

105 CMR 960.000: BIOTECHNOLOGY

Section

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960.001: Purpose

105 CMR 960.000 is set forth for the purpose of interpreting and implementing M.G.L. c.111L, Biotechnology, as enacted under Chapter 27 of the Acts of 2005, An Act Enhancing Regenerative Medicine in the Commonwealth.

960.002: Regulatory Authority

105 CMR 960.000 is adopted under the authority of M.G.L. c.111, s.3 and M.G.L. c.111L.

960.003: Citation

105 CMR 960.000 shall be known, and may be cited, as Biotechnology Regulations.

960.004: Definitions

The following terms as used in 105 CMR 960.000 shall have the following meanings, unless the context or subject matter clearly require a different interpretation:

Asexual, not initiated by the union of an oocyte and a sperm.

Donated to Research, when, in the absence of valuable consideration and after fulfillment of the requirements of informed consent, the person from whose cells the pre-implantation embryo has originated or will originate gives the pre-implantation embryo or cells to another person; provided, however, that the recipient shall use the extant or resultant pre-implantation embryo in biomedical research and shall not transfer the pre-implantation embryo beyond 14 days of development.

Embryo, an organism of the species homo-sapiens whether formed by fertilization, somatic cell nuclear transfer, parthenogenesis or other means.

Fertilization, the process whereby the male and female gametes unite to form an embryo.
Gametes, a sperm or oocyte.

Human Reproductive Cloning, the asexual genetic replication of a human being by transferring a pre-implantation embryo that has been created by somatic cell nuclear transfer, parthenogenesis or by other asexual means into a uterus or uterine-like environment with the purpose of creating a human fetus or a human child.

Informed Consent, the written consent for the donation of gametes or embryos used for research conducted pursuant to this chapter which complies with the requirements of a duly appointed institutional review board, acting in accordance with 45 C.F.R. 46.116 and 45 C.F.R. 46.117, as may be amended from time to time. The written consent shall be in a language understandable to the donor or patient and shall include all reasonably foreseeable risks, discomforts or benefits of the procedure to the donor or patient.

In Vitro, in an artificial environment, referring to a process or reaction occurring therein, as in a test tube or culture medium.

960.004: continued

In Vitro Fertilization, an assisted reproduction technique in which fertilization is accomplished outside of the human body.

Parthenogenesis, the development of an egg without fertilization.

Person, a natural person, corporation, association, partnership or other legal entity.

Pre-implantation Embryo, an embryo formed and maintained outside of the human body whether by in vitro fertilization, somatic cell nuclear transfer, parthenogenesis or other asexual means, which has not experienced more than 14 days of development; provided, however, that such length of time shall not include any interval in which such development has been suspended, such as through freezing.

Somatic cell, a nongamete cell obtained from a living or deceased human being.

Somatic cell nuclear transfer, the technique in which the nucleus of an oocyte is replaced with the nucleus of a somatic cell.

Valuable Consideration, any consideration beyond reimbursement for reasonable costs incurred in connection with the donation, removal, processing, disposal, preservation, quality control, storage, transplantation or implantation of gametes, embryonic or cadaveric tissue.

960.005: Creation of Human Embryos for Research

(A) No person shall knowingly create an embryo or pre-implantation embryo by the method of fertilization with the sole intent of donating the embryo for research.

(B) Pre-implantation embryos may be created by somatic cell nuclear transfer, parthenogenesis or other asexual means for research purposes.

960.006: Purchase, Sale, Transfer, Receipt and Donation of Embryos, Human Gametes or Cadaveric Tissue

(A) No person shall knowingly and for valuable consideration, purchase, sell, transfer or otherwise obtain embryos, human gametes or cadaveric tissue for research purposes.

(B) Persons may bank or donate their gametes for personal future use and may donate their gametes to another person or may donate their gametes for research.

(C) Persons from whose cells a pre-implantation embryo has originated or will originate may donate such pre-implantation embryo or cells to another person for research:

- (1) In the absence of valuable consideration;
- (2) After the fulfillment of the requirements of informed consent;
- (3) Provided that the pre-implantation embryo, if created by the method of fertilization, was not knowingly created with the sole intent of donating the resultant embryo for research; and
- (4) Provided that the recipient of the pre-implantation embryo shall use the extant or resultant pre-implantation embryo in biomedical research and shall not transfer the pre-implantation embryo to a uterus or uterine-like environment or nurture the pre-implantation embryo beyond 14 days of development.

960.007: Prohibition on Human Reproductive Cloning

(A) Human reproductive cloning is prohibited. No person shall knowingly attempt, engage in, or assist in human reproductive cloning.

(B) No person shall knowingly purchase, sell, transfer or otherwise obtain human embryonic, gametic or cadaveric tissue for the purpose of human reproductive cloning.

960.008: In Vitro Fertilization for Reproductive Purposes

(A) The provisions of these regulations do not prohibit the use of in vitro fertilization for reproductive purposes.

(B) A physician or other health care provider who provides a patient with in vitro fertilization therapy shall provide the patient with timely, relevant and appropriate information sufficient to allow that patient to make an informed and voluntary choice regarding the disposition of any pre-implantation embryos or gametes remaining following treatment.

960.009: Penalties

(A) A person who is found to have knowingly violated sections 960.005(A) or 960.006(A) shall be punished by imprisonment in a jail or house of correction for not less than one year nor more than two years or by imprisonment in the state prison for not more than five years or by a fine of not more than \$100,000.

(B) A person who is found to have knowingly violated section 960.007 shall be punished by imprisonment in a jail or house of correction for not less than five years nor more than ten years or by imprisonment in the state prison for not more than ten years or by a fine of not more than \$1,000,000. In addition to such penalty, and at the discretion of the court, a person who is found to have knowingly violated this section and derives a personal financial profit from such violation may be ordered to pay all or part of any such profits to the commonwealth as damages.

(C) Complaints regarding violators shall be referred to the Office of the Attorney General.

REGULATORY AUTHORITY

105 CMR 960.000: M.G.L. c.111, § 3 and c.111L.