

**VERIFICATION OF VOLUNTARY DONATION FOR
HUMAN EMBRYONIC STEM CELL RESEARCH**

Connecticut General Statutes (C.G.S.) § 19a-32d(d)(3) (as amended by P.A. No. 08-80) requires documentation to be provided to the Commissioner of Public Health prior to conducting any research involving human embryonic stem cells, regardless of the funding source. The documentation must verify that any human embryos, embryonic stem cells, unfertilized human eggs or human sperm used in embryonic stem cell research have been donated voluntarily in accordance with C.G.S. § 19a-32d(c) (attached) or if any embryonic stem cells have been derived outside the state of Connecticut, that such stem cells have been acceptably derived as provided in the National Academies' Guidelines for Human Embryonic Stem Cell Research, as amended from time to time. Additionally, documentation must be submitted of approval of the research involving human embryonic stem cells by an embryonic stem cell research oversight committee as defined in C.G.S. §19a-32d(a)(1).

Please provide the information requested below to:

Commissioner of the Department of Public Health
Office of Research and Development
410 Capitol Avenue, MS#51ORD
P.O. Box 340308
Hartford, CT 06134-0308

NAME OF PERSON CONDUCTING RESEARCH INVOLVING EMBRYONIC STEM CELLS (PRINCIPAL INVESTIGATOR):

TITLE OF PROJECT:

NAME AND ADDRESS OF FACILITY WHERE SUCH RESEARCH IS CONDUCTED:

CONNECTICUT STEM CELL GRANT NUMBER: (For research performed utilizing funds from the Connecticut Stem Cell Research Fund)_____

PROVIDE A BRIEF DESCRIPTION OF THE RESEARCH INVOLVING EMBRYONIC STEM CELLS. (If additional space is needed, attach to this Form.)

PROVIDE A BRIEF DESCRIPTION OF THE SOURCE OF THE HUMAN EMBRYOS, EMBRYONIC STEM CELLS, UNFERTILIZED EGGS OR HUMAN SPERM TO BE USED IN SUCH RESEARCH, INCLUDING THE DATE OF DONATION, IF AVAILABLE. PROVIDE THE NAMES OF THE STEM CELL LINES OR DERIVATIVES BEING USED. (If additional space is needed, attach to this Form.)

DATE SUCH RESEARCH WILL COMMENCE: _____

FOR ANY HUMAN EMBRYOS, EMBRYONIC STEM CELLS, UNFERTILIZED HUMAN EGGS OR HUMAN SPERM TO BE USED IN SUCH RESEARCH, ATTACH DOCUMENTATION FROM THE INSTITUTIONAL REVIEW BOARD, IF APPLICABLE, AND THE EMBRYONIC STEM CELL RESEARCH OVERSIGHT COMMITTEE, VERIFYING THAT THE DONATION WAS MADE VOLUNTARILY, IN

ACCORDANCE WITH C.G.S. §§ 19a-32d(c) and (d).

I hereby certify that to the best of my knowledge, any human embryos, embryonic stem cells, unfertilized human eggs or human sperm, used in the embryonic stem cell research described above, were donated in accordance with C.G.S. §§ 19a-32d(c) and (d).

Signature - Principal Investigator

Print PI name

Date

AN ACT CONCERNING STEM CELL RESEARCH.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 19a-32d of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2008*):

(a) As used in sections 19a-32d to 19a-32g, inclusive, and section 4-28e:

(1) ["Institutional review committee" means the local institutional review committee specified in 21 USC 360j(g)(3)(A)(i), as amended from time to time, and, when applicable, an institutional review board established in accordance with the requirements of 45 CFR 46, Subpart A, as amended from time to time.]

"Embryonic stem cell research oversight committee" means a committee established in accordance with the National Academies' Guidelines for Human Embryonic Stem Cell Research, as amended from time to time.

(2) "Cloning of a human being" means inducing or permitting a replicate of a living human being's complete set of genetic material to develop after gastrulation commences.

(3) "Gastrulation" means the process immediately following the blastula state when the hollow ball of cells representing the early embryo undergoes a complex and coordinated series of movements that results in the formation of the three primary germ layers, the ectoderm, mesoderm and endoderm.

