Advisory Committee to the Director (ACD)
Working Group (WG) for Human Embryonic Stem Cell Eligibility Review

Findings and Summary Regarding
University of Texas Health Science Center at Houston
Submissions 2010-ACD-003 and 2010-ACD-004

December 3, 2010

Finding regarding the two hESC lines in University of Texas Health Science Center at Houston Submissions 2010-ACD-003 and 2010-ACD-004

The ACD should consider recommending that the NIH Director NOT approve the lines from this submission for use in NIH-funded research because of problems in the informed consent process.

First Discussion

This new submission requests that two cell lines be approved for use in NIH funded research. The embryos, identified as embryo #548 and #1260, were donated by patients at a separate IVF clinic.

The submitted materials document that the embryos, which were less than 14 days in development, were initially targeted to go to UCSF. However, the researcher at UCSF left the university and the embryos were instead sent to the University of Texas Health Science Center at Houston (UTHSCH).

Documentation for both cell lines is similar, but differs in that one embryo involved a paid oocyte donor. For the latter, the request includes a separate form labeled "Consent to Donate Oocytes" (although that form is dated later than the cryopreservation date of the associated embryo).

The consents to release embryos to UTHSCH have a significant amount of handwritten annotation, some of which is troubling. Overall, the documentation is sketchy and many questions remain. There are no true research consent forms that address the donor process and some of the Section IIB elements are not addressed directly. The Working Group also needs clarification regarding dates and timing, and potentially exculpatory language within the "Release and Covenant Not to Sue" section of the "Consent to Release Cryopreserved Embryos."

The Working Group agreed that the request needs clarification throughout before a recommendation can be made. A subgroup of the Working Group will work with NIH staff to assemble a list of questions for the requester before bringing this request back to the full Working Group for review.

Second Discussion

Although the requester attempted to address the itemized questions plus several follow-on issues, a few critical items still remain.

Copies of the IVF clinical consent forms, signed by the donors are still unavailable. Although IVF clinical consent forms have not been requested routinely by the Working Group, in this case it was hoped that the forms could document what the families were told initially regarding options for embryos remaining after treatment. Subsequent information from the clinic included statements that all donors indeed wanted to donate embryos for research.

As part of the new information, the requester stated that the donors of embryo #548 were presented with all options, and they decided to release the embryo for research. Thus, they have provided some assurance on this point. Still, the Working Group members have a sense of discomfort with the written documentation, including the manner in which forms have been annotated but not properly signed and dated. For embryo #1260, options were written in the "consent to discard" form.

For both embryo donations, the forms used were "consent to release cryopreserved embryos", and in the case of embryo #1260, a "consent to discard cryopreserved embryos" was also used. In neither case was a typical "consent to donate for research" form used. There is not printed documentation on any of the forms that the embryo donations were for research purposes—the mentions of research are all handwritten (for #1260—"stem cell research" is handwritten and for #548, " UTX esc program" is handwritten). There is also no clear documentation that the donors knew that stem cell lines would be created from the embryos. This is a concern since some individuals who may donate for general research application may not agree to donate for stem cell research. This raises concerns as to whether true informed consent was obtained. The IVF clinic also states that the donors of embryo #1260 "wanted the embryos to be either discarded or use for research," but they declined in house fertility clinical research, raising questions about just what the donors of embryo #1260 understood would happen with their donated embryos.

Moreover, for both donated embryos it is uncertain what was written on the forms at the time that the donor signed them. Specifically, for #1260 it is not clear who inserted a hand-written note "please donate for stem cell research at UCSF" ("USCF" was subsequently crossed out and it appears that the IVF clinic wrote "Rel to Univ of Texas stem cell" on 10/18/05) and whether it was present on the form at the time that the donor signed. For embryo #548 it is not clear if the indication of releasing the embryo to the UTHSCH program (UCSF was crossed out) was present at time the donors signed the consent form. On the latter point, it is possible that individuals may agree to donate for research at a local institution but not for use at other sites.

Based on these issues the Working Group retained overall concern with this submission. The requester's responses to questions were sketchy in a number of areas, the written information provided to the donors at the time of consent was neither clear nor complete, and the alterations to the consent forms are unclear as to the timing and who saw the annotations. The Working Group voted unanimously to present a negative finding to the ACD.

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