

**UNAPPROVED MEETING MINUTES**  
California Department of Public Health  
Human Stem Cell Research Advisory Committee  
Stanford University  
January 9, 2014

CDPH Human Stem Cell Research (HSCR) Advisory Committee Members

Henry Greely, JD  
Bertram Lubin, MD  
David Magnus, PhD  
Elizabeth Blackburn, PhD  
Otto Martinez-Maza, MD  
Samuel Cheshier, MD, PhD  
Margaret McLean, PhD

Teleconference

Bernard Lo, MD  
Fred Gage, PhD

CDPH

Nannie Song, Human Stem Cell Research Program, CDPH  
Amber Christiansen, Immunization Program, CDPH  
Lehoa Nguyen, CDPH Legal Counsel

Members of the Public

Geoff Lomax, California Institute for Regenerative Medicine (CIRM)  
Chris Scott, Stanford University (double check)  
Maria Garcia, Stanford University (phone)

**Agenda Item 1: Welcome and Instructions**

Professor Greely welcomed the Committee members, public attendees, and CDPH staff. Established that quorum was met with 7 Committee members in attendance and 2 members who joined via teleconference.

**Agenda Item 2: Approval of Meeting Minutes from 6/27/11**

The meeting minutes were approved without amendment.

**Agenda Item 3: Discussion and Approval of Revisions to the CDPH Guidelines for Human Stem Cell Research**

Dr. Greely proposed to review the differences between the CDPH Guidelines and CIRM Regulations in order as listed on the comparison table. The Committee discussed considerations to revise Sections 4, 5, 6 and 10 of the Guidelines for Human Stem Cell Research with the aim to harmonize the Guidelines with CIRM Regulations.

- For section 4(a), the Committee approved changes to the qualifications of the SCRO committee non-scientist member of the public, which would no longer contain prohibition of remuneration. This is intended to harmonize with CIRM and to allow the possibility of stipends, which would be appropriately close to the actual expense incurred by the member for serving on the committee, such as traveling and parking costs.
- The Committee approved the deletion of section 5(d) of the Guidelines to allow IRBs instead of SCROs to perform review of clinical trials involving the use of human pluripotent stem cells or cells derived from human pluripotent stem cells. However, section 9 of the Guidelines remains unchanged, which contains additional requirements of SCRO Committee review of clinical trials involving hESC or SCNT.
- The Committee approved the addition of Section 6(a)(1) to include the Australian National Health and Medical Research Council among the list of recognized authorities by which stem cell lines be approved.
- The Committee tabled the discussion of Section 7.
- The Committee approved the revision of Section 10(b)(2) to match the exact wording of Section 100100(b)(2) of the CIRM language which refers to the informed consent process when donors are given the opportunity to impose restrictions on future uses of donated materials.

**Agenda Item 4: Discussion to develop language for a Section 10(c) to recommend informed consent of donors regarding future applications of their donations to which they would object**

Dr. Greely proposed to write language for Section 10 (c) which will encourage SCRO committees to review informed consent of donors regarding future applications of their donations to which they would object.

**Agenda Item 5: Discussion to fill the vacancy of the 13<sup>th</sup> member of the HSCR Advisory Committee**

Committee members agreed that the CDPH should fill the vacant 13<sup>th</sup> member of the HSCR. This would help to reach quorum in future meetings. The Advisory Committee will be emailing their recommendations to us.

**Agenda Item 6: General Stem Cell Update**

Elizabeth Blackburn shared that pluripotency was discovered in B cells of the hematopoietic lineage, which were originally thought not to possess self-renewal. The definition of pluripotency must be used carefully in regulatory language as science progresses. Hank Greely shared that in Japan, iPS cells from mice were used to create gametes, which were then used to successfully reproduce a live mouse.