

**Mount Sinai School of Medicine
Institutional Biosafety Committee
October 19, 2006**

Minutes

Present: Drs. Wetmur, Calfee, Linden, and Miller; Mr. Hauck; Mss. Strauss and Pollina

1. Approval of Minutes of July 20, 2006 meeting

- a. Upon motion duly made and seconded the minutes of the July, 2006 MSSM IBC meeting were approved.

2. Quorum

- a. Since neither external member of the Committee was able to attend this meeting, official decisions were deferred pending electronic communication if needed.
- b. Results will be posted as an addendum to these minutes.

3. Biomedical Research Alliance of New York (BRANY)

- a. BRANY IBC has been reviewing gene therapy protocols (only).
- b. As required by OBA, MSSM should designate BRANY as a secondary IBC. Effective immediately, the MSSM IBC will review all gene therapy protocols, as MSSM cannot delegate responsibility for lab inspections and on-site safety issues.
- c. The MSSM IBC will notify BRANY of protocol approvals and on-site compliance for BRANY-initiated studies.
- d. MSSM IBC will require MSSM researchers to provide the IBC with copies of all gene therapy trials submitted to BRANY

3. BRANY Protocol 06-02-234-05

- e. The October 11, 2006 BRANY IBC addressed this protocol, which had been approved by the BRANY IRB.
- f. The MSSM IBC was informed of the OBA response to this protocol.
- g. The Dean will be notified that the IRB and attendant study-design concerns expressed by the OBA may be a serious issue in this trial and the study should be referred to the MSSM IRB.

4. GCO #06-0978

- a. This study involves testing inhibitors for antiviral properties in Avian H5N1 flu and requires high doses of wild-type virus.
- b. Baseline serum levels and annual influenza immunization will be required of workers on this project.
- c. The protocol will not be approved until Investigator SOPs have been submitted and approved by the CDC.

5. Lentiviral Vector Guidelines

- a. Dr. Michael Linden polled several research institutions, presented his findings to the IBC and prepared draft recommendations, including that PIs using these vectors screen for replication competent virus by PCR or RT PCR using functional assays.
- b. All work except with oncogene recombinants can be performed at BSL-2.
- c. Oncogene studies will be reviewed individually.

6. NIH-OBA Site Visit – Exit Interview

- a. OBA was satisfied with the composition of the IBC.
- b. OBA reported that GemCris had identified 3 active gene therapy protocols although the MSSM IRB had reported to the IBC that there were none; this has been corrected by the IRB.
- c. PIs working on gene therapy protocols will be trained in responsibilities of conducting these studies.

7. Emerging Pathogens Unit

- a. The HVAC system is undergoing final adjustments.
- b. Training of users will be implemented; training certification will be reported to CDC.
- c. It is suggested that investigators be trained in BSL-2 procedures before training them at BSL-3.
- d. Protocols for handling animals at BSL-2 and then BSL-3 will be augmented for species specificity and included in SOPs for the Unit.
- e. IACUC will be consulted about implementation of training.