(4) "Embryonic stem cells" means cells created through the joining of a human egg and sperm or through nuclear transfer that are sufficiently undifferentiated such that they cannot be identified as components of any specialized cell type.

(5) "Nuclear transfer" means the replacement of the nucleus of a human egg with a nucleus from another human cell.

(6) "Eligible institution" means (A) a nonprofit, tax-exempt academic institution of higher education, (B) a hospital that conducts biomedical research, or (C) any entity that conducts biomedical research or embryonic or human adult stem cell research.

(b) No person shall knowingly (1) engage or assist, directly or indirectly, in the cloning of a human being, (2) implant human embryos created by nuclear transfer into a uterus or a device similar to a uterus, or (3) facilitate human reproduction through clinical or other use of human embryos created by nuclear transfer. Any person who violates the provisions of this subsection shall be fined not more than one hundred thousand dollars or imprisoned not more than ten years, or both. Each violation of this subsection shall be a separate and distinct offense.

(c) (1) A physician or other health care provider who is treating a patient for infertility shall provide the patient with timely, relevant and appropriate information sufficient to allow that person to make an informed and voluntary choice regarding the disposition of any embryos or embryonic stem cells remaining following an infertility treatment.

(2) A patient to whom information is provided pursuant to subdivision (1) of this subsection shall be presented with the option of storing, donating to another person, donating for research purposes, or otherwise disposing of any unused embryos or embryonic stem cells.

(3) A person who elects to donate for stem cell research purposes any human embryos or embryonic stem cells remaining after receiving infertility treatment, or unfertilized human eggs or human sperm shall provide written consent for that donation and shall not receive direct or indirect payment for such human embryos, embryonic stem cells, unfertilized human eggs or human sperm. [Consent obtained pursuant to this subsection shall, at a minimum, conform to the National Academies' Guidelines for Human Embryonic Stem Cell Research, as amended from time to time.](#)

(4) Any person who violates the provisions of this subsection shall be fined not more than fifty thousand dollars or imprisoned not more than five years, or both. Each violation of this subsection shall be a separate and distinct offense.

(d) A person may conduct research involving embryonic stem cells, provided (1) the research is conducted with full consideration for the ethical and medical implications of such research, (2) the research is conducted before gastrulation occurs, (3) prior to conducting such research, the person provides [documentation](#) to the Commissioner of Public Health [[documentation](#)] [in a form and manner prescribed by the commissioner](#) verifying: [[that](#)] (A) [That](#) any human embryos, embryonic stem cells, unfertilized human eggs or human sperm used in such research have been donated voluntarily in accordance with the provisions of subsection (c) of this section, [[on a form and in the manner prescribed by the Commissioner of Public Health, \(4\) the general research program under which such research is conducted is reviewed and approved by an institutional review committee, as required under federal law, and \(5\) the specific protocol used to derive stem cells from an embryo is reviewed and approved by an institutional review committee](#)] [or \(B\) if any embryonic stem cells have been derived outside the state of Connecticut, that such stem cells have been acceptably derived as provided in the National Academies' Guidelines for Human Embryonic Stem Cell Research, as amended from time to time, and \(4\) all activities involving embryonic stem cells are overseen by an embryonic stem cell research oversight committee.](#)

(e) The Commissioner of Public Health shall enforce the provisions of this section and may adopt regulations, in accordance with the provisions of chapter 54, relating to the administration and enforcement of this section. The commissioner may request the Attorney General to petition the Superior Court for such order as may be appropriate to enforce the provisions of this section.

(f) Any person who conducts research involving embryonic stem cells in violation of the requirements of subdivision (2) of subsection (d) of this section shall be fined not more than fifty thousand dollars, or imprisoned not more than five years, or both.

Sec. 2. Subsection (e) of section 19a-32g of the 2008 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2008*):

(e) All members of the committee shall become and remain fully cognizant of the National [~~Academies~~] Academies' Guidelines [~~For~~] for Human Embryonic Stem Cell Research, as [~~from time to time~~] amended from time to time, and [~~the~~] shall utilize said guidelines to evaluate each grant-in-aid application. The committee may make recommendations to the Stem Cell Research Advisory Committee and the Commissioner of Public Health concerning the adoption of said guidelines, in whole or in part, in the form of regulations adopted pursuant to chapter 54.