



NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE

Minutes
August 18, 2009
NCI-Frederick

INTRODUCTION

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

Dr. Dan McVicar, Chair; Ms. Theresa Bell, IBC Secretary and Biosafety Officer;; Dr. David Garfinkel; Dr. Serguei Kozlov; Ms. Dianna Conrad; Dr. Bruce Crise; Mr. Lucien Winegar; Ms. Alberta Peugeot; Dr. Stephen Hughes; Dr. Melinda Hollingshead; Dr. Randall Morin; Reverend David Betzner; Dr. Michael Baseler; Dr. David Derse

Members not in attendance: Dr. Stephen Creekmore; Dr. Eric Freed; Mr. Scott Jendrek; Dr. Henry Hearn

Others in attendance: Ms. Karen Barber; Dr. Scott Keimig; Dr. Robert Thomas

Dr. McVicar took over this meeting as the new Chairperson for the IBC. Dan discussed some future goals for the committee relating to how we can function better, relative to ACUC operations, and provide a more supportive versus a regulatory role. Future discussions will be necessary to determine methods for enforcing IBC registration requirements and program compliance with Standard Operating Procedures and laboratory practices. EHS will serve the compliance and enforcement requirements with respect to IBC registrations. Dan will be meeting with each IBC member individually to discuss the list of recommendations previously distributed for consideration and comment from Dr. Reynolds.

A key issue discussed was the intention to hire a dedicated IBC Administrator and Dan encouraged member participation in the candidate review and selection process.

There will also be future meetings to determine action items, prioritize those items, and document a rationale for priority rankings.

MINUTES

Meeting minutes are posted on Sharepoint for member review. A vote for approval will be collected.

REVIEW OF PROTOCOLS

NEW IBC REGISTRATIONS

09-38 (Dr. O'Brien) *Human genetic analysis.*

- A1 mentions no pathogenic virus but HIV, EBV, and Hepatitis B and C are mentioned later in the document. This will need clarified.
- Sharps are indicated. Does glass have to be used and if so, how will accidents be avoided and what will be done if an accident occurs?
- They actually suggested separating the registration into two parts:
- Work involved in isolating DNA from various tissues/cells/fluids that may contain pathogens. This work seems straightforward and SOPs are adequate.
- The EBV work. This is incompletely described as far as growing the virus, infecting target cells, generation of stable cell lines. Pathogenicity of EBV, safety measures in place, and protocol for treating an exposure should be provided.
- Does the lab have any rDNA or plasmids present?
- D6a needs to be addressed.
- Provide documentation that LGD verifies shipper training before permitting collaborators to send shipments.
- In addition, the IBC requests safety related protocols identifying how procedures will be conducted safely to include the safety equipment, engineering controls, sharps handling, PPE, and risk mitigation procedures (especially for hazardous activities as noted in the IBC document (i.e. "wear heavy gloves to protect hands and safety glasses or face shield in case of exploding vials" when generating viable freezes of cells from infectious materials).

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

09-39 (Dr. Olivo-Marston) *Studies with miR-21 genetically modified mice.*

- Part B should be completed since recombinant DNA is used to construct the miR-21 transgenic line. -A brief description of the transgene would be needed as well; If you are not involved in making the Tg mouse strain, then you can ignore most of the questions below since they all really pertain to the hazards associated with the Tg mouse model, which should be covered by 09-02. Dr. Trivers would just be handing these mice off to you for the purposes of this study. Correct me if my interpretation is not accurate. I have the information on the strain's transgene from Dr. Triver's registration also. Let me know.
- The answer to question E6 is a clear 'yes' with all sub-bullets to be addressed. Also in this section – GEM animal line is involved and an appropriate Strain

Supplementary form needs to be completed (this form is on the IBC web page listed as supplemental strain form);

