

Public Comments for HSCR Advisory Committee meeting December 5, 2007**From: Associate Director, Eli and Edythe Broad Center of Regenerative Medicine and Stem Cell Research, University of California, Los Angeles (UCLA)****Received via email: November 29, 2007**

Dear Human Stem Cell Research Advisory Committee (HSRCAC),

Thank you for the opportunity to comment on the proposed Stem Cell Research Oversight (SCRO) committee reporting forms intended to fulfill CA Health & Safety (H&S) Code requirements for non-CIRM sponsored human embryonic stem cell (hESC) research. Though the forms look great and appear very user friendly, I have concerns about the amount of proposed information to be collected by the forms, the potential undue burden without benefit on SCRO/ESCROs, and whether the information is consistent with the H&S Code.

The information the forms are intended to collect pose real potential undue burdens on SCRO/ESCROs and their staff and the requirements far out reach the legislated mandate. Additionally, it is difficult to understand the legal or ethical protections such reporting provides to anyone.

A. Regarding the non-Assisted Oocyte Production (AOP) hESC research report forms

1. The law at H&S Code 125119.3 appears very restrictive regarding data collection for non-AOP hESC research:

- a. Number of hESC projects reviewed (this should be interpreted as aggregate numbers rather than reporting on individual projects)

- b. Status and disposition of each project (this could be done in aggregate numbers. Please see my attached revised reporting form "DHS non AOP report form 071121.xls")

- c. Any unanticipated problems and the actions taken to respond, and
 - d. Any applicable information required at H&S Code 125342 about AOP (this should be reserved for the separate AOP reporting form).

2. The proposed HSCRAC form (see attached: "SCRO Reporting Form 11 13 07.xls"), however, requires specific information not contemplated by the regulations at 125119.3. All of the items inconsistent with the Code should be removed from the form, including the following:

- a. Project titles

- b. Names and addresses of PIs

- c. Names of Co-Is
- d. Lay summary/description of the project
- e. Funding source
- f. Locales of PIs and collaborators
- g. Source of oocytes/embryos
- h. Source of hESC or lines
- i. Anticipated duration of project (which is likely difficult to determine)

3. I suggest that the HSCRAC reporting requirements follow CA law as outlined in the H&S Code. The report form should be limited to the reporting requirements at 125119.3 outlined above. If there is a perceived need for more information, such requirements should have appropriate justification and be clearly linked to the existing law. The HSCRAC should not attempt to change the law without going through the required rule making procedures. Otherwise, the requirements are being created outside of the law and will create an undue labor intensive burden for ESCRO reporting.

4. I attached a draft form ("DHS non AOP report form 071121.xls") that I think would satisfy the H&S code requirements.

B. The AOP form.

1. The data collection requirements for AOP include those described above in A(1) and at H&S Code 125342.

2. The data at H&S Code 125342 include and are limited to:

- a. specific demographic points,
- b. information about every oocyte donated or used sufficient to determine provenance and disposition of the materials,
- c. adverse health outcomes, and
- d. the data should preserve the confidentiality of the donors

3. Section 2 of the form asks for specific information not contemplated by the Code that should be omitted:

- a. 3.2 Height
- b. 3.3 Weight
- c. 3.7 Parity
- d. 3.9 Born in the USA

4. The information requested in Sections 4 - 8, 10 - 14, and Section 21 are not included in the Code and should be omitted.

5. It is difficult to discern the type of information intended in Section 18, whether an unintended pregnancy is an adverse health outcome of oocyte donation (as required in 125342(a)(3)), and the time limit, if any, for investigators/clinicians to collect such data. The Section should be clarified and modified consistent with the H&S Code or omitted.

6. Sections 15 and 20 ask for the IRB/SCRO to assess moderate or severe adverse events. Such an assessment will not be possible without definitions that should be imbedded in the form.

7. I suggest that the reporting requirements follow CA law as outlined in the H&S Code. The report form should be limited to the reporting requirements in the H&S Code outlined above. If there is a perceived need for more information, such requirements should have appropriate justification for public review and be clearly linked to the existing law.

As noted above, the additional information required in the proposed reporting forms will pose an undue burden on SCRO/ESCROs and their staff and could actually injure the research endeavor through the creation of onerous data collection mandates not supported by law that provide no additional protections to anyone, including human embryos.

Thank you again for the opportunity to provide comments on the proposed forms. Please do not hesitate to contact me if you have any questions.

Sincerely,
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Proposed SCRO Committee Reporting Form for Non-AOP Projects

Stem Cell Research Oversight Committee Report Form for Non-AOP Projects				
FORM HSCR1260-1				
	Approved	Disapproved	Pending	Total Reviewed
1. Disposition of Projects	20	1	5	26
	Number of Projects			
2. Unanticipated/Unforeseen Problems	1			
3. Serious Continuing Non-Compliance	0			
TOTAL	1			
For sections 2-4, please attach a brief description of the ESCRO requirements or determinations for each reported project and reported actions to respond to these situations.				