Enhancing Regenerative Medicine

This Act is designed to actively foster research and therapies in the life sciences and regenerative medicine by permitting research and clinical applications involving the derivation and use of human embryonic stem cells, including research and clinical applications involving somatic cell nuclear transfer, placental and umbilical cord cells and human adult stem cells and other mechanisms to create embryonic stem cells which are consistent with the Act.

This Act permits research and clinical applications involving the derivation and use of human embryonic stem cells, including somatic cell nuclear transfer, human adult stem cells from any source, umbilical cord cells, parthenotes and placental cells. Research involving the derivation of human embryonic stem cells through the use of human genetic material, including somatic cell nuclear transfer, parthenogenesis and other asexual means as permitted shall only be conducted upon the written approval of a duly authorized institutional review board. The written approval of the institutional review board shall include a detailed description of the research, experimentation or study to be conducted and a detailed description of the research or a copy of the protocol, all of which shall be maintained as a permanent record by the board or by the hospital or institution for which the board acts.

This Act prohibits human reproductive cloning.

Submitted as:
Massachusetts
Chapter 27 of the Acts of 2005
Status: Enacted into law in 2005.

Suggested State Legislation

(Title, enacting clause, etc.)

Section 1. [*Short Title*.] This Act may be cited as "An Act to Enhance Regenerative Medicine in the State."

Section 2. [*Legislative Findings*.] The [legislature] finds and declares:

(a) human embryonic stem cell research and other research in the life sciences and regenerative medicine present a significant chance of yielding fundamental biological knowledge from which may emanate therapies to relieve, on a large scale, human suffering from disease and injury;

(b) the extraordinary biomedical scientists working within institutions of higher education, research institutes, hospitals, biotechnology companies and pharmaceutical companies can contribute significantly to the welfare of mankind by performing outstanding research in these fields; and

(c) it shall be the policy of this state to actively foster research and therapies in the life sciences and regenerative medicine by permitting research and clinical applications involving the derivation and use of human embryonic stem cells, including research and clinical applications involving somatic cell nuclear transfer, placental and umbilical cord cells and human adult stem cells and other mechanisms to create embryonic stem cells which are consistent with this chapter. It shall further be the policy of this state to prohibit human reproductive cloning.

Section 3. [*Definitions*.] As used in this Act, the following words shall have the following meanings:

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

"Commissioner," the [commissioner of public health].

"Council," the [biomedical research advisory council].

"Department," the [department of public health].

"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 to a uterus or uterine-like environment or nurture 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.

"Employee," an individual who performs services for and under the control and direction of an employer for wages or other remuneration.

"Fertilization," the process whereby the male and female gametes unite to form an embryo.

"Gametes," a sperm or oocyte.

"Human adult stem cell," an undifferentiated cell found in a differentiated tissue that can renew itself and differentiate to yield specialized cell types.

"Human reproductive cloning," the asexual genetic replication of a human being by transferring a preimplantation 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 Act 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.

"Institution," a corporation, association, partnership, nonprofit organization or other legal entity which conducts research authorized by this Act.

"Institutional Review Board," a board that has a minimum of [5 members] who meet regularly to review research applying the standards of 45 CFR Part 46 or 21 CFR Parts 50 and 56, as may be amended from time to time.

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

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

"Manager," an individual to whom an institution conducting research pursuant to this Act has given the authority to direct and control the work performance of the affected employee and who has authority to take corrective action regarding a violation of a law, rule, regulation, activity or policy.

"Parthenogenesis," the development of an egg without fertilization.

"Parthenote," the product of egg development without fertilization.

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

"Placental cells," cells obtained from the placenta.

"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.

"Public body," (a) the United States Congress, a state legislature, including the general court, or a popularly elected local government body, or a member or employee thereof; (b) a federal, state or local judiciary, or a member or employee thereof, or a grand or petit jury; (c) a federal, state or local regulatory, administrative or public agency or authority or instrumentality thereof; (d) a federal, state or local law enforcement agency, prosecutorial office or police or peace officer; or (e) a division, board, bureau, office, committee or commission of any of the public bodies described in clauses (a) to (d), inclusive.

"Public institutional review board," a board established pursuant to subsection (a) of section 7 that has a minimum of [5 members] who meet regularly to review research applying the standards of 45 CFR Part 46 or 21 CFR Parts 50 and 56, as may be amended from time to time.

