

Report from ACD Working Group for hESC Review

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hESC Review**

**Advisory Committee to the Director
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Findings For Consideration

Working Group findings for one line,
WA01 (H1), submitted by WiCell
Research Institute, Madison, Wisconsin,
are presented for ACD consideration today.

Submission from WiCell Research Institute

- Covers 1 hESC line, WA01 (H1), from embryos donated in the U.S. in 1998
- H1 line was previously listed on NIH Registry under prior Presidential policy
- Protocol was used for first derivation of hESCs

Submission from WiCell Research Institute

- Protocol allowed for donation of embryos remaining after standard IVF treatment of couples at University of Wisconsin Hospital and Clinics
- Protocol specific that donated embryos were those that that patients no longer needed, did not wish to have transferred to other recipients, and would otherwise be discarded.
- Protocol first approved in 1995 by University of Wisconsin-Madison Health Sciences IRB; reapproved on annual basis until study completed in 2000

Section IIB: Guidance for ACD Working Group

- For embryos donated anywhere before July 7, 2009 (if Section IIA is not met), Working Group will take into account
 - Principles in Section IIA
 - 45 CFR 46 Subpart A (Common Rule)
 - Points to Consider: During informed consent process, whether donor(s) were
 - Informed of other available options pertaining to use of embryos
 - Offered any inducements for the donation
 - Informed about what would happen to the embryos

WG Discussion of WAO1

- The protocol, the clinical IVF consent form, and the cryopreservation consent information were requested to clarify timing of signing of consent forms (particularly for donation of fresh embryos) and other options presented to patients
- Supplemental documentation addressed the WG questions:
 - 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.
 - 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.

WG Discussion of WA01

- The WG noted that certain disease types were mentioned in the informed consent as examples of potential future clinical applications, but 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 considerations 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.

Other WG Discussion

- The protocol 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. Neither procedure was part of this research protocol.
- The WG expressed its support for Section IV of the NIH Guidelines for Human Stem Cell Research: “*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.*”

In Sum, WG Findings

- The ACD should consider recommending that WA01 (H1) be eligible for use in NIH-supported research.