CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

ANNUAL MEETING OF
THE SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS WORKING GROUP (SWG) OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

AGENDA ITEM #4
SWG CLINICAL TRIALS WORKSHOP

DATE: Tuesday, February 17, 2009 – 1:00pm to 6:00pm (Estimated)
Wednesday, February 18, 2009 – 9:00am to 3:00pm (Estimated)

LOCATION: Luxe Hotel, 11461 W Sunset Blvd., Los Angeles, CA 90049

This workshop is presented as part of the CIRM Medical and Ethical Standards Working Group Annual Meeting for 2009. The workshop is incorporated into the full meeting agenda, which is posted at http://www.cirm.ca.gov/workgroups/stds.asp. The workshop goals and program are identified below.

WORKSHOP GOALS:

- Describe the regulatory policy context for developing human cell therapies;
- Understand the role of clinical trials in the context of developing new therapies;
- Understand how ethical considerations are addressed in the oversight of clinical trials and consider stem-cell specific issues;
- Understand how institutions involved in clinical trials address regulatory policy issues;
- Describe guidance and regulatory activities related to stem cell clinical trials; and
- Consider issues for further consideration by CIRM or the SWG.

PROGRAM SEGMENTS:

Segment 1: Introductions and statement of the scientific need for clinical trials.

Segment 2: The process of developing cell-based therapies: An overview regulatory policy context.

Segment 3: The role of clinical trials and fundamental design issues.

Segment 4: Issues for developing cell therapies and implementing cell-based clinical trials.

Segment 5: Ethical considerations in clinical trials generally.

Segment 6: *ISSCR Guidelines for Clinical Trials*.

Segment 7: Institutional approach to implementing trials in the current regulatory/policy environment.