"Retaliatory action," the unlawful discharge, suspension, demotion, harassment, denial of promotion, layoff or other adverse action taken against an employee affecting the terms and conditions of employment.

"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.

"Umbilical cord cells," cells derived from an umbilical cord.

"Uterine-like environment," a replicate of the uterus used for the purpose of sustaining an embryo through birth and creating a human being.

"Uterus," a uterus or fallopian tube.

"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.

Section 4. [*Research and Clinical Applications Involving the Derivation and Use of Human Embryonic Stem Cells*].

(a) Research and clinical applications involving the derivation and use of human embryonic stem cells, including somatic cell nuclear transfer, human adult stem cells from any source, umbilical cord cells, parthenotes and placental cells shall be permitted.

(b) Research involving the derivation of human embryonic stem cells through the use of human genetic material, including somatic cell nuclear transfer, parthenogenesis and other asexual means as permitted by subsection (a) shall only be conducted upon the written approval of a duly authorized [institutional review board]. The written approval of the [institutional review board] shall include a detailed description of the research, experimentation or study to be conducted and a detailed description of the research or a copy of the protocol, all of which shall be maintained as a permanent record by the [board] or by the hospital or institution for which the [board] acts.

Section 5. [*Disposition of Any Pre-Implantation Embryos or Gametes Remaining After In Vitro Fertilization Therapy*.]

(a) 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. The

physician shall present the patient with the options of storing, donating to another person, donating for research purposes or otherwise disposing of or destroying any unused pre-implantation embryos, as appropriate. The [department] shall prescribe and provide for use by physicians and other health care providers who treat patients for infertility through in vitro or any other process where an egg is extracted from a woman the following [2 documents], in multiple languages as determined by the [department]:

(I) an informational pamphlet, describing the procedure by which an egg is extracted from the patient, including all short and long-term potential health impacts of the procedure on the patient, any drugs or devices to be used, including whether they have received approval from the United States Food and Drug Administration, the risks involved, any discomfort and side effects that may be experienced, any alternatives which the patient may have and their attendant risks and benefits, medical treatment available to the patient should complications arise, and that the particular treatment may involve currently unforeseeable risks to the patient, embryo or fetus. A physician or other health care provider treating a woman with a procedure by which an egg is intended to be extracted shall provide the patient with this pamphlet or a legible copy thereof, and provide any other treatment information which may be specific to the patient's treatment; and

(II) an informed consent form, stating that the patient has been given and has reviewed and understands the informational pamphlet, has consulted with her physician or health care provider concerning the general procedures and her specific medical situation, and understanding the procedure, process and risks, consents to proceed with the procedure or process. The informed consent form shall also contain a "Notes" section, to be completed by the physician or health care provider. This notes section shall contain any medical information, alternative procedures, medicines, devices, considerations or risks relevant to the specific patient's informed consent to proceed and shall be completed by the physician or health care provider in each case. A physician or other health care provider treating a woman by a procedure by which an egg is intended to be extracted shall provide the patient with this form or a legible copy thereof, and shall keep a signed copy of this document in the patient's medical file.

(b) No physician or other health care provider shall provide this treatment before providing the patient with both the informational pamphlet and the informed consent form and without receiving, in return, a complete and fully executed informed consent form from the patient. A physician or other health care provider shall seek such informed consent only under circumstances that provide the prospective patient reasonable opportunity to consider whether or not to receive such treatment and that minimize the possibility of coercion or undue influence. The information that is given to the patient shall be in language understandable to the patient.

Section 6. [*Public Bank for Collecting and Storing Umbilical Cord Blood and Placental Tissue Donated by Maternity Patients at Participating Hospitals*.]

(a) The [department], in partnership with the [state university medical school], shall, subject to appropriation, establish and maintain a public bank for the purpose of collecting and storing umbilical cord blood and placental tissue donated by maternity patients at participating hospitals. The bank shall make the umbilical cord blood and placental tissue available for research in accordance with section 4.

