



**NCI-FREDERICK  
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes – December 13, 2005  
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. Paul Nisson	Dr. Bruce Crise
Dr. Jeanne Herring	

Members not in attendance: Dr. Stephen Creekmore, Dr. Dan McVicar, Dr. Stephen Hughes

Others in attendance: Ms. Cara Leitch, Ms. Lois Minchoff, Dr. Michael Sauri, Dr. Scott Keimig, Dr. Criss Tarr, Dr. Phil Gomez, Dr. Kimberlee Wallace, and Mr. Paul Mutulo

## **INTRODUCTION**

Dr. Morin called the meeting to order. Dr. Morin began the meeting with greetings and appreciation to Dr. Tarr for extending an invitation to the IBC to hold their meeting in his recently opened Vaccine Pilot Plant.

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.

## **PROTOCOL REVIEWS**

## **NEW BUSINESS**

**05-57 (Dr. Tarr/VPP) - Approved.**

This study involves plasmid DNA vaccine production. There are no sharps associated with the procedures and the waste will be tracked with verification of decontamination and disposal. The solid waste is disposed of using a macerator, which also acts as a steam sterilizer. The facility design is conducive to containing a spill of product or material, and less than 100 Liters will be used for this purpose. Floors are made of waterproof polyurethane epoxy materials. There is a double-walled liquid biowaste piping system for removal and treatment of liquid wastes. There is an environmental monitoring program using contact plating and air handling monitoring methods to detect any potential contamination. PCR testing will also be done during product change-overs, as another method to detect product spills. Because human cells are being used for plasmid expression, medical surveillance programs and Bloodborne pathogen training is required. Due to the nature of this facility operating under GMP conditions, there is an electronic database to store all applicable SOP's pertaining to this research. LPH and Spor-klenz will be used on a rotating basis as primary disinfectants and will be used on a recurring daily basis.

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

AT THIS POINT IN TIME THE COMMITTEE WAS INVITED TO TOUR THE VACCINE PILOT PLANT, LEAD BY DR. TARR.

**05-56 (Dr. McVicar) – Approved pending modifications.**

This research involves retro- and lenti- viral constructs and looks to determine the role of NK cells in innate immunity. The vectors used in this study are bicystronic in that they have the ability to express 2 genes simultaneously. There are identified hazards to be addressed which include bone marrow and transduction, animal handlers and the presence of proto-oncogenes, the potential for vector mobilization and the potential for shedding virus and human exposure to infectious material. The investigator needs to clarify that appropriate animal containment housing will be used, such as microisolator caging systems. There needs to be clarification on the names of the technicians who will be working on this protocol (specifically agreement on technician names between the ASP and the IBC registration documents). The SOP in Section D-1 and D-6 could be refined to more appropriately address centrifugation and equipment sharing with other laboratories, as well as other potential areas for exposure. Clarify disposable microisolator cages in ASP rather than disposable cages. Please address if there is an employee with a wound, that a medical evaluation will need to be completed by OHS before permitting the person to work in the area or on this project.

Dr. Crise made a motion to approve the protocol conditionally upon completion of requested modifications, Dr. Baseler seconded and all were in favor.

**05-58 (Dr. Reilly) - Approved.**

Given that this registration involves no viral based recombination systems, there are no issues to be further discussed.

Dr. Hollingshead made a motion to approve as written, Dr. Crise seconded and all were in favor.

**05-55 (Dr. Zhang) – Approval deferred.**

The following items require additional information before full review and approval may be granted. Item 3a lacks sufficient identification of the bacterial cloning strains. Item 5 suggests the pBabe vectors have no potential for complementation of endogenous retrovirus within murine cells. This is incorrect. Care should be taken in the handling, tissue harvest, and in vitro manipulation of tissues of the mice since the cell lines produced are going back into immunocompromised mice. This should be explained in items 9 and Other items that should be addressed are personnel protection and protecting the mice within the same areas to avoid cross-contamination. Items 7b, 7e, 9 and 14 all require additional information. The personnel listed need to be verified as to their responsibilities and their working location. Is the source material shipped to us contaminated and if so, how is this verified? Please clarify that research materials are being received from approved sources and if that is not the case, that testing and validation of incoming materials has been verified and completed. The LMT here at the NCI is a service available to researchers to screen research material for a select panel of human pathogens. Please consult directly with them if material screening is necessary.

Dr. Morin made a motion to defer this registration at the present time due to the incomplete information, all were in favor.

**AMENDMENTS**

**Pathogen P300993MHA04 PART I (Dr. Hollingshead) - Approved.**

This work will be performed by a limited number of individuals. There will be no animal care workers needed on this project nor will they have access to enter into the building where this study will take place. Two of the three designated staff are familiar with Biosafety Level 2 agent work. The animals will be housed in microisolator cages at all times and will only be manipulated while inside a Biological Safety Cabinet. Other laboratories have been working with Reovirus safely, and provisions are in place to restrict access from young, older, or immunosuppressed individuals. Two percent hypochlorite will be used as a disinfectant and has been previously used by other labs effectively who work with this agent. All cell lines being used in these studies have been subjected to the

human pathogen screening. Dosing will be administered IV to mice and is illustrated further in a facility dedicated safety manual. The laboratory will be designated as a BSL2\*.

Dr. Crise made a motion to approve, Dr. Hearn seconded and all were in favor. Dr. Creekmore, the lead reviewer, was not present at the vote so the final vote was conditionally approved pending approval from Dr. Creekmore.

**Pathogen P300993MHA04 PART II (Dr. Hollingshead) - Removed from submission.**

It was determined that this work would require GLP facilities and practices. This work cannot be accommodated at the present time and this submission is hereby removed from review.

Ms. Duley noted that the previous plan to upgrade Building 1023 to an ABSL-3 was rescinded and the facility will remain an ABSL-2 laboratory with the implementation of ABSL-3 practices and procedures.

**RENEWALS**

None

**OUTSTANDING ITEMS**

**05-29 (Dr. Rane) – On hold.**

**05-52 (Dr. Michiel/Dr. Stoughton) – Approval pending additional PI responses and/or transfer of research to another PI.**

**05-38 (Dr. Stewart) – Designated review.**

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

**OTHER BUSINESS**

- 1) An update on the compliance status of the Bloodborne Pathogen Training Program was given by Ms. Cara Leitch.
- 2) Ms. Duley and Ms. Leitch stated they continue to work on 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.
- 3) The IBC members received the latest version of the revised IBC Registration Form with Instructions for review.
- 4) A memorandum addressing timeliness for submitting Animal Study Proposals in need of IBC concurrence was distributed to all investigators, in an effort to expedite a concerted review and approval between the two committees.

The meeting was adjourned at 2:20 p.m.  
MINUTES RECORDED BY:

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Theresa Duley, MPH  
IBC Secretary  
Biological Safety Officer, EHS

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Cara Leitch  
IBC Coordinator  
Sr. Safety Specialist, EHS

APPROVED

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Randall S. Morin, Dr. P.H.  
Chairman, NCI-Frederick IBC  
Director, EHS

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DATE

xc: All Committee Members  
Dr. Wiltout  
Dr. Reynolds  
Mr. Eaton  
Dr. Arthur  
Mr. Buffer  
Dr. Keimig