



**NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes
November 21, 2006
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:04 p.m. in the Building 549 Executive Board Room with the following members in attendance:

Ms. Theresa Duley, Secretary	Dr. Michael Baseler
Dr. Henry Hearn	Dr. Bruce Crise
Ms. Alberta Peugeot	Dr. Dan McVicar
Mr. Lucien Winegar	Ms. Dianna Boissey
Dr. Stephen Hughes	Dr. Stephen Creekmore
Dr. Jeanne Herring	

Members not in attendance: Dr. David Garfinkel, Dr. Randall Morin, Dr. Melinda Hollingshead

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

INTRODUCTION

Ms. Bell called the meeting to order.

Ms. Bell informed the committee that the October minutes would be distributed through email for review and comments, and a final vote on the October meeting minutes would be taken at the December IBC meeting.

PROTOCOL REVIEWS

NEW BUSINESS

06-96 (Dr. Xin Wei Wang):

- The ACUC approval is pending animal number justification.

- The responses from Dr. Yamashita need to be integrated into the registration document before further review.
- A3: The potential hazards with the cell lines must be addressed.
- A minimal SOP is necessary to address inherent safety and health risks associated with this protocol.

Dr. Crise made a motion to defer further review and approval until a completed coherent document was submitted, Mr. Winegar seconded and all were in favor.

RENEWALS

06-94 (Dr. Dimitrov):

- Overall this document needs much more detail about what is being done, by whom, and where.
- The lab designated as a BSL2* is only 300 square feet. This does not seem possible since this is such a small foot print for this level of containment.
- Rooms 211 and 211B have an ante-chamber, but the document mentions that 211A is a BSL2* lab. Clarification needed.
- The BSC is in 211B, not 211A as the document states.
- The SOP could be further defined and expanded to include more details as to the lab procedures and safety mitigation measures.
- The areas used are shared areas so how are members of other groups provided adequate protection?
- How is the work temporally and physically separated?
- Are there other pathogens present in the lab?
- Are there multiple strains of HIV, and is there a potential for recombination events to occur? We will need a list of strains.
- Is NHP material present? If yes, further description is needed.
- There is a lack of understanding in research goals and what is trying to be accomplished.
- The document indicates that the organism is being cultured in registration document. This is not what is actually occurring (Clarification needed that the concentration may be increased by a few logs during the process).
- Use of a lab coat instead of a tyvek is not acceptable for BSL2* work. The PPE identified does not appear adequate given the biocontainment requirements and nature of the infectious material.
- Further explanation is needed regarding the specific strain(s) of HIV to be used.
- Part D: blood components:
 - D4 says "NO" to clinical specimens. But these are clinical specimens correct?
 - Are patient isolates "hot" isolates? Please address risks associated with other hazards apparent in human blood such as HBV and HCV.
 - D7 says "NO" to infecting cell lines.

Is this true that cell lines are not infected intentionally but the cells are already infected with HIV?

- It appears PHA blasts are infected with HIV but it states that HIV is not cultured. Please clarify.
- The SOP states that caution should be used if sharps are used. There should be no sharps permitted in a BSL2* lab and with HIV use.
- There is a vaccinia SOP attached – the vaccinia work should be handled separately from the HIV work, as different procedures may apply.
- BSL2* requires waste to be autoclaved out - this is not possible with the current configuration of the laboratory space
- Recombination is possible between HIV and vaccinia, will this be an issue and how will this be avoided?
- How will there be temporal and physical separation between materials, activities, and people?
- The 2002 registration was not clear and is not a good template from which to develop this revised renewal registration.
- The spill procedures should be more specific (i.e.- HIV spill or exposure procedures, removal of clothing, emergency shower, etc).
- A lab visit was recommended by the committee, so a walk through with members of the IBC and EHS will be scheduled in the near future.

Dr. Baseler made a motion to defer approval, requesting that new paperwork separating vaccinia and HIV be submitted (2 separate registrations) and a walk-through of the laboratory facilities be performed. Dr. Crise seconded and all were in favor.

06-95 (Dr. Dimitrov):

- Comments on this protocol are similar to those mentioned in 06-94.
- Clarification on particular strains to be used should be provided (specify the recombinant strains).
- SOP's are quite brief and will require further explanation of procedures, risks, and risk mitigation measures.
- The details provided do not present a clear picture of what is to be done, how, and why. The document appears inconsistent. Please provide more information on cell fusion, phage display, and amplification.
- A description for fluorescent microscopy is needed.
- Need clarification if transportation between labs will occur and how it will be done between rooms 131 and 139 .
- Sharps containers should never be “full” but filled to no more than $\frac{3}{4}$ the capacity of the container and then sealed.
- Part C – no markers are indicated (only WT strains or are there others?)
- C11: no sonication, mixing, blending? Is the material concentrated, and why or why not?
- D3: Addressing work with cell lines, the box is marked “NO” but D3a lists cell lines.

