FINAL

University of Washington
Institutional Biosafety Committee

Ad-Hoc Committee Meeting
Monday, April 25, 2005
1:00 – 3:00 pm
SCC 303
Meeting Minutes

Members Present: Michael Agy, Washington National Primate Research Center
David Emery (IBC Chair), Medicine / Medical Genetics
Ashley Fleischman, ASUW Student Representative
Elaine Jong, HH Primary Care Ctr / UW Campus Health Svcs
Stephen Libby, Laboratory Medicine
David Russell, Hematology
Carol Sibley, Genome Sciences
Paul Swenson, Seattle-King County Dept. of Public Health
Donald Wang, ZymoGenetics
Estella Whimbey, Healthcare Epidemiology and Infection Control
Bruce Whitney, Environmental Health and Safety (BSO)

Members Absent: William Atkins, Medicinal Chemistry
Mary Lampe, Laboratory Medicine
Pamela Morris, Comparative Medicine
James Woods, Environmental & Occupational Health Sciences

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

Handouts: Membership Roster
Powerpoint Presentation

1. **CALL TO ORDER**
   1a. Chair David Emery called the meeting to order at 1:08 p.m. Ashleigh Fleischman, ASUW representative was introduced as the newest member of the committee.

2. **APPROVAL OF MINUTES from December 14, 2004 Meeting**
   2a. The minutes from the December meeting were unanimously approved as submitted to the membership.

3. **ADMINISTRATIVE/INFORMATION UPDATES**
   3a. Deanna Frost (Institutional Biosafety Officer) submitted her resignation effective April 1, 2005. Environmental Health & Safety is actively recruiting for her replacement.
   3b. The proposed construction of a regional biocontainment laboratory at the University of Washington has generated immense interest both on and off campus. The U.W. has applied for a federal grant to construct this building in support of a Regional Center of Excellence for

biodefense and emerging infectious disease research. The review process for this building is proceeding in accordance with the regulations set by the NIH (the funding agency) and by the University Siting Committee. The issue has not formally come before the IBC because it is currently a UW application for the construction grant. Should the project receive funding it will then come up for review before the committee. The IBC is fully engaged in reviewing the research, given some preliminary recommendations and will continue to be involved in on-going review.
If contacted by the public or the press, IBC members have every right to discuss this issue and to feel free to do so. Interested parties may also be referred to Theresa Doherty, Assistant Vice President for Regional Affairs, Office of Regional Affairs and Tina Mankowski, Director, HS/UW Medicine News and Community Relations.

3c. The University of Washington Infectious/Biomedical Waste Management Plan has been under development and the committee has already reviewed two draft versions. This final draft was reviewed in depth by two IBC members: Pam Morris and Don Wang. Dr. Morris could not be present at today's meeting but has conveyed to chair, David Emery that she approves the plan. Dr. Wang also recommends approval. There was no further discussion by the committee, the vote was taken and the plan was approved unanimously.

4. SPECIFIC RESEARCH PROPOSALS

4a. Principal Investigator: David A. Saperstein
Research Title: An Open-Label, Phase 1, Single Administration, Dose-Escalation Study of AdGVPEDF.11D in Neovascular Age-Related Macular Degeneration (AMD), IBC reference number 1425-593

Brief Summary: This is a re-review of a clinical gene transfer. The study involves the injection of a replication-defective adenovirus vector for human pigment epithelium-derived factor (PEDF) into the eyes of patients with age-related macular degeneration (an eye disease). This project was originally approved by the IBC in June 2003. However, the trial was subsequently suspended by the PI, and in our September 2004 meeting it was decided that this project should be reviewed prior to re-initiation. In addition, Dr. Saperstein has requested to extend the study to include patients with less severe AMD.

