18 January 2010

Working Group for Embryonic Stem Cell Eligibility Review
Report to the Advisory Committee to the Director

Findings and Summary Regarding WAO1 (H1)
WiCell Submission 2009-ACD-001

Finding Regarding WA01

The ACD should consider recommending that the NIH Director make the WiCell line WA01 (H1) available for use with NIH funds.

Summary of First Discussion Regarding WA01

The Working Group considered the documents submitted in support of the request for the WA01 (H1) human embryonic stem cell line to be approved for use in NIH funded research. The embryos used for the derivation of this cell line were donated in 1998. After their consideration of all submitted documents, the Working Group agreed that several items needed to be clarified before they could reach a clear finding on whether the cell line was responsibly derived. Because the protocol, the clinical IVF consent form and the cryopreservation consent information were not included with the submitted materials, the primary issue was the timing of the signing of the consent form for research purposes.

It was not clear whether the embryos were fresh or frozen at the time of consent; if the embryos were fresh when the patients were approached for consent for the embryos to be used for research purposes, this would provide them with less time to make a decision. The Working Group requested receipt of the cryopreservation agreement to resolve this point. In addition, it was not clear whether the donors were informed of other options available for embryos no longer needed. The Working Group requested submission of the clinical IVF consent document to resolve this point.

The Working Group voted unanimously to table this submission pending receipt of the clinical IVF consent form and the cryopreservation consent form to clarify the timing of the actual sequence of events. It was agreed that a record of the IRB discussion of the protocol would be helpful to the Working Group's review of this submission. In addition, it was agreed that it would be helpful to see an example of a single cycle, showing the timing of events: clinical consent form signed, egg retrieval documented, IRB-approved consent for research signed. The patient's identifying information should be deleted from these documents.

Summary of Second Discussion Regarding WA01

The WG reviewed the additional materials submitted by WiCell in response to the request for information following the discussion at the first meeting. WiCell was asked to provide the following information:

- the research protocol (as approved by the University of Wisconsin Madison IRB)

- a record of the IRB discussion of the research protocol
- for a given embryo donor(s) during the time period relevant to WA01 (with patient identifiers redacted):
    - a signed, dated consent form for clinical care
    - a signed, dated consent form for embryo crypreservation
    - documentation of the date of oocyte retrieval
    - a signed, dated consent form for donation of the embryos for research

In its review of the supplemental documents, the WG noted that all information requested was provided and that all questions and concerns, particularly regarding timing of consent in the case of donation of fresh embryos, were satisfactorily addressed. More specifically, the clinical consent forms include several options for management of embryos created in excess of clinical need, including discarding them or maintaining them in a cryopreserved state for future reproductive efforts. The research protocol and IRB approval clearly state that the embryos used for research purposes are in excess of clinical need for couples undergoing fertility services and would otherwise be discarded.

The WG also noted that certain disease types were noted in the informed consent as exemplars, and not to indicate that the purpose of the research was to develop specific information about, or cures for, those diseases.

The WG agreed that Section IIB criteria were met and voted unanimously to put forward a positive finding to the ACD suggesting recommendation of the cell line WA01 for use in NIH-funded research.

Additional Discussion

The WG noted that the protocol reviewed by the IRB cited the NIH 1994 Report of the Human Embryo Research Panel, Ad Hoc Group of Consultants to the ACD. That report recommended against federal funding of certain types of research involving embryos, including studies designed to increase the number of embryos with the same genotype and the development of chimeras. The WG noted that neither procedure was part of this research protocol. The WG expressed its support for the NIH policy in Section IV of the NIH Guidelines for Human Stem Cell Research, which states: “the following uses of these cells are nevertheless ineligible for NIH funding, as follows: A. Research in which hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells are introduced into non-human primate blastocysts.”

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