- The study duration should be more specific. “minimum of one year” in E10 – should this be assumed as the maximum? Will we be notified once breeding activities are no longer ongoing since IBC and ASP documents are valid for a period NTE 3 years? Time and end points which are clearly defined more accurately reflect what needs to be accomplished in the study;
- Research Locations – what is being used in 571? An animal facility, a BSL2 lab, or both? Can you further complete Addendums 1 and 2 (employee roster and research locations).
- Employee Roster – will everything be done by one animal tech and one CRTA fellow with no other LASP personnel/animal folks in the picture?? Can you specify who will perform the injections and will they be trained according to LASP SOP? If you cannot the animal facility manager may be able to tell us this. We really just need to know if you will be the one performing the injections or if LASP staff up here will do so.
- Is there another PI under which these breeding activities will be conducted?

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

09-41 (Dr. Anver) PHL- Human sample processing.

- In D9a it is documented that a chemical fume hood will be used for processing samples. This is acceptable provided that sterility of the specimens is not a requirement.
- The committee suggested that PHL limit the number of samples processed simultaneously or install more air to accommodate additional exhausted containment enclosures. There has been documentation in the past of overexposures of personnel to formaldehyde (Dec. 4, 2006) although more recent sampling indicated no overexposure on July 17, 2009.
- It has been requested that all personnel in PHL working on these specimens be enrolled in the HIV surveillance program, since they have the potential to come into contact with human tissue containing HIV.
- For questions D4 and D5 the answers should be “YES” only.
- Why is the nanoparticle work separated out from other work?

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

09-42 (Dr. Jagoda) Breeding only protocol.

- Provide supplemental strain information sheet.

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

09-43 (Dr. Stevens) Respository for clinical trials.

- Is the outside of the primary container decontaminated and how?
- D9a should include a provision that if there is a visual problem with a parcel received, the package will be opened in a BSC first.
- Confirm that the program verifies the shipper's compliance with all applicable regulatory requirements and may want to request that shipper wipes outside of primary containers with disinfectant prior to shipment.
- Appropriate PPE will be worn and all materials handled as BSL-2, as if potentially infectious.

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

RENEWALS

09-40 (Dr. Dewar) Renewal of IBC #07-05 and addition of flu virus strains.

-A statement was added to confirm that those employees suspected or confirmed to have the flu, will not be permitted to perform this work activities until they are well. An OHS evaluation for those questioning their health status may be required.

Dr. Derse made a motion to approve this renewal document, Dr. Hughes seconded and all were in favor. Dr. Baseler abstained from the vote.

AMENDMENTS

08-36 (Dr. Sayers) – pending PI submitting amendment request.

06-109 (Dr. Bustin) – pending PI submitting amendment request.

06-76 (Dr. Hughes/Rein) – pending edits for clarification.

06-102 (Dr. Kuehn) – pending PI submitting amendment request.

09-11 (St. Croix) – pending PI submitting additional information.

All other amendments submitted at this time have been approved.

OUTSTANDING ITEMS

Updates were provided to the Committee by Ms. Bell.

OTHER BUSINESS

BBP Compliance: 95%

OHS Accident Update:

2 needlesticks and 1 near miss with a sharp were reported by Ms. Alberta Peugeot, OHS.

Human Pathogen Screen Update:

-The human pathogen screening should transition from AHDL to MGD sometime Fall 2009. Updates will be forthcoming.

XMRV:

XMRV and new research protocols associated with this “up and coming” virus were discussed. The brief discussion focused on recommended biocontainment levels, practices and procedures for work with this material.

Principle Investigator responsibility for IBC registrations:

The IBC discussed the importance of having a Principle Investigator sign off on all IBC registration documents, especially if a post-doc, CRTA, or other research associate is submitting the paperwork. Ultimately, the PI has the responsibility for those individuals and the laboratory itself and they should be aware (and sign off) on all work associated with their laboratory.

The meeting was adjourned at 2:15 p.m.

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

Date

APPROVED:

Dan McVicar, Ph.D.
Chairman, NCI-Frederick IBC

Date

- xc: Dr. Reynolds
- Mr. Wheatley
- Dr. Arthur
- Mr. Buffer