

Final
University of Washington
Institutional Biosafety Committee

Ad-Hoc Committee Meeting
Wednesday, July 20, 2005
1:00 – 3:00 pm
SCC 354
Meeting Minutes

Members Present: Michael Agy, Washington National Primate Research Center
David W. Emery (IBC Chair), Medicine / Medical Genetics
Mary Lampe, Laboratory Medicine
Stephen Libby, Laboratory Medicine
David Russell, Hematology
Paul Swenson, Seattle-King County Dept. of Public Health
Donald Wang, ZymoGenetics
Bruce Whitney, Environmental Health and Safety (BSO)
James Woods, Environmental & Occupational Health Sciences

Members Absent: William Atkins, Medicinal Chemistry
Ashley Fleischman, ASUW Student Representative
Elaine Jong, HH Primary Care Ctr/UW Campus Health Svcs
Pamela Morris, Comparative Medicine
Carol Sibley, Genome Sciences
Estella Whimbey, Healthcare Epidemiology and Infection Control

Guests: Susan Alexander, Environmental Health and Safety
Patricia Azeltine, Environmental Health and Safety

Handouts: Powerpoint Presentation
IBO Reports

1. CALL TO ORDER

1a. Chair David Emery called the meeting to order at 1:06 p.m.

2. APPROVAL OF MINUTES from April 25, 2005 Meeting

2a. The minutes from the April meeting were unanimously approved as submitted to the membership.

3. ADMINISTRATIVE/INFORMATION UPDATES

3a.

Responding to community concerns over the recently proposed regional biocontainment laboratory, the University of Washington is planning for two additional public members to the membership roster. The goal is to identify candidates from the public sector who are knowledgeable about biological issues either in a general sense or with specific expertise that they could bring to the committee.

This increase in committee membership is in addition to the current need for an IBC member from the University with expertise in plant genetics. The Dean's Office is actively recruiting for candidates

and suggestions from current committee members should be directed to David Emery, IBC Chair, or Karen VanDusen, Director, Environmental Health & Safety.

3b.

Susan Alexander, Manager, Occupational Health & Safety, provided a powerpoint presentation on several pertinent issues:

- a. The recently established Research & Biological Safety (RBS) Office in EH&S
- b. Compliance questions involving SAGE
- c. Ongoing review and revision of the Research Project Hazard and Assessment form (RPHA)

4. SPECIFIC RESEARCH PROPOSALS

4a. Biosafety Officer Reports

There was no Biosafety Officer from Deanna Frost at the April 25th meeting of the IBC due to her recent resignation. In the interim, Susan Alexander compiled a report based on Deanna Frost's documentation covering the period September 18, 2004 through April 1, 2005. Bruce Whitney, as sole Biosafety Officer, has been approving both select agent and non-select agent projects. His report contains approvals covering the period of April 25, 2005 through July 8, 2005.

Bruce began by noting that his report contains a footnote that the only BL-3 approvals listed in the report are for renewals since the IBC administrative policy is that the BSO can only approve up to BSL-2. Bruce asked the committee's assistance in helping to clarify already existing but broadly stated policies in the EH&S Biosafety Manual regarding research involving cloning or inserting oncogenes into cells with vectors. What would the committee advise as to the appropriate biocontainment level? Should these protocols be presented to the full committee with specific criteria?

David Emery, Chair, acknowledged that the cloning of genes has been a recurrent safety issue. The most current information is available on the internet where a list can be found of genes that have been associated with human cancer such as the Sanger website.

Questions about biocontainment levels for research protocols involving genes on this list is a more complicated issue due to the number of different delivery methods. For example, plasmid genes are delivered by electroporation and the risk to the investigator does not increase because the chances of the gene entering their blood cells is imperceptibly small. A wild type virus known to infect humans and can integrate into the genome of the blood cells is already at a high level of biosafety containment. There is the gray area of replication defective viruses that can at some rate infect humans but don't actively divide and will not spread. Some of these viruses will integrate into the genome and are maintained after cell division while others are not maintained. A subcommittee will be formed to address these concerns and to develop an abbreviated list addressing the properties of delivery systems and their corresponding risk level.

David Emery had the following comments in regards to Deanna Frost's report:

Robert Richard's protocol (Gene Therapy for HIV Infection) was approved appropriately. The research involves growing small amounts of wild-type HIV. The material will be handled with BSL-3 practices within a BSL-2 facility. This was deemed appropriate for several other investigators at the UW at a previously convened meeting of the IBC based on the NIH standards. Dr. Richards has completed the process of developing a lab safety manual and training requirements. He is the first of several researchers with similar proposals who has completed this necessary step for IBC approval. Dr. Richard's lab safety manual has been reviewed and approved by Environmental Health & Safety. Committee members can obtain a copy of this manual for review from Bruce Whitney.

Deanna Frost's report also contains several approved proposals listed as BSL-3 and in each case these are re-approvals of previously approved protocols with one exception which is in error. Principal investigator, Nancy Haigwood's research proposal (Role of Neutralizing Antibodies in

Transmission of SHIV) has not been approved and is, in fact, the same protocol that appears on Bruce's more recent report under principal investigator, David Anderson.

4b. Principal Investigator: Oliver Press

Research Title: "A Phase I Study to Evaluate the Safety of Cellular Immunotherapy Using Genetically Modified Autologous CD-20 Specific CD8+ T-cell Clones for Patients with Relapsed CD-20+ Indolent or Mantle Cell Lymphomas"

Subcommittee Review and Recommendations

Dr. Press has submitted several significant changes to his clinical gene transfer trial. This trial involves the plasmid transfection of patient blood cells, the growth of these cells in culture for an extended period, and the reinfusion of these cells back into the patient. The project was last reviewed in the spring of 2004. The protocol was deemed very low risk, due in large part to the use of plasmid as the means of gene delivery and the delivery of the plasmid ex vivo. The changes, in essence, involves the modification of the enrollment criteria to include patients with other forms of lymphoma for which the therapy is relevant, modifications of the adjuvant chemotherapy consistent with these new forms of lymphoma, the addition of a second consent process, and the replacement of Dr. Press with Dr. Eric Chen as principal investigator. The changes in patient population and the principal investigator would not increase risk. These changes have been approved by the FHCRC IRB. David Emery, Chair, reviewed the changes and recommended approval.

A vote was called to approve/disapprove the protocol with its' significant changes and the results were as follows:

APPROVE: 9
DISAPPROVE: 0

5. ISSUES FROM THE FLOOR

5a. There were no issues from the floor.

Meeting Adjourned at 2:05 pm.

Meeting Minutes by Patricia Azeltine