



**NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes – January 17, 2006
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:04 p.m. in the Vaccine Pilot Plant Conference Room with the following members in attendance:

Dr. Randall Morin, Chair	Ms. Alberta Peugeot
Dr. Henry Hearn	Ms. Theresa Duley, Secretary
Mr. Lucien Winegar	Dr. David Garfinkel
Dr. Michael Baseler	Dr. Melinda Hollingshead
Dr. Bruce Crise	Dr. Stephen Creekmore
Dr. Dan McVicar	
Dr. Stephen Hughes	

Members not in attendance: Dr. Jeanne Herring and Dr. Paul Nisson

Others in attendance: Ms. Cara Leitch, Dr. Scott Keimig, Dr. Dexter Poon

INTRODUCTION

Dr. Morin called the meeting to order.

Dr. Morin requested the IBC members to review the November meeting minutes, which were previously distributed by email. A vote for the November meeting minutes was taken. Dr. Morin made a motion for approval of the minutes as written, Mr. Winegar seconded and all were in favor.

The December 2005 meeting minutes were distributed at today's meeting and a review and comment period will be offered through Friday January 27, 2006. An email vote will be taken on January 27 for final approval of the December 2005 minutes.

PROTOCOL REVIEWS

NEW BUSINESS

06-01 and 06-02 (Dr. Poon):

These two studies both involve large scale recombinant adenovirus preparations.

- The paperwork does not guarantee a satisfactory level of safety is to be integrated into the practices and procedures.
- Clarify what will be done in large-scale and pilot experiments.
- Increase the physical scale for 10^{14} infectious units
- Page 2 of the attachments has the statement “emphasis on low-pressure” with respect to the concentration and purification of viruses. This is perceived as a problematic statement. The closed system should not only be run on low pressure at all times, but a riboflavin test run should also be conducted to ensure procedures and preventive measures are in place should the closed system be compromised during the purification process.
- It was noted that the potential hazards associated with GMCSF vector, a biologically active molecule, and the Herpes Simplex Virus-associated sr39TK viral genome are not sufficiently addressed.
- Be more specific as to the Personal Protective Equipment to be used in relation to procedures being performed.
- The employees identified to be involved in these projects must be revisited, as it is not recommended that an employee be involved in both of these projects simultaneously.
- Identify a primary group of individuals to work on each protocol, and then secondary or tertiary groups of back-up personnel, all of which would require training pertinent to these protocols.
- Further explanation of medical surveillance programs and health counseling, training, and clarifying each employee’s roles and responsibilities is required. For those employees who may have medical contraindications for working on this protocol, a more extensive occupational health risk assessment must be completed and OHS approval given for those individuals to work on these projects.
- More detailed information on procedures to be performed is also requested. It is understood that all of the large scale portions of the work will occur in a Class 100 containment or an appropriate Biological Safety Cabinet. Clarify that all other portions of the protocol will be conducted in a biological safety cabinet. Please describe particular procedures and manipulations that will not be performed, to reinforce safe practices and procedures.
- Describe practices to be used when transporting hazardous material from room to room. -An inspection of the BSL-3 prior to initiation of work is warranted by the EHS office and is scheduled tentatively for tomorrow January 18, 2006.

Dr. Hughes moved to defer approval pending resolution of the above noted outstanding issues, and all committee members were in favor. Dr. Creekmore abstained from the vote.

05-60 (Dr. Kopp):

These studies involve the use of several biological hazards to include Vesicular Stomatitis Virus, Sendai Virus, and Respiratory Syncytial Virus. All of these are

available through ATCC and are classified as Biological Safety Level 2 agents. All of these agents are known to be infectious to humans. The group proposes to infect established cell lines with the wild type gene, to challenge the cells with virus after interferon is introduced and measure the amount of virus produced. The procedures will involve centrifugation of cells after infection and volumes used will range between 1 and 100 milliliters.

-It was mentioned that the VSV is being ordered in a freeze-dried form, and the committee would request the VSV be ordered in the alternative liquid form, to avoid an additional aerosol hazard when handling the material.

-In item 9.1.7, please verify the information surrounding Ana Gamero's involvement with this protocol and clarify locations for various work activities.

-There are many transmissibility concerns involving the mice and their sensitivity to Sendai potentially leading to other facility animal concerns, employees taking certain medications which may be contraindicated for performing work with these hazardous materials, and for those employees whose activities with farm animals outside of the workplace may present an additional hazard. Sendai and VSV infect farm animals and it is recommended that staff should not work with this if they work with farm animals – VSV is a reportable disease to the USDA.

The committee moved to conditionally approve this registration pending resolution of the above issues and acquisition of any necessary permits. All were in favor.

05-59 (D. Sohn/Perwez):

-Where will animal work be done? Bldg. 539 or 571

-Who is performing injections?

-Verify that a chemical fume hood will be used with all work involving carcinogens to eliminate the hazard

-Please address concerns associated with volumes to be used.

-Incineration might be an issue with sulfates being used, is there a charcoal scrubber on the autoclave to be used and if not, is one necessary?

-How will any potential contamination (even trace amounts) be detected if a spill of material occurs? Describe methods for detection and spill clean up.