- D7: Response of “No” to infecting cell, but isn’t it true the cell lines will be infected with the viral material?
- There are no aerosol precautions outlined (vaccinia can pose a significant aerosol threat).
- PPE should be clearly defined in the SOP.
- How are target cells infected with vaccinia safely contained?
- There is no mention of how the BSC will be disinfecting after work. If this is a shared area there should be stringent procedures in place to disinfect the work space before the next group comes in to work. Does equipment come and go with the group or is it fixed location and shared?
- An IBC audit will be necessary to walk through the laboratories involved in this work.
- Verify those working with or in and around the area where vaccinia is handled have been offered the vaccinia immunization (since this is a shared area).
- A BSL-2* laboratory needs to have an autoclave in the area so waste can be autoclaved before removal from the BSL 2* area (Verify location of nearest autoclave and waste disposal procedures).

Dr. McVicar made a motion to defer approval, requesting that new paperwork separating vaccinia and HIV be submitted (2 separate registrations) and a walk-through of the laboratory facilities be performed. Dr. Crise seconded and all were in favor.

AMENDMENTS

06-76 (Hughes):

- Confirm that the presence of endogenous retroviruses and mobilizable elements pose an insignificant hazard to the employees for the purposes of this work. Murine retroviral vectors are used but have not previously been in animals.
- A request was made for the reviewers to be provided with an original protocol copy when reviewing amendments. When requested by the lead reviewer, a copy of the original document will be provided.
- A safety focus should be identified – If there is a change in a vector, how will that affect the safety of the lab personnel?
- An individual from Nancy Colburn’s laboratory will be working in Dr. Hughes’ lab now, and this person has experience doing this same work.
- Please address risks to children, if applicable.
- The IBC recommends putting in a set of oncogenes to see if murine or avian vectors act differently.
- The virus being used in these studies can only be spread through direct contact; there is no aerosol hazard with these viruses.

Dr. Crise made a motion to conditionally approve this registration pending the modifications noted above, Dr. Baseler seconded and all were in favor. Dr. Hughes abstained from the vote.

05-08 (Weissman):

Dr. Melinda Hollingshead is serving as the lead reviewer on this protocol and was unable to attend today or provide comments. The IBC will defer a motion on this amendment request pending comment from Dr. Hollingshead.

OUTSTANDING ITEMS

06-36 and 06-37 (Dr. Schneider) – To be put on hold.

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

06-79 (Dr. Whiteley) – PI to address questions regarding aerosols

06-39 (Dr. Kopp) – Pending riboflavin run-collecting documentation to resolve

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

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

06-85 (Dr. Klinman) – Revisions sent for final review by lead reviewers on 11/21/06

06-70 (Dr. Wiltrout) – Met with members of Dr. Wiltrout's lab on November 2, 2006 - revised registration will be forthcoming

06-86, 06-87, 06-88, 06-89 (Dr. Pavlakis) – Sending memo to Dr. Strathern for assistance with registration requirements

05-02 Amendments B and C (Dr. Durum): Currently under review by lead reviewer(s)

OTHER BUSINESS

The Bloodborne Pathogen Program continues to hold compliance around 95.8%. Ms. Leitch continues to notify program members of their requirement to complete this annual training.

The IBC "Breeding Only" registration form is being finalized for electronic availability. This should be completed by the end of the year.

P&P 604 is still awaiting final approval from the government.

Dr. McVicar opened up for discussion the topic of establishing a list of pre-approved Transgenic and Knock-out mice made with standard techniques. If a strain is already worked with here at NCI-Frederick and is approved per protocols with various experimental use, then it should be identified on a "pre-approved" list. If on this list, it should not require additional IBC registrations for that particular animal and procedure. Essentially, Tg and KO animals would be treated like cell lines, with the provision that mice could only be obtained if they meet the standard criteria as required.

The Outstanding Items were reviewed to update the committee on their status. Ms. Leitch and Ms. Bell hope to reduce the number of outstanding items significantly prior to the end of 2006. Registrations with an outstanding status for 6 months or longer will be put on HOLD until the registering program actively seeks to complete the registration process.

No other issues were raised to the committee's attention and the meeting was adjourned at 4:15 p.m.

MINUTES RECORDED BY:

Theresa D. Bell, 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