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

Findings and Summary Regarding
Jawaharlal Nehru Centre for Advanced Scientific Research
Submission 2010-ACD-005

November 26, 2010

Finding regarding the two hESC lines in Submission 2010-ACD-005

The ACD should consider recommending that the NIH Director approve the two lines in this submission (BJNhem19 and BJNhem20) for use in NIH-funded research.

First Discussion

This new submission from the Jawaharlal Nehru Centre for Advanced Scientific Research requests that two sibling cell lines be approved for use in NIH funded research. The lines were derived from human embryos that were created using in vitro fertilization for reproductive purposes but were of poor quality (Grade III) and not usable for fertility treatment. The protocol complies with government of India's guidelines, and the lines have been published and are in use in India.

The submission is very concise, with nearly all of the elements of informed consent worded and formatted to fit on a single page. Although the documentation is brief, it is clear, well-stated overall, and all required information is provided. A minor issue is that the consent form is not particularly clear about the fate of the embryos after donation for research. It is clear that they will be used for research purposes and there is mention of stem cells, but no direct connection is made. However, the form does mention that any stem cell lines created may be kept indefinitely.

Although the content of the consent form is clear, it is in template form with all information specific to the donation, including dates, left blank. The Working Group had no concerns about the consent form as written. However, they needed assurance that the donors signed the same version of the consent form that is provided with the submitted materials. If a redacted consent form is not available, an affidavit from someone who saw the actual signed consent forms would suffice, affirming this was indeed the consent signed by the donors.

The Working Group voted unanimously to present a positive finding, contingent on receipt of affirmation that the consent form provided in the submission was the consent form signed by the donors.

Second Discussion

The Working Group continued discussion of this submission. At the previous meeting, the group noted that the application did not contain a redacted donation consent form or an attestation from

a Centre official stating that they had seen the signed donation consent document. Upon request by NIH, the submitter noted that providing signed copies of the consent would not be possible, but provided assurance by email that the signed consent was reviewed by the appropriate officials at the IVF clinic and that the donors of the embryos from which the lines were derived had signed the form. The Working Group agreed that this assurance was sufficient for a positive finding. It was also noted that a different submission had been approved in the past based on the receipt of a similar email assurance.

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