



**NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE**

Minutes
December 16, 2008
NCI-Frederick

The NCI-Frederick Institutional Biosafety Committee was convened at 12:07 p.m. in the Building 549 Board Room with the following members in attendance:

Dr. Randall Morin, Chair	Dr. Dan McVicar
Dr. Bruce Crise	Ms. Alberta Peugeot
Ms. Renee Kahn, IBC Administrator	Dr. Michael Baseler
Ms. Theresa Bell, Secretary and Biosafety Officer	
Dr. David Garfinkel	Mr. Lucien Winegar
Dr. Eric Freed	Dr. David Derse
Dr. Stephen Hughes	Ms. Dianna Conrad
Dr. Hollingshead	Dr. Serguei Kozlov

Members not in attendance: Mr. Scott Jendrek, Dr. Stephen Creekmore, Dr. Henry Hearn.

Others in attendance: Dr. Scott Keimig, Dr. Robert Thomas, Dr. Rachel Bagni (Biomarker testing group leader in the Virus Technology Laboratory), Dr. McVicar's student, Mr. Peter Gorelick, Dr. Hsieh.

MINUTES

November minutes will be completed and distributed by email for review and approval by email vote in the upcoming weeks.

October minutes were reviewed and approved by an email vote on December 3, 2008.

NEW BUSINESS

-Human Pathogen Screen discussion:

One of the main focal points in determining human pathogen screens required by the IBC is based on available treatments should someone be potentially exposed. HIV, Hepatitis B and C would definitely require treatment. The availability of or need for treatment for exposures to EBV, HTLV 1/2, SIV and Herpes Simplex Virus would be determined on a case-by-case basis. Given the immediacy of these exposures a known treatment would need to be determined ahead of time prior to commencement of work activities and be made readily available should an exposure event occur.

Cell lines need to be screened for HIV prior to injection into animals. Too much information is better than not enough. There is also a cost issue associated with this screening requirement that must be taken into consideration. SIV may also be added to the screening panel. There are University's that offer this testing service as well as research programs within NCI-F that may also have these capabilities. A representative from the VTL mentioned that assays could be developed in-house to accommodate necessary screening tests at a minimal cost to the programs.

The IBC Secretary will send a list of requested pathogens for screening to the VTL for assay development and feasibility as well as costs. External service providers will also be pursued for comparison purposes.

The clarification was also made that there is a difference between a cell line that is only being propagated in vitro versus a primary human cell line being injected into an animal. When the materials are being injected into animals it is imperative to identify as many potential hazards as practicable. Before considering a final policy on screening requirements, it must also be considered that material can be handled and treated as if it is infectious until results are returned documenting otherwise, so not to hold up research activities pending screening results.

REVIEW OF PROTOCOLS

NEW IBC REGISTRATIONS

08-73 (Dr. Kurdziel) *Evaluation of a multimodality imaging parameter correlation in human MNNG/HOS-LUC osteosarcoma metastatic lung tumor mouse model*

- Still need to obtain comments from one of the lead reviewers
- Provide more details on how the cell lines were generated
- Answer E7

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

08-76 (Dr. Colburn) *Proteomic analysis for serum markers of efficacy of dietary intervention*

- A3 needs more detail to show that they understand what the hazards are associated with these samples
- A5a: This verbiage needs to be transferred into a lab-specific SOP, with a statement for employees to acknowledge that they have read and understand the specifics in the SOP, as well as the reference documents mentioned in the SOP.
- The lead reviewer would like to review the SOP prior to issuing final approval.

Dr. Baseler made a motion to approve pending resolution of the items above, Dr. Morin seconded and all were in favor.

08-71 (Dr. Jin/Dr. Wang): Transcription Regulation in *E. coli* and *H. pylori*

- 70 % ethanol is not appropriate for spill clean-up
- the in-vivo portion of the research needs to be clarified by Dr. Wang (Part E needs work)
- How will the infectious material be loaded into the gavage needle?
- A1 requires clarification as to what exactly is being done
- A2: identify the source of the bacteria (*H. pylori*)
- Provide an SOP for both the in vitro and the in vivo portions of the protocol
- Is the *H. pylori* being modified?
- Clarify C3a.
- Are aerosol hazards created?
- Should animals be housed in microisolators and cage changes occur in biological safety cabinet or other approved cage changing stations?
- B10 mentions blending, mixing, and sonicating-where will this occur and with which materials?
- Provide the SOP from the animal facility for the injections to verify technician training and that injections (or gavage in this case) are done safely, if applicable.

