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

Findings and Summary Regarding
University of Connecticut
Submission 2009-ACD-005
June 3, 2010

Finding regarding all hESC lines in Submission 2009-ACD-005

The ACD should consider recommending that the NIH Director approve the four hESC lines this submission (CT-1, CT-2, CT-3, and CT-4) for use in NIH funded research.

First Discussion

The Working Group (WG) considered all submitted information in this request from the University of Connecticut Health Center (UCHC) for approval of four human embryonic stem cell lines for use in NIH-funded research. UCHC is requesting approval of lines developed from embryos from patients who used reproductive services at the Center for Advanced Reproductive Services at UCHC. The plan stated in the protocol was to develop five to ten lines.

The WG found the submitted documentation to be complete and clear overall, including a concise, focused consent form. Prior the discussion, UCHC confirmed that the cell lines were derived from embryos for which both members of the couple seeking reproductive treatment gave consent to donate to research.

The only concern raised by the WG pertained to the date of the submitted consent form, which appeared to be valid at a later date than the date of embryo donation. The consent form submitted was valid from November 24, 2008 through February 14, 2009, but it appeared that the donation preceded this period. It was not clear if the form included with the submitted materials was the same form used at the time the embryos were donated and if this was the most recent version of the document.

The WG agreed that that the Section IIB considerations were met and voted unanimously to present a positive finding to the ACD, contingent on receipt by NIH staff of clarification to ensure that the consent forms in the application cover the time period in which embryos were donated and lines derived. If there is an earlier version that is more relevant to the time embryos donated, NIH staff would review this. If NIH staff determined that the earlier consent form has substantive differences from the version already submitted, this submission would be brought back to the WG for further consideration.

Second Discussion

Following the first WG discussion, UCHC submitted the correct version of the donation consent, as well as the correct versions of the cryo-preservation consent and the protocol used during the time of embryo donation. These documents satisfied the WG's concerns and the WG agreed that the previous vote to present a positive finding to the ACD stood, with the receipt of the correct consent form erasing the contingency clause.

###