



**NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes April 18, 2006
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:05 p.m. in the Building 549 Executive Board Room with the following members in attendance:

Dr. Randall Morin, Chair	Ms. Alberta Peugeot
Dr. Henry Hearn	Ms. Theresa Duley, Secretary
Dr. David Garfinkel	Dr. Paul Nisson
Dr. Michael Baseler	Dr. Stephen Hughes
Dr. Bruce Crise	Dr. Stephen Creekmore
Dr. Melinda Hollingshead	Dr. Dan McVicar
Dr. Jeanne Herring	

Members not in attendance: Mr. Lucien Winegar

Others in attendance: Ms. Cara Leitch, Dr. Scott Keimig, Dr. Yueqing Xie

INTRODUCTION

Dr. Morin called the meeting to order.

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

PROTOCOL REVIEWS

NEW BUSINESS

05-52 (Dr. Xie):

This is a straightforward protocol with low volumes, proteins, no continuous flow centrifugation, no toxins and no oncogenes. Bleach as a disinfectant is acceptable.

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

06-34 (Dr. Parchment):

This is a very well written submittal involving risk mediated sample screening. There is appropriate containment for critical functions such as centrifugation. This proposal sets the standard for a well written, well documented, and complete registration submittal.

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

06-35 (Dr. Fisher):

The committee requested the following modifications:

1. A Biosafety Cabinet should be used for this work. There may be some BSCs available in surplus. What other engineering controls will be in place for lab safety purposes? If you need assistance with this, we can certainly help.
2. Question A6 should this be checked yes, since you will probably be retrieving samples from the repository? If Yes, please describe transport procedures (i.e., primary and secondary containers with absorbent material).
3. Please provide a more detailed SOP specifically addressing the safety procedures used in your laboratory (i.e., waste handling procedures, spill procedures, accident procedures, etc.)
4. Can you verify that the Biacore 2000 does not produce any aerosols? This should account for individual susceptibility and occupationally acquired infections (how these will be avoided). Popping a top on a tube can produce aerosols. All tubes should be opened in a BSC.
5. The IBC recommends wearing a faceshield instead of a mask and eyewear. The eyewear tends to fog up when worn with the mask.
6. Is there product or additive that may be introduced into the sample to kill the infectious material, but keep the antibodies prior to manipulating samples?
7. Will the P20 dilution buffer inactivate mycobacterium?
8. Can the samples be diluted and loaded in another area? We would recommend diluting samples and Biacore activities be performed in a plexiglass containment device?

9. Question D6 should be YES. Please answer the corresponding questions.

10. Is the area proposed for this work a shared area, potentially exposing others? Please verify training programs completed and proposed for those working in and around the work environment.

Dr. Baseler requested to defer approval until modifications are made as appropriate and approved through an email vote from the full committee, Dr. Crise seconded and all were in favor.

06-36 and 06-37 (Dr. Schneider):

1. Can you work with more benign material?

2. The registration only describes techniques used in the lab. What is the objective and goal of each project? It is unclear what the lab is proposing to do. Please specify in A1.

3. Please provide additional paperwork describing the source of the material (certification that the material received is in fact what the provider says it is). Question A2.

4. Question A3 should elaborate more on the hazards that are present in the lab (i.e. manipulations, aerosols, sharps, centrifugation, etc.)

5. Question A4 should include more detail as to what spill procedures are used, how medical waste is handled, etc. Also, please change the word "hood" to Biological Safety Cabinet (BSC). Please provide any SOP's applicable to laboratory practices, procedures and engineering controls.

6. Question A5a - please describe the training given to employees in the lab specific to their job functions. Also, the PI is not listed on the training list. The committee suggested that 1 hour of training is insufficient. A more detailed "apprenticeship" training program is necessary so that staff work their way up to demonstrating proficiency in new techniques. It is understood that this is primarily a chemistry lab expanding their capabilities to perform biological research.

7. Question A6 should probably be checked YES since two rooms are listed and material will be transported between the two rooms. The recommended procedure for transporting materials between buildings or rooms is to use primary and secondary containers with absorbent material, in case the material is dropped or primary containers are compromised.

8. Please provide the committee with additional information on the particular strains used in these studies.

9. The committee recommended a demonstration of techniques using riboflavin to demonstrate movements within the cabinets and potential for creating and spreading aerosolized materials.

10. A lab inspection will need to be conducted by the EHS office.

06-37 only

- Question #C12 - please describe the filtration method and explain how it will be done safely.

- Is there an attenuated strain or vaccination available for influenza?

- Please provide a more detailed description of how fluorescent microscopy is prepared and done.

06-36 only

- Question C6 - Verify that no toxins are produced.

- Question #C8 - With a concentration of 10^9 /mL with 100 mL volumes, this can be readily aerosolized. How will this be avoided? Please clarify volumes (up to 2L).

- Question #C12a - How will centrifugation steps be contained?

Dr. McVicar made a motion to defer approval on both protocols until the above items can be resolved. Dr Crise seconded and all were in favor.

06-39 (Dr. Kopp):

This protocol generated much discussion questioning the presence of vaccinia virus in the blood from clinical cancer patients who have been recently immunized with vaccinia virus. The committee posed the question as to the potential for virus to be circulating in the blood post-vaccination on days 14, 28 and 56 blood draws.

1. The IBC recommends vaccinia immunization for those employees identified as processing this clinical material.

2. It was mentioned that the Red Cross does not accept blood donations from persons who have received vaccinia vaccination within the last 8 weeks.

3. OHS and biosafety staff were tasked with contacting CDC to investigate the issues identified above and to determine a path forward for immunizing workers and identifying methods for temporal and physical separation of work.

Dr. Crise made a motion to conditionally approve this protocol pending resolution of the vaccination issue and other biological safety concerns. Dr. Herring seconded and all were in favor.

06-40 (Dr. Kopp):

This study deals with P24 and lentivirus.

1. For question A1, identify the impact of ½% NP-40 on the P24 assay and further clarify use of NP-40 and Tween 20 since this is result dependent.
2. At the top of page 2 of the registration form, clarify source material coming from “student intern” and how integrity of material to be received will be verified.

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

06-41 (Dr. Gildersleeve):

1. Please provide a copy of your standard operating procedures specific to safety precautions taken in your laboratory. This should include how medical waste is disposed of, disinfecting procedures, spill procedures, safe work practices with biological materials, etc.
2. Question A4b - please be specific as to how glassware and/or sharps are handled safely and disposed of.
3. A5a - Describe what training is provided to lab staff prior to working with potentially hazardous biological material.
4. Do you have a biological safety cabinet (BSC) for work with biological materials? If not, we can help you attain one either through surplus or perhaps using one in another area.

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

RENEWALS

None.

AMENDMENTS

None.

OUTSTANDING ITEMS

06-27, 06-23, and 06-22 (Dr. Sei) – PI to address IBC questions.

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

05-29 (Dr. Rane) – On hold.

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

06-15 (Dr. Tarr) - PI to address IBC questions

06-16 (Dr. Acharya) - PI to address IBC questions

06-11 and 06-12 (Dr. Moschel) - PI to address IBC questions

06-28 (Dr. McMahon) - PI to address IBC questions

OTHER BUSINESS

Dr. Morin discussed budget cuts and medical surveillance programs.

The meeting was adjourned at 1:50 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. Wiltrout
Dr. Reynolds
Mr. Eaton
Dr. Arthur
Mr. Bufter
Dr. Keimig