relevant SOP was provided, however specific safety precautions for working with influenza should be addressed.
- Please address how immunocompromised individuals will be handled with respect to working with influenza.
- The registration is still unclear on the intent of the work and what manipulations occur.
- Is it possible to work with a strain of influenza that the staff is already immunized to?
- PR8 - how much protection is there?

Approval deferred. Ms. Duley made a motion to defer approval pending receipt and further review of requested modifications. Dr. Crise seconded and all were in favor.

06-52 (Dr. Melillo):

All issues on this protocol have been resolved with the exception of the PI responding to previously submitted questions from the committee and the IBC coordinator.

06-64 (Dr. Melillo):

- IBC questions and comments previously submitted have not been addressed.

- A3 - should mention that the lentiviral vector material should be dealt with as if it is hazardous via aerosolization; how will aerosols be minimized and will the centrifugation process be contained?
- B5d - provide assurance that the lentiviral vector cannot be mobilized once established as a provirus, explain why this is not possible.
- There are potential hazards with shRNA since they are non-immunogenic. Describe what the hazards are and how they are mitigated.
- There are hazards with centrifuging, pipetting, and aerosols, PI to address mitigation measures.
- Address the expanded tropism issues with VSVg.

06-62 (Dr. Melillo):

- IBC questions and comments previously submitted have not been addressed
- Further describe the details of transport issues in Question A6.
- Describe the potential hazards with primate cells and how those hazards are being addressed.
- One of the committee members was surprised to hear of this work. Is this research in the proposal stages, or are those employees proposed to perform this work knowledgeable regarding the details?

06-63 (Dr. Melillo):

- Classify and type the genes proposed for use, in addition to the inventory list already provided.
- Clarify A1
- Describe the interactions between the lentiviral vectors possibly mixing and matching to form oncogenes, how this may happen and why. What will be done to avoid hazards possibly caused by this condition?
- How do the 4 separate protocols intersect (if at all)?
- Where will the samples originate from, are these samples from cancer patients, have the patients or their samples been pre-screened, and how will the samples be transported to NCI-Frederick?

Dr. Baseler made a motion for the following protocols 06-52, 06-64, 06-62, and 06-63 to be deferred approval until the above items can be resolved. Dr. Crise seconded and all were in favor.

RENEWALS

06-65 (Dr. Reilly):

The committee decided they will accept safety grams as documentation of safe laboratory practices used, provided safety mitigation measures are also integrated into the registration document as applicable.

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

AMENDMENTS

06-29 (Dr. Zhu):

This was a very well written registration. Decontamination and risk mitigation was sufficiently addressed, and there are only active cytokines, no active toxins involved in this work.

Dr. Crise made a motion to approve as written, Dr. Baseler seconded and all were in favor. Dr. Creekmore abstained from the vote.

06-48 (Dr. Hollingshead):

Dr. Hollingshead verified how the cell line in question was made using a murine retrovirus construct.

Dr. Hughes made a motion to conditionally approve pending documentation of source material, Dr. Baseler 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

OTHER BUSINESS

The Bloodborne pathogen update reported 99% 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. Assistance from the IBC members was also offered during the meeting.

The IBC continues to receive comments on the proposed IBC short form for breeding activities.

The ACUC and IBC will collaborate activities such as meeting during the same week (ACUC on Thursday and IBC on Tuesday). Deadlines for registration receipt and consideration for the next monthly meeting will also be coordinated to be 3 weeks prior to the regularly scheduled meeting date. ASP approval will continue to require IBC approval first, when animals are involved in IBC registrations.

The concerns raised recently involving BSE were briefly discussed. The committee considered issuing a "report" on the present state of the BSE situation as an "FYI". A safety gram on BSE and/or a majordomo may be issued to inform the research community of the potential hazards involving BSE, prions in general, and to emphasize the importance of proper safety techniques when manipulating materials potentially contaminated with these hazards in the laboratory.

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