



NCI-FREDERICK
INSTITUTIONAL BIOSAFETY COMMITTEE

Minutes
March 17, 2009
NCI-Frederick

INTRODUCTION

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

Dr. Randall Morin, Chair

Ms. Renée Kahn, IBC Administrator

Ms. Theresa Bell, Secretary and Biosafety Officer

Dr. Michael Baseler

Mr. Scott Jendrek

Dr. Stephen Creekmore

Dr. Serguei Kozlov

Dr. Bruce Crise

Dr. Stephen Hughes

Dr. Eric Freed

Ms. Alberta Peugeot

Dr. David Garfinkel

Mr. Lucien Winegar

Members not in attendance: Dr. Henry Hearn, Dr. Melinda Hollingshead, Dr. David Derse

Others in attendance: Dr. Scott Keimig, Dr. Rachel Bagni (VTL), Dr. Jim Hartley

MINUTES

-February 2009 minutes will be sent to members and a vote will be collected through email.

REVIEW OF PROTOCOLS

NEW IBC REGISTRATIONS

09-13 (Dr. Hartley/Troy Taylor) *Growth of microorganisms recombinant DNA's*

- Large scale procedures will be in use but the document does not mention the large scale risks and how those risks will be mitigated.
- Identify methanol quantities to be used.
- What is the method used to dispose of fermentation broth?
- All of the small scale issues with materials with less than 2/3 of the genome are acceptable.
- The document cannot exclude all viral elements.
- The document must describe how work will be performed safely at all times with all materials in order for the IBC to grant a broad scope permission.
- Procedures must be in place to address spill response and how spills will be contained (with respect to large scale operations).
- Clarify restrictions of what will not be done.
- Clarify that no virus will be reconstituted by recombination reactions.
- Refer to BDP SOP's with Mr. Jendrek providing guidance since the SOP's currently in place need updating.
- Clarify in A1 that these are standard laboratory microorganisms and that the operations are restricted to BSL-2-Large Scale and Risk Group 2 agents.

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

09-07 (Dr. Durum) Regulation of BCL-2 family members by IL-7 in mouse T cells

- Identify aerosol hazards and provide a spill SOP
- Answers to questions need to be provided by the PI, procedures clarified, as the document is written it is unclear what is being done and how it will be done safely.

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

09-15 (Dr. Mackem) Analysis of mice with genetically altered developmental regulators controlling morphogenesis

- This is a good registration document, and no changes are needed. This is for breeding only.

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

09-16 (Dr. Mackem) Analysis of developmental regulators controlling vertebrate morphogenesis

- There is one outstanding question regarding the RCAS Vectors. There is a statement made in A2 of the registration that "RCAS vectors only infect avian cells and cannot infect mammals, including humans." Please clarify that the strains being worked with are to be inserted into chicken embryos or cells and only have the potential of integration into

chick cells or embryos. There are RCAS vector systems that are capable of insertion into mammalian cells depending upon their envelope. The strains that are specific to only avian species would be classified as requiring BSL-1 containment; however those strains of RCAS vectors that would infect mammalian species/cells would require BSL-2 containment, practices and procedures. In B5f1 and A2 please specify the specific strains of RCAS vectors for use and verify that they would only be capable of infecting avian cells.”

Dr. Hughes made a motion to approve, pending receipt of the above clarification, Dr. Crise seconded and all were in favor.

RENEWALS

09-06 (Dr. Durum) Regulation of T-lymphocyte development by IL-7

- The responses provided to the questions in an email do not match existing information already in the proposed registration document.
- Clarification is needed with respect to recombination with MuLV and why this is not relevant with respect to lentivirus.

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

09-08 (Dr Gril/Dr. Steeg) Effect of Pazopanib on primary tumors from breast cancer and melanoma cell lines

This registration requires the following clarifications:

- B5a states that apart from viral transduction of the cell line done 5 years ago "no further viral transduction steps will be performed under this IBC registration" (last sentence of their B5a). However B5e3 answers "yes" to the question of whether viral vectors infectious for humans will be used. The answer to this section should be 'no'. Under B5e3 and B5e4, are you planning to use the amphotropic viruses to deliver ErbB2? From the rest of the paperwork, it appears you are using a plasmid (not viral) delivery system and cell lines which were transduced with the virus 5+ years ago. Please clarify.
- Bf51 is still in contrast to E6g and A3-- both state that mobilization may occur. B5f1 should be answered “Yes”, and then explain that endogenous virus in the nude mouse host may serve to mobilize the vector.
- E6 needs to be answered yes. The recombinant material is going into the cells which are then going into animals.
- E6a and E6a1 need to be answered yes: (mobilization by endogenous viruses may lead to transmission to the mouse).
- E6b should be answered yes (because human cells are susceptible to infection by endogenous viruses from the mouse).
- E9 needs to be corrected. Injections performed with a transformed cell line are a distinct hazard; the retroviral vector in the human cells can recombine with endogenous viruses if infected after injection and/or the vector can be mobilized.

Dr. Kozlov made a motion to approve pending receipt of responses to the above issues, Dr. Crise seconded and all were in favor.

09-11 (St. Croix) Generation of DNA vectors for functional analysis of various endothelial markers

-One minor recommendation was made to dispose of tips into a bleach bucket in lieu of the suggested baggies, which could be punctured.

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

AMENDMENTS

09-04 (Salcedo) Role of immune responses induced by haptans of Colitis and colitis-induced colon cancer

-Verify the same handling procedures will be used as outlined in the original registration 09-04.

-Will multiple mice be injected from the same syringe and needle? Will injections be pooled?

Dr. Creekmore requested the responses to the above items before issuing an approval.

All other amendments were approved outside of committee meeting.

OUTSTANDING ITEMS

-Amendment of 07-09 (Dr. Wolff): Waiting on responses from PI.

-08-71 (Dr. Jin and Dr. Wang): Working with PI to make changes on IBC documents.

OTHER BUSINESS

BBP Compliance: 97.9%

Human Pathogen Screening:

Dr. Rachel Bagni attended the meeting representing the VTL. The VTL will be providing the IBC with a summary of their in-house screening capabilities, turn-around time, costs, and how samples are to be submitted. Once the IBC receives this information from the VTL, a summary document including both University of Missouri and VTL screening capabilities will be provided to Dr. Reynolds for review and comment.

Risk Acknowledgement Statement Status:

-SAIC has reviewed and approved a format for this risk statement. A similar document has been edited and submitted to SAIC upper management for review and concurrence prior to being submitted to the NCI for consideration and comment.

OHS Accident Update:

Nothing to report this month.

Outside IBC Member:

The IBC currently has two community members and had decided to pursue a third outside community member. This will help to ensure that we ensure attendance of community members at every meeting. Suggestions have been received and Dr. Morin will contact these individuals to determine their interest in IBC membership.

Review Charter:

The IBC Charter will be sent to members to collect final comments.

The meeting was adjourned at 1:45 p.m.

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

Renée 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. Bufter