

Public Comments for HSCR Advisory Committee meeting December 5, 2007**From: The Stem Cell Research Oversight Committee,
Stanford University****Received via email: December 4, 2007**

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Re: Draft Stem Cell Research Reporting Forms

Dear Dr. Ahmad:

In response to the Department's invitation for public comment, the Stanford University Stem Cell Research Oversight committee ("Stanford SCRO" or "SCRO") is pleased to submit comments on the Department's draft reporting forms (HSCR1260-1, -2).

The Stanford SCRO is committed to reviewing and approving stem cell research in accordance with high ethical standards and legal requirements. The SCRO is familiar with S.B. 1260 as it affects non-CIRM-funded research, but is concerned that the draft reporting forms substantially exceed the statutory requirements. The law requires reporting to the Department of only the following information:

1. **SCRO reports:** The law requires a report of the following: (i) the number, status, and disposition of human embryonic stem cell (hESC) research projects that the SCRO has reviewed; and (2) unanticipated problems, unforeseen issues, or serious continuing investigator noncompliance and actions the SCRO has taken in response. S.B. 1260 Sec. 4 (Health & Safety Code § 125119.3).
 - Accordingly, we agree with draft form HSCR1260-1, "SCRO Committee Information," to the extent it requires information about the number of hESC projects reviewed (item 4). We also agree with the second part of HSCR1260-1, "Individual Project" reports, to the extent it requires information about project disposition (item 3) and serious investigator noncompliance and SCRO response (items 17-18). However, S.B.1260 neither authorizes the Department to mandate, nor requires any SCRO to report, the remaining information in the draft forms.

2. Reports re: oocyte procurement for research: The law requires a report of the following: (i) a written record of de-identified participant demographic information; (ii) information sufficient to determine provenance and disposition of each oocyte used or donated; and (iii) adverse health outcomes. S.B. 1260 Ch.2 (Health & Safety Code § 125342).
 - Accordingly, we agree with draft form HSCR1260-2, “Written Record of Subjects Involved” in egg retrieval, to the extent it requires demographic information (items 2 and 3, with limited exceptions), and adverse health outcomes (items 15-20). We also agree with the second part of HSCR1260-2, “Human Oocyte Retrieval for Research Reporting Form,” to the extent it asks if the facility is a Society of Assisted Reproductive Technology member (item 3) and asks for the name, city, state, and zip code of the facility and IRB (1, 2.9-2.11, 4, 6.9-6.11). However, S.B. 1260 neither authorizes the Department to mandate, nor requires any facility or SCRO to report, the specific remaining information in the draft forms. In addition, should the Department continue to seek such broad information about oocyte procurement, there are a number of terms in this form that we believe are ambiguous and would have to be clarified.

We respectfully seek the Department’s commitment to revise the forms in a manner that stays within the statutory mandate. In addition to the Stanford SCRO’s main concern that the draft forms exceed the statutory authority to require reporting, the detail and breadth of the draft requirements would be unprecedented in the research community. For example:

- No other state supporting stem cell research imposes such detailed reporting requirements on SCROs or their institutions. Most states require summary reports without specifying the format.¹
- The federal research framework has reporting requirements as directly authorized by federal statute or regulation. For example, the federal Office for Human Research Protections (OHRP), which interprets and enforces the Common Rule (45 CFR Part 46), requires IRB oversight, but in no way requires an IRB to report that each participant has provided informed consent or has received other protections in any studies, including any perceived as sensitive; such a reporting requirement would exceed the federal agency’s authority and would be extremely onerous to implement. In contrast, the draft HSCR1260-2 form would require detailed reports, beyond the statutory authority, about each participant in oocyte retrieval research. The reporting form instead should ask the SCRO to represent whether it and the IRB have reviewed and approved the study, and all participants have given consent and not been paid more than reimbursable expenses. This would establish provenance in a reasonable and effective way.

¹ For example, see Massachusetts Department of Public Health policy on annual stem cell research reports, http://www.mass.gov/?pageID=eohhs2terminal&L=5&L0=Home&L1=Provider&L2=Certification%2c+Licensure%2c+and+Registration&L3=Programs&L4=Human+Embryonic+Stem+Cell+Research&sid=Eeohhs2&b=terminalcontent&f=dph_quality_healthcare_p_stem_cell_instruction&csid=Eeohhs2.

- As another example, OHRP requires certain basic IRB information pursuant to express regulatory requirements (concerning “assurances” to the federal agency), and the agency lists IRB simply by IRB name and city/state. The Department’s draft forms, however, seek detailed contact information about the SCRO and the IRB which would be made public, despite the fact that S.B.1260 contains no IRB reporting requirements and no IRB or SCRO registration requirements.
- Certain hESC research conducted in California is or will be subject to FDA Human Cells, Tissues, Cellular and Tissue-Based Products (HCT/P) regulations (21 CFR Part 1271), among other FDA regulations. Adding the Department’s detailed reporting requirements that are not legislatively authorized to FDA regulations on recordkeeping and reporting would be onerous for California SCROs. In particular, we note that the Department’s draft forms would require completion of more than 50 fields, per participant, in research involving egg retrieval (Form 1260-2) and nearly 50 fields per individual research project (Form 1260-1). As noted above, only a small number of these fields are authorized by statute.

We also note that certain information requested about participants who undergo egg retrieval is likely identifiable information, contrary to S.B.1260. Height and weight seem unnecessary and could be used to identify individuals, in connection with other information, given that the number of participants in a SCRO-approved egg retrieval study may be limited. Further, the law calls for “income bracket,” which is preferable to the participant income field in the draft form.

We appreciate your consideration of these comments and are pleased that these forms will receive further discussion at the public meeting on December 7, 2007.

Sincerely,

The Stem Cell Research Oversight
Committee of Stanford University