(b) Notwithstanding any general or special law to the contrary, all licensed hospitals shall inform pregnant patients under their care, not later than [30 days from the commencement of their third trimester of pregnancy], of the opportunity to donate blood and tissue extracted from the umbilical cord and placenta following delivery of a newborn child to a publicly accessible certified umbilical cord blood and placental tissue bank. Donations to research pursuant to this Act shall be made at no expense to the donor. Nothing in this section shall

prohibit a maternity patient from donating or storing blood extracted from the umbilical cord or placenta of the patient's newborn child to a private umbilical cord blood and placental tissue bank.

(c) Institutions conducting research pursuant to this Act may reach agreement with the public umbilical cord blood and placental tissue bank to acquire donated umbilical cord blood or placental tissue for the purpose of conducting research. This agreement shall provide for the payment of the estimated expenses of the collection and storage of the donated umbilical cord blood and placental tissue, as well as any reasonable administrative fees established by the public umbilical cord blood and placental tissue bank.

(d) Nothing in this section shall obligate a hospital to collect umbilical cord blood or placental tissue if, in the professional judgment of a physician licensed to practice medicine in all its branches or of a nurse, the collection would threaten the health of the mother or child.

(e) Nothing in this section shall impose a requirement upon an employee, physician, nurse, or other medical staff to the extent that blood transfer conflicts with sincerely-held religious practices or beliefs.

(f) The [department] shall establish a program to educate maternity patients with regard to the subject of cord blood banking. This program shall provide such patients with sufficient information to make an informed decision on whether or not to participate in a private or public umbilical cord blood banking program. This program shall include, but not be limited to, an explanation of the difference between public and private umbilical cord blood banking, the medical process involved in umbilical cord blood banking, the current and potential future medical uses of stored umbilical cord blood, the benefits and risks involved in banking umbilical cord blood, and the availability and cost of public or private umbilical cord blood banks.

Section 7. [*Public Institutional Review Board*.]

(a) The [state university medical school] shall establish and maintain, subject to appropriation, a [public institutional review board]. The [public institutional review board] shall be available on an ongoing basis to an institution having not more than [50 full-time employees] for review of that institution's experimentation, study and procedures for the purposes of conducting research pursuant to this Act.

(b) An institution may access the services of the [public institutional review board] only through a written instrument of contract. The contract shall include the payment to the [public institutional review board] of a reasonable fee, calculated pursuant to a methodology approved by the [state university medical school] to account for the costs of operating and maintaining the [public institutional review board], and the relevant portion of those costs attributable to the particular institution receiving the benefit.

Section 8. [*Creation or Use of Pre-Implantation Embryos in Relation to Human Embryonic Stem Cell Research to the Extent that Such Research Conflicts with the Religious Practices or Beliefs of The Employee*.]

(a) No employee shall be required to conduct scientific research, experimentation or study that involves the creation or use of pre-implantation embryos in relation to human embryonic stem cell research to the extent that such research conflicts with the sincerely-held religious practices or beliefs of the employee.

(b) An institution conducting research pursuant to this Act, or an institution or person with whom an institution conducting research pursuant to this Act has a contractual relationship, shall not take any retaliatory action against its employee because the employee:

(I) discloses or threatens to disclose to a manager or a public body an activity, policy or practice of the institution conducting research pursuant to this Act, or of another

institution conducting such research with whom the employee's institution has a contractual relationship, that the employee reasonably believes is in violation of this Act; or

(II) objects to, or refuses to participate in, any activity, policy or practice that the employee reasonably believes is in violation of this Act.

(c) The protection against retaliatory action shall not apply to the public disclosure of confidential or proprietary information, trade secrets or other confidential materials unless such confidential disclosure is made by the employee directly to and exclusively with the [office of the attorney general] or the [department]. The [department] shall not publicly disclose any such confidential information but shall submit the information to the [attorney general] forthwith.

(d) Any employee aggrieved by a violation of this section may, within [2 years], file a complaint with the [attorney general], who may bring an action in the name of the [state] against the institution alleged to have violated this section. Within [90 days] of receiving a complaint, the [attorney general] shall notify the complainant in writing as to whether he intends to bring an action in the name of the [state]. If the [attorney general] declines to bring an action based on the complaint filed, the aggrieved employee may, within [1 year], institute a civil action in the [superior court]. A party to that action may claim a jury trial. All remedies available in common law tort actions shall be available to prevailing plaintiffs. These remedies are in addition to any legal or equitable relief provided in this Act. The court may:

(I) issue temporary restraining orders or preliminary or permanent injunctions to restrain continued violation of this section;

(II) reinstate the employee to the same position held before the retaliatory action, or to an equivalent position;

(III) reinstate full fringe benefits and seniority rights to the employee;

(IV) compensate the employee for [3 times the lost wages, benefits and other remuneration, and interest thereon]; and

(V) order payment by the institution of reasonable costs, and attorneys' fees.

