NOTE: THIS GUIDANCE HAS BEEN REPLACED BY OHRP'S MARCH 19, 2002, GUIDANCE ENTITLED, "GUIDANCE FOR INVESTIGATORS AND INSTITUTIONAL REVIEW BOARDS REGARDING RESEARCH INVOLVING HUMAN EMBRYONIC STEM CELLS, GERM CELLS, AND STEM CELL–DERIVED TEST ARTICLES." CLICK HERE FOR THE MARCH 19, 2002 GUIDANCE.

Office for Human Research Protections
Department of Health and Human Services

Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells and Cell-Derived Test Articles

The Office for Human Research Protections of the Department of Health and Human Services offers the following guidance for Institutional Review Boards (IRBs), investigators and sponsors considering research activities involving human embryonic stem cells (HESCs), HESC-derived test articles, human embryonic germ cells derived from fetal tissue, and/or human embryonic germ cell-derived test articles.

***In vitro* research using cell lines that are already derived and established, from which the identity of the donor cannot readily be ascertained by the investigator, is not considered human subject research and therefore is not governed by 45 CFR 46 or 21 CFR 50&56. IRB review is not required for such research.**

Research using cell lines that are identifiable with a donor, including cells that retain links to coded information that would allow identification of donors, is generally considered human subject research, except for cases in which the investigator obtains a written agreement from the holder of the identifiable private information (e.g., the deriver of the cell line) that such information will not be released to the investigator or, if applicable, a consultant, under any circumstances, and that the research will be conducted within the terms of the applicable Assurance by all parties engaged in the research (see guidance offered at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/engage.htm and http://ohrp.osophs.dhhs.gov/humansubjects/guidance/reposit.htm for additional details.

All human subject research involving the use of cells derived from human embryos or fetal tissue is governed by 45 CFR 46 (see in particular Subpart B; state and local laws may also apply), may be subject to FDA regulations, and are required to have IRB review and approval.

All Federally supported research involving human embryonic germ cells derived from human fetal tissue must be conducted in compliance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells, section on fetal tissue (http://www.nih.gov/news/stemcell/NOT-OD-00-050.html). Research involving the derivation of new human embryonic stem cells from human embryos cannot be conducted with Federal support. Research involving the derivation of human embryonic germ cells from fetal tissue can be conducted with Federal support.

All research and clinical trials involving human transplantation of cells or test articles, such as differentiated cells derived from human embryos or human fetal tissue, must be conducted in compliance with FDA regulations and Public Law 103-43, "Research on Transplantation of Fetal Tissue". Further information can be found on the OHRP website

(http://ohrp.osophs.dhhs.gov/human subjects/guidance/publiclaw103-43.htm) and in the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps_2001/).

Investigators who engage in HHS-supported research or who are affiliated with institutions that receive HHS support for such research must comply with the Office of Human Research Protection (OHRP) requirements regarding an Assurance of Compliance for such research.

In addition to the considerations above, clinical trials involving HESCs, HESC-derived test articles, human embryonic germ cells derived from fetal tissue, and/or human embryonic germ cell-derived test articles are subject to regulation and oversight by FDA (see http://www.fda.gov/cber/ltr/fetal113000.htm). Clinical research trials involving the use of stem cells and stem cell derived test articles are subject to FDA:s IND regulations regardless of source of funding. All human studies conducted under INDs require IRB review of the clinical protocol(s). Anyone contemplating such trials should contact the Center for Biologics Evaluation and Review (CBER) at http://www.fda.gov/cber/tiss.htm or 301-827-5102 for specific advice regarding fulfillment of these requirements.

Institutional Review Board (IRB) review of human research involving stem cells derived from human embryos or human fetal tissue research must be in accordance with the Department of Health and Human Services (HHS) regulations for the Protection of Human Subjects, 45 CFR, Part 46, and FDA regulations at 21 CFR 50 and 56 as appropriate.

The NIH policy for Just-in-Time IRB review does apply to such research.

For further information, please contact OHRP (ohrp@osophs.dhhs.gov or 301-496-7005).

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