Public Comments for HSCR Advisory Committee meeting December 5, 2007

From: Susan Berke Fogel, on behalf of the Pro-Choice Alliance for Responsible Research

Received via email: December 3, 2007

Comments on SB 322 forms:

1) On the Written Records of Subjects Involved in AOP:

3.9 Delete:
We don't think this question is appropriate, and there is no basis for the requirement that we can see. The statute references race/ ethnicity. Whether or not a person was born in the U.S. is not necessarily an indication of either. In addition, this question raises issues of immigration status that are not relevant.

We would suggest adding “other” after questions 15.2 and 16.7 instead of question 20

Additional questions:
Does the physician/surgeon or his or her immediate family members have any professional interest in the outcome of the research or of the oocyte retrieval procedure?

What is that interest?

Was it disclosed to the subject?

Was the subject provided an objective and accurate statement about the existing state of the research for which thesubject is providing oocytes.

Did subject document any preference regarding the use of her donated material?

What were those preferences?

2) Informed Consent Form Checklist:

Basic state and federal requirements:
12. What legal rights does this question reference? Should be more explicit.

CHPH requirements:

Question 11 should be framed as a statement: Donors are offered an opportunity to document their preferences regarding future uses of donated materials.

Add:
Statement as to any professional interest of the physician/surgeon or his or her immediate family in the outcome of the research or of the oocyte retrieval procedure.

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