



**NIH Advisory Committee to the Director
Teleconference Meeting Summary
Eligibility of an hESC Line for Listing on the
NIH Human Embryonic Stem Cell Registry
January 22, 2010**

Overview: Dr. Francis Collins, Director of the National Institutes of Health (NIH), greeted the Advisory Committee to the Director (ACD) members and thanked them for participating in today's teleconference to receive and discuss a report from the ACD Working Group for Human Embryonic Stem Cell (hESC) Eligibility Review. Dr. Jeffrey Botkin, Chair of the Working Group (WG), gave the WG's report on a submission regarding a cell line from the WiCell Research Institute. This line, WA01, or H1, is the first line that the NIH has reviewed that was eligible for use by NIH-funded researchers under the prior Presidential policy. The National Stem Cell Bank made well over 300 shipments of H1 in the last year alone, and it is one of the most utilized lines in the world.

General Update: Before hearing Dr. Botkin's report, Dr. Collins gave the ACD a general update on the NIH stem cell activities. Acting on the ACD's December recommendations, Dr. Collins approved stem cell lines from Harvard University, with the exception of one line. Also, it was decided as a general policy that the NIH will honor the exact language regarding use of hESC lines as written in the informed consent form signed by individual(s) donating embryos for use in research. Therefore, the Harvard lines are listed in the NIH registry with the restriction language.

The NIH is also reviewing lines through the administrative review process. As of January 19, two new lines, which were reviewed by the NIH and found to meet the requirements of the Stem Cell Guidelines, were added to the Registry.

Review of the WA01 Cell Line: Before Dr. Botkin's report, Dr. Collins recognized the recusal of ACD member, Dr. David DeMets, who is employed by the same institution as the Principal Investigators of the WiCell Research Institute.

Dr. Botkin summarized the WG's findings regarding hESC WA01 (H1), submitted by WiCell Research Institute in Madison, Wisconsin. This submission was compliant with Section IIB of the NIH Stem Cell Guidelines, demonstrating in the protocol that:

- hESCs were derived from donated human embryos after standard IVF treatment.
- Donated embryos were those that patients no longer needed, did not wish to have transferred to other recipients, and would have otherwise discarded.

- The protocol was first approved in 1995 by the University of Wisconsin-Madison Health Sciences Institutional Review Board (IRB) and reapproved on an annual basis until the study was completed in 2000.

The WG reviewed submitted materials and took into account the principles articulated in Section II (A), 45 C.F.R. Part 46, Subpart A. An additional point to be considered was whether, during the informed consent process, including written or oral communications, the donor(s) were: (1) informed of other available options pertaining to the use of the embryos, (2) offered any inducements for the donation of the embryos, and (3) informed about what would happen to the embryos after the donation for research.

The WG noted that the informed consent mentioned certain disease types as examples of potential future clinical applications, but they agreed this did not indicate that the purpose of the research was to develop specific information about or cures for those diseases. As such, mention of these disease types was not regarded as a research restriction. Language in the informed consent also identified types of research that would not be performed with the donated embryos:

"In particular, two experiments that will not be performed with embryonic cell lines derived from this study are: (i) Intermixing of human embryonic cells with an intact embryo, either human or nonhuman, and (ii) Attempting to make genetically identical whole embryos by any method."

This spurred a WG discussion and formal group support for Section IV of the NIH Guidelines for Human Stem Cell Research, that research would be ineligible for NIH funding where hESCs or human induced pluripotent stem cells are introduced into non-human primate blastocysts.

Discussion: The ACD members commended the WG on their thorough review of the WA01 submission. Dr. Collins reiterated that the NIH, as a policy, will honor the exact language regarding use of hESC lines as written in the informed consent form signed by individual(s) donating embryos for use in research. Conditions will be posted in the NIH Stem Cell Registry, and program staff will be reviewing research for adherence. Dr. Collins stressed that the NIH is charged with defining hESC guidelines for use with Federal funds. For research that receives non-Federal funding, it will be up to the IRBs to determine compliancy and adherence.

Action Taken: The ACD moved to recommend approving the WA01 (H1) cell line as eligible for use in NIH-supported research. The ACD unanimously approved this recommendation with no opposition and one recusal.

Teleconference Attendees:

ACD:

- Dr. Mary Beckerle
- Dr. Joan Brugge
- Dr. Colleen Conway-Welch
- Dr. David DeMets (on listen-only line during presentation, discussion, and vote)
- Dr. Maria Freire
- Dr. Thomas Kelly
- Dr. Alan Leshner
- Dr. Jeffrey Murray (also a member of the Working Group)

ACD Working Group for Human Embryonic Stem Cell Eligibility Review:

- Dr. Jeffrey Botkin, Working Group Chair
- Dr. David Grainger, Primary Reviewer of WA01 submission

NIH:

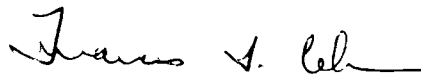
- Dr. Francis Collins, Director, NIH
- Dr. Raynard Kington, Deputy Director, NIH and ACD Executive Director
- Dr. Lana Skirboll, Acting Director, Division of Program Coordination,
Planning and Strategic Initiatives, NIH

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.



FEB 02 2010

Raynard S. Kington, M.D., Ph.D.
Executive Director, Advisory Committee to the Director
Deputy Director, NIH



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Francis S. Collins, M.D., Ph.D.
Chairman, Advisory Committee to the Director
Director, NIH