

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

**Findings and Summary Regarding
University of New South Wales
Submission 2010-ACD-008
June 3, 2010**

Finding regarding the hESC line in Submission 2010-ACD-008

The ACD should consider recommending that the NIH Director approve the human embryonic stem cell line (Endeavor-2) described in this submission for use in NIH funded research.

Discussion

The University of New South Wales requested the inclusion of 1 human embryonic stem cell (hESC) line in the new NIH Registry. The Australian license allowed for the development of up to six lines for the treatment of diabetes. This line was derived from embryos remaining after IVF treatment of couples at a separate IVF clinic.

The Working Group (WG) reviewed all documents in support of this submission, the first non-U.S. submission received. 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.

The protocol was approved by the IVF clinics' ethics committee and assurances are provided in all key areas. The consent form is different from those seen in submissions from other entities, consisting of a single page with numbered points for individuals to understand the nature of their choice. Both male and female partners provide signatures.

Although the consent form is not typical by U.S. standards, the WG agreed that it covers most, but not all relevant items of a U.S. informed consent form. There is no discussion of reasonable risks or discomforts, but it does discuss destruction of embryos themselves. Alternative approaches to treatment are not discussed in the single page consent form, but they are covered in other documents. The WG agreed that none of the absences from the consent form is problematic. An email from the Director of the Embryology Lab at the IVF clinic assures that the treating IVF clinician was not involved in research or in the consent process for research.

This request was moved to review under Section IIB primarily because of the question of exculpatory language within the consent form. Point 8 on the research consent form states: "That embryonic stem cells produced may be used in the treatment of human diabetes and may result in financial gain to the researchers and/or their organizations. We understand that we have no claim or interest in such outcomes from this research and are donating our excess embryos for altruistic purposes." Given this language, it is clear that the donors are giving up claims to financial compensation. The WG understands that donors should not be unduly influenced by

some promise or suggestion of financial gain; they need to be told clearly that will not happen, but at the same time, the language should not be exculpatory. The WG is not aware of Australian research regulations that have any language parallel to ours prohibiting exculpatory language. It was agreed that the consent language that appears to border on exculpatory is appropriately intended to let the individuals know they will not benefit financially, and the Working Group is comfortable with the language as written.

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 lines (Endeavor-2) be eligible for use in NIH-funded research.

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