



**NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes
April 15, 2008
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:02 p.m. in the Building 549 Executive Boardroom with the following members in attendance:

Ms. Theresa Bell, Secretary	Dr. Stephen Creekmore
Dr. Randall Morin, Chair	Dr. Stephen Hughes
Dr. Melinda Hollingshead	Mr. Lucien Winegar
Dr. Bruce Crise	Dr. David Derse
Dr. Dan McVicar	Mr. Scott Jendrek
Ms. Dianna Boissey	

Members not in attendance: Dr. Mike Baseler, Dr. David Garfinkel, Dr. Henry Hearn, Dr. Eric Freed, Dr. Serguei Kozlov, Ms. Alberta Peugeot

Others in attendance: Dr. Scott Keimig, Mr. Mike Stockman, Ms. Cara Leitch

Dr. Morin made a motion to vote the potential new IBC members into the Committee, and all were in favor. New IBC members include Dr. David Derse, Dr. Eric Freed, Dr. Serguei Kozlov, and Mr. Scott Jendrek.

NEW BUSINESS

08-25 (Anderson) "Expression of K-ras Variant 4A"

- This study involves using mutant forms of RAS and standard plasmid DNA.
- Human cell lines, CMV and SV40 promoters are in use but are used in vitro only. Human pathogen testing is recommended, but not required.
- B5 says "Yes" but should be "No".
- B5e should be corrected to reflect the use of standard transfection systems and no virus.
- D5 should be "No".

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

08-26 (Anderson) “Human Lung Adenocarcinoma Cells for Xenograft Studies of Nitric Oxide-Releasing Drugs”

- Human tumor lines (human lung adenocarcinoma) are used for tumor development and histology.
- This study involves no rDNA.
- Injections will be performed in the BSC and with techniques to prevent needlesticks.
- Ensure use of BSC versus CFH to protect the operator.
- Screening is not an issue since the hazards are being minimized through the use of engineering controls.

Dr. Crise made a motion to approve with the modification noted above, Dr. Hollingshead seconded, and all were in favor.

08-23 (Hornung) “Isolation of Blood Products for Vaccinia Vaccinated Volunteers and the Study of the Induction of Cytokines Post Vaccinia Inoculation”

- This work will be conducted in a BSL-2 lab with BSL-3 practices and procedures.
- The paperwork is good; however, there are specific concerns regarding vaccination requirements for the individuals working with the material.
- The individual who is medically contraindicated cannot work with the material. Employees should not have the right to elect to expose themselves to risk. If employee is hypersusceptible, they are not permitted to perform the work.
- Blood samples will be received as early as 3 days post vaccination.
- The IBC recommends the two individuals who are not medically contraindicated to consider being vaccinated. If either or both decide on receiving the vaccination, the PI must address how they will be kept separated from the individual who is medically contraindicated, until the scabs from the vaccination fall off completely (usually about 2 weeks).
- An explanation of how the vaccinia work will be kept away from the individual who is contraindicated must be provided (temporally and physically). Will there be a dedicated BSC to conduct the work in? What work is conducted in the BSC versus on the benchtop (this includes what equipment is being used and where)? How will equipment (specifically the Elisa machine) in the lab be decontaminated after use with this material? Vaccinia is long-lived on surfaces so decontamination is of the utmost importance if she will be sharing space in the same lab area.

Dr. McVicar made a motion to defer approval until issues above are resolved, Dr. Crise seconded, and all were in favor.

AMENDMENTS

07-10 (Cuttitta) “Breeding of Transgenic Mice having TET ON/OFF Overexpression of Adrenomedullin or Aryl Hydrocarbon Receptor Repressor Genes in Targeted Organs”

- More information is needed from the PI before approval can be granted.
- PI must acknowledgement regarding mobilization of the vector by endogenous mouse viruses and when cells are removed from mice, they could have virus in them.
- Animal facility location is to be determined.

This amendment is being handled by IBC subcommittee. No motion needed.

OPEN ITEMS

- Ms. Bell briefed the IBC on the outstanding items.

OTHER BUSINESS

- Discussion ensued regarding the award fee comments and concerns with the operations and efficiency of the IBC. Ms. Bell responded to all of the IBC/EHS Biosafety comments explaining IBC procedures, requirements, and the rationale to support them.
- The Bloodborne Pathogen Program is maintaining a compliance rate of 99.2%.
- OHS reported a needlestick injury involving a metastatic human breast cancer cell line to an NCI/NIH employee who was working in building 571. OMS was contacted by OHS to report the incident. EHS will follow up with an accident investigation in accordance with NIH DOHS. It was discussed that the employee injured was frustrated as part of the procedure was not going well. The IBC agreed that when employees become frustrated for whatever reason, the best recommendation is to walk away from the work and take a break. Frustration and distraction usually lead to further errors and make way for accidents.
- Several alternatives to the IBC renewal process were discussed. These changes included revising the renewal time period of every 3 years. The overall consensus of the committee was to continue with the 3 year renewal process in agreement with ACUC 3-year renewal procedures. The renewal date would be on the anniversary or approval date of the originating document. An additional contributor to the justification for continuing the renewal process is so the committee will continue to be current so when regulations change, adjustments to comply should only be minor. The recommendation to perform annual updates to IBC registrations was made initially to replace the renewal process, but the committee seemed to agree that the annual update was a good idea, but that renewals needed to continue. Focused laboratory inspections were also discussed in that BSL-2 laboratories using BSL-3 practices and procedures should be performed independently of the regularly scheduled EHS annual lab inspections.

The meeting ended at 1:38 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