Subcommittee Report and Recommendations: The revised application was reviewed by IBC members David W. Russell and David W. Emery. Dr. Russell's re-review summary states that he has read the revised Saperstein/GenVec protocol submitted for IBC review. This protocol is a revision of an already approved protocol for treatment of age-related macular degeneration (AMD) with an adenovirus vector expressing Pigment Epithelium-Derived Factor (PEDF) to inhibit angiogenesis. No major adverse events were noted in the original protocol. The revision extends this study to patients with less severe AMD. Dr. Russell recommends approval by the IBC of the revised protocol and Dr. Emery concurs with this recommendation.

The vote for the approval of this application was done electronically and the results of that vote are as follows:

15 APPROVE
1 ABSTAIN

4b. Principal Investigator: A. Dusty Miller
Research Title: Transduction of the Upper Airway Epithelium in Patients with Cystic Fibrosis by an AAV2 Vector that Encodes Human Alkaline Phosphatase

Brief Summary: This project involves the administration of a recombinant vector based on human adeno-associated virus, serotype 2 (AAV2) designed to express a reporter gene (human alkalin phospatase), into the upper airway (nasal) tissue in patients with cystic fibrosis. The goal of this trial is to establish the efficacy and safety of this vector in support of future trials in a which a similar vector designed to express normal human CFTR, the gene that is defective in patients with cystic fibrosis patients. The results of this trial will also be used in support of future trials comparing the

safety and efficacy of a similar vector based on AAV serotype 6. Recombinant vectors based on AAV are generally considered very safe and are approved for use at BSL-1. There are no outstanding safety issues with the proposal.

Subcommittee Report and Recommendations: The subcommittee consisted of Mary Lampe (IBC member) and William Osborne (ad hoc reviewer). Mary Lampe stated in her review that the vector has been shown to be safe. The AP gene is a normal human protein and should not stimulate an immune response. The study procedures carry a risk but patients are adequately notified in advance and have consented to participate in the study. Safety measures are extensive and patients will be monitored for life. Safety data will be reviewed and the study will proceed only if the initial dose levels are found to be safe. William Osborne, in his summary review stated that he had no concerns regarding the biosafety of this protocol to patients and staff. Dr. Osborne is in agreement with the deliberations of the NIH Recombinant DNA Advisory Committee and the review by the Data and Safety Monitoring Board. Both members of the subcommittee recommend approval of the protocol.

Mary Lampe could not be present at today's meeting but conveyed her approval of the proposal to chair, David Emery. There were two questions raised as to whether it had been reviewed elsewhere (yes, such as the RAC) and whether the Human Subjects Office had looked at it? (Yes, and will so again when the IBC gives final approval.) A vote of the committee was called (two members having recused themselves) with the following results:

9	APPROVE
2	ABSTAIN

The A. Dusty Miller protocol was approved by the committee.

4c. Biosafety Officer Reports

Dave Emery reiterated that research proposals that include human gene transfer or environmental releases, biosafety level 3 research or select agent research is reviewed and voted on by the committee. For all other research including biosafety level 1 and 2, the committee has set standards by which the biosafety officers provide administrative approval on behalf of the IBC and then notify the IBC with written reports. These reports are reviewed at the next meeting and a committee member can bring up any questions or issues.

Deanna Frost, Biosafety Officer, was responsible for the majority of these administrative reviews but has, as previously mentioned, recently resigned. The report consisting of approximately 74 biosafety level 1 and 2 protocols that Deanna has approved is not ready at this time. Environmental Health & Safety is working on completing this report and it will be available at the next committee meeting.

Bruce Whitney, Biosafety Officer, is predominantly responsible for research involving select agents and exempted select agents and toxins. There were two approvals since the last committee meeting of 12/14/04. One approval is for principal investigator, Michael Katze, for a biosafety level 2 protocol involving a mouse strain of influenza. The second approval was for a biosafety level 2 protocol involving human cell lines containing EBV with Melissa Austin as principal investigator.

5. IBC MEMBER TRAINING – David Emery

5a. Dr. Emery provided training on the function, responsibilities, and operating guidelines of the IBC committee as required by the NIH.

6. ISSUES FROM THE FLOOR

6a. There were no issues from the floor.

Meeting Adjourned at 2:00 pm.
Meeting Minutes by Patricia Azeltine