-Ensure those requiring respiratory protection are enrolled in the program, fit tested and trained before initiating work.

Dr. Creekmore made a motion to defer approval pending modifications as described above, all were in favor.

06-03 (Dr. Acharya):

Work with Vesicular Stomatitis Virus will be performed in a Biosafety Cabinet by a limited number of people. Waste will be chemically inactivated by each individual as the work is done.

-The committee asked for verification of the volume to be centrifuged.

- State that transport from a BSC to any other location outside of the BSC will be done so in a sealable tight container which is leakproof.
- Please do not use TC dishes for virus.
- Ensure that containment tops are in place on rotor buckets.
- Purchase virus in a frozen liquid form (this is how it is shipped by vendor) and not lyophilized.
- Integrate some additional detail on safety practices within the lab in the existing SOP.
- The committee encouraged the researcher to set up a non-viral expression system
- Eliminate sharps altogether (A4b)
- A laboratory inspection will be performed by EHS prior to work beginning.

Dr. Morin made a motion for conditional approval pending resolution of the above items, Mr. Winegar seconded and all were in favor.

05-55 (Dr. Zhang):

- #5: pBabe statement is not correct – remove the statement that it is harmless and indicate “yes” to match #9 and #14
- #7: Identify source of virus and give more detail regarding the oncogene pBabe-H-ras, reassess risk level, and further explain ecotrophic packaging
- #8: need to screen for human pathogens on MCF10A cells
- Answer #8b – should be no
- Potential hazards to animal handlers need to be addressed

Dr. McVicar made a motion to approve pending modifications requested above, all were in favor.

AMENDMENTS

P230902JLA01 (Dr. Lu):

No further modifications were requested at this time.

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

RENEWALS

None

OUTSTANDING ITEMS

05-29 (Dr. Rane) – On hold.

05-52 (Dr. Xie) – Approval pending additional PI responses.

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

05-55 (Dr. Zhang) – Lead reviewer working with PI.

OTHER BUSINESS

1) The IBC discussed a needlestick incident that occurred on January 12, 2006 containing lentivirus. The individual was pulling lentivirus in media from a tube with a needle, recapped the needle, causing her to stick herself. The individual and her supervisor reported to OHS after the incident. Individual is on the Bloodborne Pathogen Program and is current. She worked previously in another lab with live virus (HIV) where no sharps are used. The individual did not have much experience performing this particular procedure, however, prior to working in this lab, she worked in another lab with live virus (HIV) where no sharps are used. She explained to EHS that she knew the written procedure called for use of a pipet for media draws, however, she chose to use the needle and syringe to get the last drop of media from the tube and it saved her a step during the procedure. As they were interviewed by OHS and EHS, it became apparent that the supervisor did not know what particular genes were present in the lentivirus the individual was working with. According to the supervisor, he had offered to help the individual with the procedure since she was filling in for an absent senior lab worker, and she declined. Since a member of the IBC had reviewed the supervising PI's registration and was familiar with the work being conducted, EHS contacted him for input on the risks associated with a replication incompetent lentivirus needlestick.

The following discussion ensued after the IBC was briefed on the incident.

- What lab did she transfer from?
- Why were there sharps in the lab?
- Why did she recap the needle?
- Was she trained?
- An antiviral drug would prevent mutagenesis, not infection since the lentivirus was replication incompetent
- Conduct an audit of the lab
- Reassess all current work conducted in the lab
- Establish SOPs for medical response to lentivirus and adenovirus exposures.
- How does the staff know they are working with the correct materials?
- Vacate active production and provide a path forward
- Lab to submit SOPs with signatures of staff stating that they have read and understand procedures and have been trained on the hazards particular to what they are working with.
- Follow rules of production vs. research?

- Protocol approved based on the fact that no sharps would be used in the lab
- Use registrations as a tool to conduct lab inspections
- Lab stand down to revisit issues, take inventory, provide training
- Laboratory procedures employing sharps demonstrates a lack of productive involvement of the supervisor
- The exposed individual was not familiar with the nature of the material she was manipulating; therefore, basic standards of “informal consent” for work with potentially hazardous materials were not met.
- The supervisor allowed unsafe practices to proceed in the laboratory

As a result of the discussion, the NCI-Frederick IBC voted unanimously to instruct the SAIC-Frederick Environment, Health, and Safety (EHS) Program to suspend all activities with biological materials and recombinant DNA. Extensive remediation of the management of the lab is required to ensure that potential future exposures be prevented. Dr. Morin made the motion and Mr. Winegar seconded, all were in favor.

2) The IBC discussed the issue of a PI receiving a lysate containing an attenuated vaccine strain of H5N1 Avian Influenza. The material is to be secured by the EHS office until further guidance is issued by the USDA.

3) An update on the compliance status of the Bloodborne Pathogen Training Program was given by Ms. Cara Leitch.

4) Ms. Duley and Ms. Leitch distributed a draft updating the Policy and Procedure #604 to include all pathogenic material used at the NCI, to eliminate the restrictions of the document to only HIV. Comments will be discussed at the February meeting.

The meeting was adjourned at 2:50 p.m.

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. Bufter
Dr. Keimig