

## **Public Comments for HSCR Advisory Committee meeting December 5, 2007**

**From: Co-Chair of the ESCRO Committee for the University of California San Diego (UCSD)**

**Received via email: November 30, 2007**

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To: Human Stem Cell Research Advisory Committee

I am writing as the Co-Chair of the Embryonic Stem Cell Research Oversight Committee for the University of California San Diego (UCSD). These comments are based on a review of the attached 11/13/07 drafts of proposed reporting forms for Oocyte Retrieval and SCRO Committee Reporting. Unfortunately, the comments that follow are not based on a campus consensus, nor do I have time to be specific about individual items on the forms, because we only learned of the proposed review and opportunity to comment at the end of last week. I am generally in agreement with separate comments submitted 11/29/07 by Steve Peckman of UCLA, but I hope the following comments will also be of use to the Advisory Committee.

### **Overall**

Overall, I am concerned that the scope of the proposed reporting form extends well beyond what is spelled out in California regulations. Importantly, it is very difficult to see how most of what is requested is designed to provide needed legal or ethical protections. Further, while the benefit is difficult to see, the cost is clear. The extent of the information requested is likely to significantly increase burden on review committees and probably investigators as well. The result is that we risk diverting efforts and resources away from real and identified areas of concern in order to complete the reporting forms.

### **Value of Reporting Forms**

The attempts to create a clear, user friendly reporting form so that necessary information can be collected from California SCRO/ESCRO Committees is much appreciated. Since we first heard at UCSD about the reporting requirement, we were particularly concerned that it was not clear what information would need to be reported. Following incorporation of recommendations from reviewers of the draft report forms, this effort will be of great help.

### **More Data Requested Than Needed**

However, in reviewing the proposed reporting forms for Oocyte Retrieval and Embryonic Stem Cell Research, it appears that the extent of the data requested is often neither necessary nor appropriate. That said, I can appreciate the interest in having answers to most of the questions listed. It will be of great interest to be able to collect information on these questions (e.g., what % of hESC research projects in California are funded by various entities). However, to the extent that such data are for the purpose of research and not for the purpose of legal or ethical protections, such a project should be

designed and conducted by researchers rather than incorporated into a reporting form created to meet a regulatory responsibility.

### **Risk of Loss of Confidentiality**

It was surprising to see the number of identifying details requested for oocyte donors. Although this is not my area of expertise, it seems plausible that the listed information will be more than sufficient to identify some and perhaps many individuals who had presumed their identities would be kept confidential.

### **Awareness of Proposed Discussion of Reporting Forms**

Based on an informal survey of others in San Diego and other ESCRO Committees in California, it appears that a surprisingly large number of people were not aware of this pending meeting to discuss the form. Although I'm sure efforts were made to get the word out, it's possible that there would be value in doing more than has already been done. For example, unless I'm mistaken, no notices were sent out via the mailing list at CIRM, which would seem to be a logical mechanism for reaching stem cell researchers and institutions in California. It also appears that this issue did not make its way from the Office of the President of the University of California out to the campuses of the University.

### **Recommendations**

1. My suggested alternative is that for each question asked it should be clearly justified directly by regulation or by analysis that the information provided will in fact be useful and usable.
2. If my assumption that a large proportion of stem cell research institutions had little or no time to review the proposed changes, then it would be worth considering a delay to get out a second, more comprehensive, request for comment. This would allow for a more considered review of these very important reporting forms.

Thank you for your time and consideration. Although I would have been interested in participating in the upcoming meeting, I heard about the meeting too late to change appointments already scheduled.

Sincerely,  
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