



NCI-FREDERICK INSTITUTIONAL BIOSAFETY COMMITTEE

Minutes
April 10, 2007
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:00 p.m. in the Building 549 Executive Boardroom with the following members in attendance:

Ms. Theresa Bell, Secretary	Dr. Henry Hearn
Dr. Randall Morin, Chair	Mr. Lucien Winegar
Ms. Alberta Peugeot	Dr. Mike Baseler
Dr. Bruce Crise	Dr. Stephen Creekmore
Ms. Dianna Boissey	Dr. Melinda Hollingshead

Members not in attendance: Dr. Jeanne Herring, Dr. Dan McVicar, Dr. David Garfinkel, and Dr. Stephen Hughes

Others in attendance: Ms. Cara Leitch, Dr. Robert Thomas, Dr. Raymond Harris, Ms. Eva L. Andersson, Mr. Senad Diglisic, Ms. Beverly Keseling, Mr. John Roach, and Mr. Samir Shaban

INTRODUCTION

Dr. Morin stated the February minutes would be distributed by email for review and vote for final approval at the end of the week.

PROTOCOL REVIEWS

07-20 (Harris, Diglisic, Keseling)

- Ray Harris described the proposal for using replication conditional adenovirus.
- Adenovirus serotype 3 is being used and carries no transgene.
- The study involves preparation and growth of GMP material, chemical lysis of infected cells, and isolating virus using ion exchange capture.
- Needles with a luer lock syringe will be used to sample the closed system. The use of needles will be eliminated for the upstream portion of the procedure. Max volume to be used is 12-10 tier cell factories.

- After chemical lysis, the material is harvested into bags containing 1300 mls each for a total volume of 15 L. The procedures involve filling the bags, filtering to clarify material, using the quick-connect clamps and tubing with a luer lock syringe, and withdrawing 30-50 mls. All these steps take place inside of a biological safety cabinet.
- Registration modifications should reflect the avoidance of needle use.
- BSL-3 gowning practices are described, implementing the use of sterile tyvek, scrubs, two pairs of booties, two hairnets, facemask, eyewear, and two pairs of gloves.
- Standard practices will also include the use of two operators at all times; there are two teams with two operators to meet this requirement.
- Clearly state that no needles are to be used or located in the BSL-2*/BSL3 laboratories

Dr. Crise made a motion to conditionally approve the request pending responses to the issues addressed above, Mr. Winegar seconded and all were in favor. Dr. Creekmore abstained from the vote.

07-21 (Jendrek, Shaban, Harris)

- This study involves purification procedures using the customized containment device with glove ports.
- Attempts to fail the containment system have been made; however, it was determined that the peristaltic pump is not strong enough to compromise the containment system.
- No sharps will be used.
- A statement should be provided to summarize the maximum pressures obtained when using the peristaltic pump and the pressure gauge.
- The tubing will be disposed of after each use.
- How will everything be decontaminated after the project? A summary statement should describe the use of the VHP as the means to decontaminate the equipment and materials involved with this project and implementation of VHP decontamination procedures between projects.

Dr. Crise made a motion to conditionally approve the registration pending resolution of the above items, Dr. Hollingshead seconded and all were in favor. Dr. Creekmore abstained from the vote.

07-16 (Perantoni)

- There are no particular risks associated with the animals in this study.
- The pre-review questions were sufficiently answered by the PI.
- Dr. Hollingshead reviewed a brief tutorial on mouse injections and handling mice when using needles.
- Latex and deerskin gloving should be used when working with 23-25 gauge needles.

Dr. Hollingshead made a motion to conditionally approve the protocol provided the issues mentioned above surrounding the use of needles and PPE are sufficiently addressed. Dr. Crise seconded and all were in favor.

07-18 (Steeg)

- The new cell lines made from the original cell line should be screened.

Dr. Hollingshead made a motion to defer approval pending resolution of the above item. Dr. Crise seconded and all were in favor.

07-19 (Morrison)

- This work involves adenovirus and human cell lines so the Bloodborne Pathogens requirement must be met.
- On the lab location Addendum, the lab is indicated as a BSL2*. The area is a BSL-2 lab and the BSL-2 requirements are met and acceptable to conduct this work. The form should be revised to reflect this.
- The annual lab inspection should be completed prior to approval and Dr. Crise would like to accompany EHS on the inspection.

Ms. Bell made a motion to approve pending the items listed above, Dr. Crise seconded and all were in favor.

05-39 (Green)

- This study has human hazards involving human isolets with H. pylori.
- All microisolator caging will be autoclaved.
- Extra caution and containment features should be used (perform cage change operations in a Biosafety Cabinet).
- BSL2 and ABSL-2 laboratories apply.
- The material should be treated with precautions consistent with a fecal-oral risk.
- Animal care and technician workers will need to be enrolled in the Bloodborne Pathogen Program, if not already.
- Dr. Green should restate safety requirements and inherent hazards (such as the risk of chronic ulcers associated with H. pylori infections in humans).

Dr. Hollingshead made a motion to conditionally approve provided the above issues are sufficiently addressed and restrictions are clearly stated in the modifications, Mr. Winegar seconded and all were in favor.

AMENDMENTS

P190705RHB01 (Anderson)

- This amendment was previously reviewed by Dr. Crise, and he recommended approval with no modifications necessary.

OUTSTANDING ITEMS

Ms. Bell update the IBC on the outstanding items listed on the agenda.

OTHER BUSINESS

- The Bloodborne Pathogen Program is currently 97% compliant. The Outstanding Items draft SOP references P&P #604. Restate the word outstanding to on hold or

delinquent. A penalty clause should be included and the PI should have to sign the document acknowledging this statement.

- Dianna Boissy is checking on the status of P&P #604.
- The Supplemental Breeding Form should include the IBC number and PI name.
- Discussion ensued to keep the third Tuesday of each month as the usual meeting day and to maintain meeting location in the 549 Board Room. These dates sometime conflict with the New Employee Orientation training, which would involve members of EHS who attend the IBC meeting. A decision will be made later on about changing the meeting dates.

ANNOUNCEMENTS

The First Red Cross blood drive will be held on 4/26/07 in Building 426, compliments of OHS.

The meeting was adjourned at 1:23 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