Applications Proposing Use of Human Embryonic Stem Cells

Interim Reviewer Guidance

This Reviewer Guidance is provided to cover issues that may arise during the review of applications which propose research using human embryonic stem cells (hESC) and certain uses of induced pluripotent stem cells. Refer to the NIH web resource for stem cell research http://stemcells.nih.gov/ for general and updated information on policy, FAQs, current research topics and historical data.

NEW APPLICATIONS

NIH is continuing to accept new and competing applications and R&D contract proposals proposing to use hESCs. Until hESC lines are listed on the new NIH Registry, applicants and offerors should not identify a specific hESC line, but should include a statement that one from the new Registry will be used.

ARRA AND PENDING NON-ARRA APPLICATIONS

- Review of all hESC Challenge/RC1 applications and some non-ARRA applications proposing hESC may be delayed. Review of all Grand Opportunity (GO/RC2) applications that propose the use of hESC will be completed by late August 2009. For more details, see NOT-OD-09-123.
- In order to maintain consistency in review, additional information will *not* be accepted for the initial peer review of hESC applications during this time.
- Only restricted awards will be issued until eligible hESC lines are approved.
- Reviewers will be instructed that the choice of hESC line in the research plan should not affect the individual criterion scores, assessments of overall merit, or overall impact/priority scores.
- 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, and is not governed by 45 CFR 46 or 21 CFR 50 & 56.

INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL

Under most circumstances, hESC research 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/.

THE NIH HUMAN EMBRYONIC STEM CELL REGISTRY

The NIH Human Embryonic Stem Cell Registry is under development and will be available at the NIH website: http://grants.nih.gov/stem_cells/registry/current.htm.

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, include them in the Summary Statement as an Administrative Note, but they are not a part of and should not affect the scientific evaluation. 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 human embryonic stem cell lines and related background materials about stem cell research can be found at http://stemcells.nih.gov.