



**NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes
August 21, 2007
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:05 p.m. in the Building 549 Executive Boardroom with the following members in attendance:

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

Members not in attendance: Dr. Jeanne Herring, Ms. Dianna Conrad, Dr. Michael Baseler

Others in attendance: Ms. Cara Leitch, Dr. Scott Keimig, Dr. Robert Thomas, Ms. Gail Housaman, Ms. Robin Pickens

Randall Morin briefed the committee on some changes in committee operations due to the IBC Secretary and IBC Coordinator being out on maternity leave in October and November 2007.

Dr. Morin made a motion to approve the June IBC minutes. No modifications were requested and the June minutes were approved as written. Dr. Crise seconded and all were in favor.

The May 2007 minutes were distributed for review. These minutes were delayed due to some complex issues handled during the meeting that were redacted from the minutes due to confidentiality issues. Also, in future minutes, the registration titles will be included with the IBC number for easier reading.

New Business

McNeil (07-39 – Determination of Nanoparticle Disposition and Acute Toxicity)

- A3, B10a, & E9: Hazards and safety measures must be outlined in the IBC form, rather than referencing the animal study proposal.
- A4: Sharps disposal procedures must be addressed.
- A6a1: Transport procedures to be specified (i.e. primary and secondary containment with absorbent materials).
- B5f: The explanation in B5f1 is inconsistent with your answer in B5f.
- B5i: Plasmid vector used should be classified.
- B5h & B11: Is this work done in a chemical fume hood or a biosafety cabinet?
- Clarify which cabinet is used per work activity.
- B6: Box should be checked YES and sub-questions should be answered. The BPV is considered replication incompetent and not infectious.
- A copy of the SOP outlining safety practices and procedures in the lab is necessary.

Dr. Crise made a motion to conditionally approve the registration pending responses to the questions above, Dr. Hollingshead seconded and all were in favor.

Stevens (07-42 – Measurement of lymphocyte proliferation and intracellular cytokine production in patient peripheral blood mononuclear cell (PBMCs) stimulated with Staphylococcal enterotoxin B (SEB)

- The highest risks posed with SEB are associated with mucous membrane exposures. These can be minimized with appropriate practices.
- A written acknowledgement was requested regarding the following: the staff are sufficiently trained to use SEB and understand the LD50 limits and the risks posed by the .020 ug/kg = LD50 amounts; tiny amounts are lethal, especially given toxicity via the inhalation route; a log of the amounts used must be maintained by the users; the total amount in possession at one time may never exceed 5 mg; freezers used for storage of SEB must be locked
- A follow up for all users of SEB may be necessary to ensure adequate training and medical surveillance.
- D5: Is an HIV screen needed or performed? What about others working in the area but not directly with SEB?
- Is CFSE a mutagen? Cytoplasmic? Does it bind to DNA?

Dr. Garfinkel made a motion to conditionally approve the registration pending responses to the questions above, Dr. Crise seconded and all were in favor.

Feigenbaum (07-43 – Determination of metastatic potential of A549 cells by bioluminescent imaging)

- A3: Section J does not provide the IBC with enough information to conduct an adequate risk assessment. Specifics are needed as to how the lentiviral vector and human cell lines may pose hazards to the workers in the lab.
- A6: This should be YES since different labs are listed and materials will have to be transported between them.
- A6a1: These questions must be answered (i.e. primary and secondary containment with absorbent materials).
- B5h: This should be YES since the manipulations being performed (centrifuging, blending/pipetting) can generate aerosols.
- B5h1: This response needs revised to be consistent with B5h.
- D5a: Cell lines must be screened for human pathogens?
- D10: Is a containment centrifuge available or is the centrifuging done in a biosafety cabinet?
- E6: Both YES and NO are checked.
- E6b1: Why are cells not permissive to further infection?
- E6e1: Why it is unlikely that the viral segment would help mobilize the transgene.
- E8a: Explanation is needed as to why the material will not be shed from the animal.
- E9: The statement "No hazards" should be changed to "Hazards are minimal because..." Reasons must be stated in E9 rather than referencing Section J of the ASP.
- In the Intraperitoneal and Intravenous SOPs, sharps are put into the sharps container, but in the A549-Luc/GFP SOP, it states that sharps are disinfected prior to disposal. Clarification needed. The IBC does not recommend decontaminating needles and syringes prior to disposal since more sharps handling will more likely present a hazard. A small sharps container should be placed inside the BSC.
- More detail is needed regarding the restraint of the mouse to prevent accidental sharps injuries to the workers.
- At what point does the experiment stop? Is anything else done after the mice have been injected?

Dr. McVicar made a motion to conditionally approve the registration pending responses to the questions above, Mr. Winegar seconded and all were in favor.

Amendments

Young (07-03 – Gene expression or gene knockdown in natural killer cells using a lentiviral system)

- B8b – Some of the genes in questions are potent immuno modulators and can have certain hazardous consequences; therefore, this should be answered YES.
- B8b1 – This question needs answered since B8b is YES.

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

Outstanding Items

Ms. Bell reported on the Outstanding Items. If six of the Principle Investigators have not responded to the committee by the September meeting, a Delinquency Memo will be submitted to the registering Principle Investigator requiring them to take action on their pending registration within 30 days.

Other Business

- BBP update: 96 % Compliant
- BBP compliance policy: EHS is in the process of drafting a compliance policy to enforce annual OSHA Bloodborne Pathogen training requirements.
- PPE/footwear policy: Policy and Procedure 602 currently addresses PPE requirements, as does Safetygram ISM 130. It is the supervisor's responsibility to enforce PPE requirements within their laboratory areas.
- Modifications to IBC form: A medical surveillance/Post-exposure prophylaxis question will be added/relocated to Part A of the form; however, the PI cannot be responsible for medical questions. It is evident that for most work with viral vectors, no prophylactic treatments are available. Reasonable parameters need to be established for what can be done if an exposure event occurs. Prevention of the exposure is the best practice. The PI should be responsible for identifying the pathogenesis of the material and the potential for harm, both with and without a PEP. The IBC cannot be prescriptive in their questioning. A general question regarding human subjects training will be added to Part D.
- Storage only form: No Storage Only form will be initiated. If a PI has the material, it must be registered to describe the intentions for the material. The PI will need to describe what happens to the material when they are done with the experiment, complete sections A1 and A3, and describe mitigation of hazards by not working with the material. If a need arises to work with the material, an amendment can be submitted to the IBC for review at that point in time.

The meeting was adjourned at 1:50 p.m.

Immediately following the regular monthly IBC meeting, an IBC-appointed subcommittee met to discuss Post Exposure Prophylaxis requirements for working with ***Borrelia burgdorferi***.

PEP Subcommittee Meeting

Ms. Peugeot began the discussion and distributed a hand out for a Post Exposure Prophylaxis protocol. For those working with ***Borrelia*** as well as for the public health population, there is no community consensus on treatment for this spirochete. The committee agreed that if a needlestick with ***Borrelia*** were to occur, treatment may be warranted as deemed appropriate by a treating physician. It was established that a baseline would be more useful if taken at the time of the injury, since ***Borrelia*** is endemic to this geographical region and many individuals may have antibodies. Antibiotic treatments with doxycycline

and ceftin would also be available. There are a limited number of employees working with this material, and a set of exclusion criteria has been established to determine if there are those who may not be permitted to work directly with or in an area where the material is handled.

The PEP Subcommittee Meeting adjourned at 2:00 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: Dr. Reynolds
Mr. Wheatley
Dr. Arthur
Mr. Bufter