

**Mount Sinai School of Medicine
Institutional Biosafety Committee
July 10, 2008**

Minutes

Present: Drs. Wetmur, Daefler, Miller, Pullium, and Simon; Mr. Hauck; Mss. Erlitz, Strauss and Sadock

Also Present: Drs. Goldschlager, Lowen and Steel

1. **Approval of Minutes** -- Upon motion duly made and seconded, the minutes of the April 17, 2008 meeting were unanimously approved.

2. **Cell Sorting *ad hoc* Committee Report:** Until an appropriate facility is in operation at Mount Sinai, all sorting of live human cells must be done at the Aaron Diamond Research Center. The PI has agreed.

3. Project Reviews

a) GCO# Pending (Kalman) (Celladon Protocol No. CELL-001)

- i) The Committee unanimously voted to approve this project.
- ii) This project will use a commercially available AAV 1, circuit 2 vector previously approved by this Committee. All required documentation has been filed with the Biosafety office.
- iii) Mr. Hauck will issue the required notifications.

b) GCO# 08-0476 (Kim)

- i) The Committee voted not to approve based on the following:
 - (a) This non-recombinant virus may be shed for an extended period of time by an immunocompromised person.
 - (b) No indication of toxicity testing in primates.
 - (c) No indication of containment standards at BSL-2.
 - (d) Safety has not been established.
 - (e) No indication that baseline blood values would be obtained on workers or that workers would be informed of the risks.
 - (f) The sponsoring company should assume the financial burden of implementing the recommended precautions and procedures.
- ii) Procedures for handling polio virus should be required.
- iii) These concerns must be forwarded to the PPHS for review.
- iv) If the PPHS approves the project in the future, the IBC requests that it be re-submitted for Biosafety clearance.

c) GCO# 07-0475 (Sung)

- i) The Committee voted unanimously to approve this project.
- ii) The vector used for this project is a gutted, non-transmissible virus.

- d) **GCO#03-0058** (Palese et al.)
 - i) The Committee approved this project pending implementation of the specifications in item 5) b) below.
- e) **OBA Approval for NIH Protocol #0802-905** (Woo and Sung).
 - i) The Committee reviewed the OBA approval letter.
 - ii) The Committee will inform Drs. Woo and Sung that the IBC will verify compliance with the OBA specifications before work begins.
- 4) **Report on Potential Biohazard Exposure in the EPF**
 - a) The Committee reviewed the report of a potential exposure to a select agent when bio indicators showed that specimens in the autoclave had failed to achieve the temperature required for a kill. A special investigation determined that the autoclave had reached time and temperature as verified by other indicators-including condensate within the stacked containers; the determination of the investigating committee was that no exposure had occurred.
 - b) SOPs will be modified to require that rubber gloves and N-95s be worn when removing specimens from the autoclave in the "clean side" work area.
 - c) Since the room on the "clean" side of the autoclave is under negative air pressure (within the Secondary Containment of the EPF), this was not considered to be a reportable event.
- 5) **CDC Approval of Amendment to Registration**
 - a) On June 28, 2008, the CDC approved the EPF for projects working with 1918 influenza virus.
 - b) Dr. Daepler, as the ARO for the EPF is to arrange for baseline blood tests to be drawn on researchers before beginning work in the EPF and to provide TamiFlu for administration according to CDC regulations.
 - c) The Committee asked that the minutes reflect its appreciation for the efforts of Mr. Philip Hauck in superintending the process leading to this achievement.
- 6) **New Business**
 - a) The RAC will be notified that Dr. Wetmur is the Chair of this Committee and that Mr. Hauck is the Institutional Biosafety Officer.

Addendum

Revisions to GCO protocol# 08-0476; PI: Kim (item 3, b above) required by this Committee at the July 10, 2008 meeting were submitted to the Committee electronically for review. The revisions were approved by a vote of 4 yeas and 1 nay. Two Committee members did not respond.