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

Findings and Summary Regarding
Advanced Cell Technology
Submission 2010-ACD-007
June 3, 2010

Finding regarding the hESC line in Submission 2010-ACD-007

The ACD should consider recommending that the NIH Director approve the human embryonic stem cell line in this submission, MA135, for use in NIH-funded research.

Discussion

The Working Group (WG) reviewed all documents in support of this request from Advanced Cell Technology (ACT) for a single cell line, MA135, to be approved for use in NIH funded research. The IVF clinic is not affiliated with ACT, but they have arranged to send embryos to ACT. This request was initially submitted to NIH for administrative review under Section IIA consideration, then moved by NIH to review under Section IIB by the WG.

Both the IVF clinical consent and the consent to donate excess embryos for research were signed in December 2005. The protocol covered by this consent was approved for the period July 27 2006 to March 28, 2007, and embryos were donated on January 19, 2007, about a year after they were originally frozen. The WG noted that some language in the signature block of the embryo donation consent form was obscured due to redaction of donor signatures by ACT. The WG requested a clear copy of the consent form with all language visible in order to confirm that the text raised no issues.

The consent form to donate excess embryos is fairly thorough, covering all the major points (e.g., embryos no longer needed for reproductive purposes and couples given other alternatives). The research consent form states that the donating couples can withdraw their consent up to the time the embryos are removed from storage at the IVF clinic for transfer to ACT. Therefore, it is clear in the consent that once the embryos transferred to ACT, that is when the ability to withdraw consent ends. Although the submitted documents state that on average the time between consent and actual transfer is 2 weeks, the actual time for the cell line in question is not given. The WG requested the actual date of transfer of the embryos from the IVF clinic to ACT. The WG agreed that a 2 week interval provides sufficient time for the donors to change their minds, given that the consent form clearly states that the right to withdraw terminates upon transfer of embryos to ACT.

The WG agreed that the Section IIB considerations were met and voted unanimously to put forward a positive finding to the ACD suggesting recommendation that the cell line (MA135) be eligible for use in NIH-funded research, contingent on receipt by NIH staff of the actual date of transfer of embryos to ACT to document that the donation and transfer dates were at least two

weeks apart. After the WG meeting, ACT sent a blank copy of the embryo donation consent form and the date of actual embryo transfer from the IVF clinic to ACT. The WG agreed the information was satisfactory.

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