



NCI-FREDERICK INSTITUTIONAL BIOSAFETY COMMITTEE

Minutes
January 16, 2007
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:01 p.m. in the Building 549 Executive Boardroom with the following members in attendance:

Ms. Theresa Duley, Secretary	Dr. Henry Hearn
Dr. Randall Morin, Chair	Dr. Stephen Hughes
Ms. Alberta Peugeot	Dr. Melinda Hollingshead
Dr. Bruce Crise	Dr. Michael Baseler
Ms. Dianna Boissey	Dr. Stephen Creekmore
Dr. Jeanne Herring	

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

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

INTRODUCTION

Dr. Morin called the meeting to order.

November and December IBC minutes will be distributed via email.

PROTOCOL REVIEWS

NEW BUSINESS

Poiley-Nelson (06-105)

- How are the PCR samples lysed? It is suggested that after lysing, the lysate be transferred to a new tube to eliminate possibility unlysed virus may be present. (pg. 8)
- Clarify who is working with what virus in what facility at what time? There is an overall concern with how the work will be managed/controlled and when and where the risk stops. How is the staff kept safe? Who works with live vs. disrupted material? Is Trevor going to have a hot virus lab? State the BDP-specific training for each person. Is this addressed in one of the SOPs?

- How will cross contamination be minimized? 4 bldgs, 7 labs – Is this addressed in SOP 22923? Provide a copy of all SOPs referenced.
- Waste transport issue – chemically decontaminated but not sterilized since no autoclave in 433 (pg. 4). Verify if this is a BSL 2 or BSL 2* lab.
- “low traffic hours” does not sound good (pg. 15).
- Offices within labs in 325/118 (pg. 17). Is the virus inactivated at this point? On page 16, it mentions that the virus is inactivated in Room 118. Clarify.
- LAL testing requires work with virus outside a BSC in open containers. What is the concentration and volume of virus used? Explain how the risks of working with virus in the open on a bench top can be done safely. May need plexiglass box made. (pg. 19)
- Provide assurances that you are not working with the viruses listed on page 2 as live viruses.
- No mention of introducing plasmid sequence into cell is made. Assurance needed that this is the case.
- Are the ELISA samples inactivated with detergent prior to assaying? Applies to all ELISA assays in the registration (pg. 8)
- It is suggested that NUPAGE samples lysates need to be transferred to a new tube to eliminate possibility that unlysed virus may be present.
- Page 26, item C13 – is other containment equipment besides the BSC (i.e. containment rotors, if applicable)?
- Is the fluid retention filter a HEPA filter?
- Describe “other virus work performed in room” 325/118 (pg. 15).

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

Poon (06-108)

- Recommend sequencing the plasmid first since it is from an outside vendor.

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

Bustin (06-109)

- What is the source of the DNA/plasmid?

Dr. Hollingshead made a motion to conditionally approve this registration pending response to the question above, Dr. Hughes seconded and all were in favor.

Wang (06-96)

- A1: Indicate how tumors are being processed for histology or how that will be handled.
- A5: Must be Yes, need clarification.
- A6a1: Elaborate on the description of transportation safeguards. In addition, this section refers to use of a flow cytometer to sort these cells, yet no precautions (other than decontaminating the machine after) are listed. More information is needed here.

- E9: It is mentioned that animal personnel will be trained but this section is very brief. There should be more detail about how the animal personnel will be informed of the hazard and how they will handle the tumor lines and the mice.

Dr. McVicar made a motion to conditionally approve this registration pending the modifications noted above, Dr. Hughes seconded and all were in favor.

Merlino (06-106)

- A3: The risks associated with retroviral vectors of different classes - mobilizable MLV and HIV-1 based vectors should be sorted out. Each virus has its distinct hazards.
- B5: What went into each of the retroviral vectors used? What is being put into them, and how will they be manipulated?
- There is a long list of genes to be used - information to differentiate the gene types is needed.
- More detail regarding the differences in the RNAi material as applicable for human and/or mouse origins should be provided.

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

AMENDMENTS

Trinchieri (04-07)

- Responses to the lead reviewer's questions have not yet been received.

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

OUTSTANDING ITEMS

Kuehn (06-102) – PI to address questions

Whiteley (06-79) – PI to address questions

Munroe (06-13) – need SOP

Dimitrov (06-94 & 06-95) – PI to address questions

Wiltrout (06-70) – Revised registrations submitted on 1/10/2007

Pavlakis (06-86, 06-87, 06-88, 06-89) – Revised registrations submitted

Keller (06-51 & 06-38) – PI to address questions

Chatterjee (Pathogen & 05-49) – on hold

OTHER BUSINESS

- The Blood borne pathogen update was given. Currently we are at 96.4% compliance.
- Proposed charter: In item #6 of the proposed draft with changes to the Charter, Option #2 was selected. The revised Charter will be submitted to the NCI for concurrence and signature.
- SOP review: The SOP was modified giving 3 chances to both the PI and/or their supervisor before notification of non-compliance is sent to the SAIC or NCI Institutional Official. Also, a 2 week deadline between notifications was established, with the

committee retaining the right to modify deadlines as necessary. The SOP may be sent out to members for review and final vote.

- Ms. Peugeot provided an update regarding PEP issues. The Lentiviral vector protocol draft was discussed in brief, noting assistance from outside consultants and sources. Legal issues and concerns were raised, with respect to the right of refusal. Specifically, if there is no documentation available to support the idea that treatment may prevent infection, and if an exposed individual who refused treatment happens to seroconvert, what are the legal implications and what parties are liable relating to the incident? There are accredited HIV testing assays available, however there are no approved screens for lentivirus. A 2 hour window for treatment will continue to remain the recommendation. All documents drafted to address these issues should be cleared with the corporate SAIC legal department, with a mechanism for dissemination.
- A recommendation was made by 2 specific members of the committee to consider putting together a course for lentiviral/retroviral issues and to address pertinent NIH guidance document recently released.
- Issues with Dr. Klinman have been resolved.
- The Pavlakis/Felber registration status was discussed in brief. A 2-week review period by IBC members will be allowed at which time comments will be collected, summarized and provided to the PI's for consideration and response.
- Keller amendment: A new registration and Animal Study Protocol will be needed in reference to IBC # 05-50.

Meeting adjourned at 2:06 p.m.

Theresa D. Bell, MPH, CBSP
IBC Secretary
Biological Safety Officer, EHS

Ms. 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