

Applications Proposing Use of Human Embryonic Stem Cells

Reviewer Guidance

This Reviewer Guidance is provided to cover issues that may arise during the review of applications that propose research using human embryonic stem cells (hESCs) or research involving certain uses of human 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.

REVIEW OF HESC APPLICATIONS

The NIH lists approved hESC lines on the NIH Human Embryonic Stem Cell Registry (the Registry) at http://grants.nih.gov/stem_cells/registry/current.htm. Applicants and offerors should propose to use approved hESC lines on the NIH Registry, if appropriate for the work proposed. However, if appropriate hESC lines are not yet listed on the NIH Registry, applicants and offerors should not identify a specific hESC line, but should include a statement that one from the Registry will be used.

HUMAN SUBJECTS RESEARCH

Under most circumstances, hESC research will not involve human subjects and, therefore, will not be considered human subjects research. 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 be considered human subjects research and require an IRB review. The guidance by the Office of Human Research Protections (2002) may be found at: <http://www.hhs.gov/ohrp/policy/stemcell.pdf>.

FEDERALLY-ELIGIBLE HESC RESEARCH

This guidance is found at <http://stemcells.nih.gov/policy/>.

ISSUES REGARDING AN INVESTIGATOR'S ACCESS TO A PARTICULAR STEM CELL LINE (E.G., MATERIAL 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.