NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE

Minutes
September 16, 2008
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:06 p.m. in the Building 549 Executive Boardroom with the following members in attendance:

Ms. Theresa Bell, Secretary	Dr. Michael Baseler
Dr. Randall Morin, Chair	Dr. Stephen Creekmore
Dr. Serguei Kozlov	Dr. David Derse
Ms. Dianna Boissey	Mr. Lucien Winegar
Mr. Scott Jendrek	Ms. Alberta Peugeot

Members not in attendance: Dr. Henry Hearn, Dr. Eric Freed, Dr. Daniel McVicar, Dr. David Garfinkel, Dr. Bruce Crise, Dr. Stephen Hughes, Dr. Melinda Hollingshead

Others in attendance: Dr. Scott Keimig, Dr. Kunio Nagashima, Ms. Kristen Pike, Ms. Cara Leitch

Dr. Morin called the meeting to order. The August minutes were sent out by email for review. A vote will be taken via email in one week.

LMT Screening Process

- Ms. Kristen Pike from the Laboratory of Molecular Technology (LMT) spoke about the 10-panel human pathogen screen service. Testing assays are performed via DNA extraction. LMT receives only established cell lines, not clinical samples.
- The JCV screen originated with Dr. Matt Gonda and DTP DCT. For JCV, most samples are negative, although by age 14, most folks (85%) are positive for JCV.
- HCV and EBV screens were added later.
- LMT does obtain positive samples for MMLV, EBV, but most samples are negative for the 10 viruses
- The cost of the 10-panel screen is currently $297 or $24 per each virus requested separately. There may be a potential change in cost with new testing

requirements.
- There is a need to further define the purpose of the safety testing and if it is working or useful information.
- Questions from the IBC:
    - Is virus in sample a marker for something else that will affect the experiment (is the sample contaminated and with what)?
    - Will that contaminant negatively affect the sample and assays to be performed?
    - How often does LMT see positive results for a contaminant and what are those contaminants?
    - Is there an SOP for positive results?
    - What does the profile look like?
    - Provide a list of all testing and how it's carried out.
    - What about RNA viruses? If a DNA assay is being run, then RNA viruses would not be detected with this assay; therefore, this assay cannot detect HCV or other RNA viruses.
    - Would the LMT consider developing an alternative assay so that RNA viruses could also be part of this screening process? What is the ability to add other viruses to the screening test?
- Ms. Pike will get back to the IBC regarding the questions listed above.

NEW BUSINESS

08-54 (Nagashima) "EM Virus Diagnosis Shared Service"
- This is a service study provided by the Electron Microscopy lab that provides virus diagnosis for NCI and NIH investigators.
- All samples are chemically inactivated by 4% formaldehyde and/or 2% glutaraldehyde prior to receipt.
- The IBC requested that the PI verify that the fixative has been applied to the material. The PI addressed this question prior to the IBC meeting.

Dr. Baseler made a motion to approve, Lucien Winegar seconded, and all were in favor.

08-58 (Hurwitz) "Isolation of Leukocytes from Human Prostate Specimens"
- This protocol involves tissue disruption with fresh human tissues that are not screened for pathogens.
- It was recommended that HIV surveillance be offered to employees working with this material since it is not screened.
- PI should elaborate on how the clinical material is kept separated from other work in the lab (i.e. lentivirus).
- The use of glass slides in combination with unscreened samples may pose an additional hazard. An alternative method for tissue disruption should be implemented. If an alternative to glass slides for tissues disruption is not agreeable, special gloves or plastic holders or "sleeves" to secure and handle

slides would be needed to protect hands and avoid cuts and further injury with the sharps hazards posed by the use of glass slides.
- Can more information regarding the samples be obtained? Can the sample material be screened?

Dr. Baseler made a motion to approve pending an agreeable solution to safely disrupting tissues, Dr. Derse seconded, and all were in favor.

RENEWALS

08-57 (Ruscetti) "Molecular Basis for the Pathogenesis of Murine Retroviruses"
- This protocol involves the use of multiple agents, viruses, recombinant retroviruses, oncogenes, and human and animal cell lines.
- Question A3 needs to be completed to demonstrate acknowledgement and appreciation for hazards apparent in the research material (use of known oncogenes, human cell lines, etc. in conjunction with injections and sharps).
- Appropriate waste disposal procedures must be addressed.
- Questions B6 states that there is no documented biological hazard – this is not true.
- Additional information is needed regarding the research activities associated with the immunotoxin.

Dr. Derse made a motion to conditionally approve pending resolution of the above issues, Dr. Kozlov seconded, and all were in favor.

08-59 (O'Keefe/ McMahon) "Recombinant Engineering of Anti-Viral Proteins"
- This is a recombinant bacteria study involving BL21 and its derivatives.
- No issues were identified with this study.

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

OUTSTANDING ITEMS
- 08-31 (Whitby) – PI is resubmitting the registration

- 08-53 (Wang) – EHS coordinating training session for *Listeria monocytogenes*

- Amendment of 07-09 (Wolff) – PI to address IBC questions

- Amendment of 06-90 (Wiltrout) – EHS is coordinating a training session for Diphtheria toxin. Dr. Creekmore asked Ms. Peugeot a question regarding Diphtheria toxin and how many of those immunized actually have active titers. He also questioned the pharmacokinetic challenge dose. Ms. Peugeot said she

would continue to do more research, and OHS/EHS will conduct training prior to initiation of research activities.

OTHER BUSINESS

- Adenovirus training was requested for animal care staff working in Buildings 550 and 553. Dr. Kozlov requested the training for those working in the animal facility in Building 538 as well.

- The Bloodborne Pathogen Program is 96% compliant.

- No potential biological exposures were reported this month.

The meeting ended at 1:20 p.m.

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Theresa D. Bell, MPH, CBSP	Ms. Cara Leitch
IBC Secretary	IBC Coordinator
Biological Safety Officer, EHS	Sr. Safety Specialist, EHS

APPROVED:

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

xc: Dr. Reynolds
Mr. Wheatley
Dr. Arthur
Mr. Bufter