REVIEWER GUIDANCE FOR APPLICATIONS PROPOSING USE OF HUMAN EMBRYONIC STEM CELLS

NIH can support human embryonic stem cell (hESC) research if it meets the criteria established by President Bush on August 9, 2002. This Reviewer Guidance is provided to cover those issues that may arise during the review of these applications which are specific to human embryonic stem cell research. Refer to the NIH web resource for stem cell research http://stemcells.nih.gov/ for general information on policy, FAQs, current research topics and historical data.

- **Streamlined Review:** Effective 2006/05 Council Cycle, all applications proposing the use of human embryonic stem cells may be subjected to Streamlined Review by initial review groups.

- **Limited Preliminary Data:** Investigators may not have had previous access to human embryonic stem cell lines and may have generated little or no preliminary data. Also, you may have questions about the feasibility of the proposed research. In such cases, the scientific review should focus on determining whether the investigator has included credible plans for using these cells. The research plan may include discussion about the investigator's experiences in research using embryonic stem cell lines of other species or other types of stem cells, or a plan to acquire the necessary skills and technical abilities. Frequently asked questions that provide additional information on this issue: http://stemcells.nih.gov/info/faqs.asp.

- **Institutional Review Board (IRB) approval**: Under most circumstances these activities will not involve human subjects and, therefore, will not require IRB review or approval. Basic research using cell lines from which the identity of the donor(s) of the embryo that yielded the cell lines cannot readily be ascertained by the investigator, is not considered human subjects research, is not governed by 45 CFR 46 or 21 CFR 50 & 56, and does not require IRB review. Research using cell lines that are identifiable with a donor(s) of the embryo, including cell lines that retain links to coded information that would allow identification of the donor(s) may require an IRB review. The guidance by the Office of Human Research (2002) may be found at: http://www.hhs.gov/ohrp/humansubjects/guidance/stemcell.pdf

- **Federally-eligible hESC research:** This guidance is found at http://stemcells.nih.gov/policy/. Ineligible areas of research are defined at http://stemcells.nih.gov/research/registry/eligibilityCriteria.asp

- **The NIH Human Embryonic Stem Cell Registry** is available at the NIH website: http://stemcells.nih.gov/research/registry/. This registry provides information, including a unique identifying code, about each human embryonic stem cell line that is eligible for research to be conducted with federal funding. The grant application must reference the NIH code for the human ES cell line involved. Applicants are encouraged to describe the proposed use of these cells in the abstract.

- **Issues regarding an investigator's access to a particular stem cell line (e.g., materials transfer agreements or intellectual property rights agreements):** These elements are not a component of the scientific review and will be handled by NIH grants administrative practices. If you encounter such issues during the initial review, they should be included in the Summary Statement as an Administrative Note, but they are not a part of and should not affect the scientific evaluation. It is commonplace that programmatic issues involving, for example, budget, special authorizations, clearances, and intellectual property are managed by NIH Institute and Center

program officials. Under these circumstances, NIH grants administration expertise is used to assure that the necessary agreements and materials are in place prior to making an award.

- **Additional Information:**
  Information about what constitutes an embryonic stem cell line and related background materials about stem cell research can be found at the following resources: http://stemcells.nih.gov/info/basics/ and http://stemcells.nih.gov/info/scireport/

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