



**NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes
March 18, 2008
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:03 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. Mike Baseler
Dr. Bruce Crise	Dr. Stephen Hughes
Ms. Dianna Boissey	Mr. Lucien Winegar
Dr. Dan McVicar	Dr. Stephen Creekmore

New Members:

Dr. Eric Freed	Dr. Serguei Kozlov
Dr. David Derse	Mr. Scott Jendrek

Members not in attendance: Dr. Melinda Hollingshead

Others in attendance: Ms. Cara Leitch, Dr. Scott Keimig, Dr. Robert Thomas, Ms. Gail Housaman, Ms. Teresa Stitley, Ms. Courtney Kennedy, Dr. Denise Ekstrom, Dr. Dennis Michiel, Dr. Steve Giardina

Randall introduced Drs. Derse, Freed, Kozlov and Mr. Scott Jendrek who are sitting in and observing as they have been asked to consider joining the IBC as new members.

Ms. Stitley and Ms. Kennedy demonstrated the Sharepoint system for all IBC members. Comments and feedback were as follows:

- A VPN was requested for community members.
- Resolve inability to insert comments.

- Need Adobe Professional to use this system – this may be a problem for NCI employees.
- Can comments be inserted anonymously to pass along to the registrant without further edits from IBC administrative staff?
- Can more than one reviewer access a document at the same time and comment simultaneously or can only one person at a time check out a document for review, which would require someone else waiting and having to go back in later?

08-16 (Ekstrom) “Formulation and Aseptic Filling of three Recombinant Malaria Vaccines (Adsorbed)”

- The antigen is used only to evoke an immune response.
- PI must have a spill SOP. The IBC recommends performing a spill drill to mimic an actual response.
- A dead air hood is in use.
- Paper masks are worn.
- Product protection is required for the recombinant.
- Blunt cannulaes are being used to reduce the risk posed by a sharp.

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

08-17 (Michiel) “The Production of Protein hlg-h4-1BBLs in Chinese Hamster Ovary Cells (Phase 1)”

- This study involves the use of recombinant proteins in CHO cells and transfection with pcDNA.
- Need a description of the DNA used to express proteins in the cell.
- There is no potential for aerosol hazards, and no hazards with TNF injections.
- PI should provide a description of DNA to cause protein expression.
- Cells have not been sent yet for testing, but the cells will be tested prior to growing them up as a result of master cell bank requirements through the FDA.

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

08-10 (Perry) “Developmental Defects in Mdm2 Hypomorphic Mice

- Targeting constructs are not virally derived.
- IACUC ASP form references several strains that do not match the list in the IBC registration. A description of each strain should be provided.

Dr. McVicar made a motion to approve, Dr. Crise seconded, and all were in favor.

08-15 (Van Dyke) “In Vitro Analysis of Primary Mouse Prostate Cells”

- There is no adenovirus exposure to animals directly. The material is only going into cells.
- The material is replication incompetent and has minimal hazards by design.
- The material is grown in HEK293 cells.
- Volumes used are up to 10^{12} .
- PCR test up to 10^9 .
- Personnel are to treat all stock material as if it is infectious.
- PI must provide a statement acknowledging concerns, BSL-2 containment requirements, use of a BSC, use of a face mask, and all shaking will occur only in a BSC.

Dr. Creekmore made a motion to approve, Mr. Winegar seconded, and all were in favor.

OUTSTANDING ITEMS

Ms. Bell provided an update on these items.

OTHER BUSINESS

- Microinjection with Mouse Prion protein gene
 - Is the DNA intended to be a potent amyloid protein?
 - Does the protein have the potential to be a human prion?
 - The mouse prion is only promoter.
 - Huntington gene derivatives can cause amyloid disease.
 - Misfolded proteins (prion) can create an amyloid condition.
 - The prion material can be hard to inactivate.
 - A strong base or incineration is necessary to inactivate (2 or 3 molar NaOH w/ or incineration).
 - All associated materials must be handled the same way as the material itself.
 - Injections must be performed with the utmost care.
 - This is NOT a BSL-1 containment project; BSL-2 w/ prion precautions.
 - Animals should be in microisolators – cages must be disposable and incinerated
 - In this experiment, the promoter is only being used to drive expression of the gene.
 - How the material is transmitted is unclear.
 - There is no data available on the potential for aerosol transmission.
 - Is there proof that the HTT gene does not give rise to prion constructs in the last 10 years?
 - Misfolded proteins must be destroyed.
 - Everything associated with this is hot.

- Should the material be sequenced?
- What are the hazards associated with the mice?
- Specific protocol with > BSL-2 practices.
- Microinjections are performed to fertilize eggs using very tiny needles.
- Where do animals go and where are mice (the embryos that have not yet given birth but were already fertilized)?
- Transmission is inefficient with latent development.
- End users are not comfortable yet with this protocol.
- A meeting needs to be scheduled with the PI and technicians performing injections.
- How are mice getting shipped?
- Change blanket approval process – from now on PI must wait for approval of each request.

- Ms. Peugeot provided an update on a recent needlestick incident.

- The Bloodborne Pathogen Program is currently 99.7% compliant.

Meeting ended: 1:24 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. Butfer