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

08-72 (Dr. Keller): Recombinant DNA

No modifications are necessary to this registration.

Dr. Kozlov made a motion to approve as written, Dr. Crise seconded and all were in favor.

08-74 (Dr. McVicar): Signal Transduction of Leukocytes

This project involves no virus and is very straightforward.

-Clarify A4

Dr. Hughes made a motion to approve, Dr. Freed seconded and all were in favor. Dr. McVicar abstained from the vote.

AMENDMENTS

06-66 (Dr. St.Croix) Anthrax Lethal Factor and Protective Antigen

- More information is needed in A1 regarding the anthrax toxin Lethal Factor and Protective Antigen and mixing of these components. It appears they will be treating tumor-bearing mice and attacking the tumor.
- What is the toxicity associated with the mixture?
- How should the material be handled (if differently) after it is mixed?
- 20 mL seems to be a large volume.

- How will injections be done safely and will mice restraints be used.
- Part C of the IBC registration form needs to be completed.
- It was clarified this does not involve any select agent issues.
- What does affect humans and would treatment with anti-toxin be warranted in the unlikely event of an exposure?
- More information should be obtained from the source provider of the material(s).
- How will the mixture be disposed of and/or neutralized?
- How will the mixture be put into the syringe?
- C10 should note the toxin will be inactivated prior to disposal
- Animals can possibly shed virus so bedding and cage changing should be handled appropriately.

Dr. McVicar made a motion to defer approval pending resolution of the outstanding issues, Dr. Crise seconded and all were in favor.

06-107 (Dr. Wakefield)

- This amendment has been sent out for comment to lead reviewers today, 12/16/08.

OUTSTANDING ITEMS

- Amendment of 07-09 (Dr. Wolff): PI returned responses, with IBC for further review.
- 08-31 (Dr. Whitby): Waiting on responses from PI.
- 08-57 (Dr. S. Ruscetti): With IBC reviewers for comment. There are still some unanswered questions regarding oncogenes and there are clarifications needed between the text and the appendices.
- 08-68 (Dr. Hu): PI will resubmit after clarification from lead reviewers on outstanding issues to resolve.

OTHER BUSINESS

Renewals and modification requests: Dr. Hughes made a motion to defer approvals for modifications or amendments sent to the IBC until any applicable out-of-date IBC document (current within the last 3 years) is renewed and approved. Dr. Crise seconded and all were in favor. This new IBC policy will be enacted January 1, 2009.

BBP Compliance: 99.97 % compliant (25/1092)

Human Pathogen Screening: Requests have been made to IBC members for their selections on which pathogens are appropriate for screening requirements.

Informed consent: Informed consent document may be renamed and will be distributed to IBC members for further comments and edits. Document will also be routed through Human Resources and Corporate Legal for further clarification and edits.

Vaccinia protocol: A recently approved IBC registration covering work with vaccinia in blood samples was brought up for reconsideration from the PI, given that all of his staff have been determined to be medically contraindicated to receive the vaccination. The

IBC has decided to maintain their original vote to require immunization to process these blood samples, given data that 4/200 samples were shown to be positive for active viremia in the blood. This information will be relayed to the PI through Occupational Health Services given this is a medical issue.

OHS Accident Update: An employee was working with blood samples from HIV infected patients, loading the sample into a Nexcelom Cellometer™ slide and removing the slides from the BSC to read them on a cell counter. The employee was preparing to discard the slide samples for the day when a slide went under the edge of her fingernail bed, separating the skin from the nail bed. There was no bleeding, although the slide did compromise the glove. The employee was instructed that double gloving and changing of the gloves frequently is recommended and the slides should be kept in the BSC at all times. Methods for discarding the slides should be reconsidered to avoid future incidents of this type, perhaps using mechanical means to pick up and discard the slides. Although the slides have small circular windows into which the sample is deposited, it is possible for the sample to splash out of the slide or for contamination on other portions of the slide to occur. EHS will follow up on this issue through accident investigations.

Meeting was adjourned at 1:55 p.m.

Theresa D. Bell, MPH, CBSP
IBC Secretary
Biological Safety Officer, EHS

Ms. Renee Kahn
IBC Administrator
EHS

APPROVED:

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

Date

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