Mount Sinai School of Medicine  
Institutional Biosafety Committee  

July 22, 2009

Members Present: Drs. Wetmur, Bishop, Meseck, Simon; Ms. Erlitz and Mr. Wieder (by teleconference); Mr. Hauck.

Also Present: Mr. Maglione.

1) Approval of Minutes
   a. Upon motion duly made and seconded, the minutes of the May 21st meeting were unanimously approved.

2) Stem Cell Sorting Facility
   a. The facility is fully operational and used for sorting primary cells.

3) CDC Site Visit
   a. Mr. Hauck summarized some of the key feedback from the April visit:
      i. Inspectors recommended splitting the Standard Operating Procedures (SOP) into three sections: Security, Biosafety and Incident Response.
      ii. Emergency Management procedures were stressed.
      iii. Rigorous hand washing is encouraged.

4) Protocols
   a. Unanimous approval was given for the following studies:
      i. GCO #09-0367 (Judith Neugroschl) Double Blind, Placebo-Controlled (Sham Surgery), Randomized, Multicenter Study Evaluating CERE-110 Gene Delivery with Mild to Moderate Alzheimer’s Disease – previously approved, but additional language has been inserted at the request of the IRB.
      ii. GCO #08-0844 (Jill Kalman) A Phase 1 Trial of Intracoronary Administration of MYDICAR in Subjects with Heart Failure Divided into Two Stages: Stage One Open-Label, Sequential Dose-Escalation Cohorts and in Stage Two by Randomized, Double-Blind, Placebo-Control, Parallel Cohorts – renewal – initial approval given a year ago.
      iii. GCO #09-0614 (Roger Hajjar) Phase II Gene Therapy with AAV1.SERCA2a in Diabetic Cardiomyopathy.
      iv. The Impact of Resistance to Oseltamivir and Expression of the Virulence Factor PB1-F2 on the Pathogenesis and Transmission of Novel Influenza A/H1N1 (Swine-origin) Virus” – to be done in ABSL-3N enhanced pathogen facility.

5) Other Business
   a. Approval was given to recategorize current novel H1N1 study from BSL3 to BSL2.