(e) In any action brought by an employee under subsection (d), if the court finds the action was without basis in law or in fact, the court may award reasonable attorneys' fees and court costs to the institution.

(f) An employee shall not be assessed attorneys' fees under subsection (e) if the employee moves to dismiss the action against the institution or files for a dismissal, within a reasonable time after determining that the institution would not be found liable for damages.

(g) Nothing in this section shall diminish the rights, privileges or remedies of any employee under any other federal or state law or regulation, or under any collective bargaining agreement or employment contract, but the institution of a private action in accordance with subsection (d) shall be deemed a waiver by the plaintiff of the rights and remedies available to him, for the actions of the institution, under any other contract, collective bargaining agreement, state law, rule or regulation or under the common law.

(h) An institution shall publicly display notices reasonably designed to inform its employees of their protection and obligations under this section, and use other appropriate means to keep its employees so informed. Each notice posted pursuant to this subsection shall include the name of the person who has been designated by the institution to receive written notification of a suspected violation of this Act.

Section 9. [*Human Reproductive Cloning*.]

(a) Human reproductive cloning is hereby prohibited. No person shall knowingly attempt, engage in, or assist in human reproductive cloning. No person shall knowingly purchase, sell, transfer or otherwise obtain human embryonic, gametic or cadaveric tissue for the purpose of human reproductive cloning.

(b) No person shall knowingly create an embryo by the method of fertilization with the sole intent of donating the embryo for research. Nothing in this section shall prohibit the creation of a pre-implantation embryo by somatic cell nuclear transfer, parthenogenesis or other asexual means for research purposes.

(c) No person shall knowingly and for valuable consideration purchase, sell, transfer or otherwise obtain human embryos, gametes or cadaveric tissue for research purposes. Nothing in this section shall prohibit a person from banking or donating their gametes for personal future use, or from donating their gametes to another person or from donating their gametes for research. Nothing in this Act shall prohibit or regulate the use of in vitro fertilization for reproductive purposes.

(d) A person who is found to have knowingly violated subsection (a) shall be punished by imprisonment in a jail or house of correction for [not less than 5 years nor more than 10 years or by imprisonment in the state prison for not more than 10 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 state as damages].

(e) A person who is found to have knowingly violated subsection (b) or subsection (c) shall be punished by imprisonment in a jail or house of correction for [not less than 1 year nor more than 2 years or by imprisonment in the state prison for not more than 5 years or by a fine of not more than $100,000].

Section 10. [*Biomedical Research Advisory Council*.]

(a) There shall be a [biomedical research advisory council]. The [council] shall consist of [15 members], [1 of whom shall be the secretary of health and human services, or his designee; 1 of whom shall be the commissioner of public health, or his designee; 1 of whom shall be a scientist designated by the dean of the state university medical school, who shall have experience in biomedical research in the field of cell differentiation, nuclear programming, tissue formation and regeneration, stem cell biology, developmental biology, regenerative medicine or a related field; 1 of whom shall be a physician licensed to practice in this state who shall be appointed by the governor; 1 of whom shall be designated by the dean of the state university medical school who shall have experience in medical ethics; 4 persons to be appointed by the president of the senate, 1 of whom shall be a scientist with experience in biomedical research in the field of cell differentiation, nuclear programming, tissue formation and regeneration, stem cell biology, developmental biology, regenerative medicine or a related field; 1 of whom shall be a physician licensed to practice in the commonwealth; 1 of whom shall have experience in medical ethics; and 1 of whom shall be a member of the state Bar with a background in legal issues related to biotechnology, stem cell research, in vitro fertilization or health law; 1 person to be appointed by the minority leader of the senate who shall be a member of the public; 4 persons to be appointed by the speaker of the house, 1 of whom shall be a scientist with experience in biomedical research in the field of cell differentiation, nuclear programming, tissue formation and regeneration, stem cell biology, developmental biology, regenerative medicine or a related field; 1 of whom shall be a member of the state Bar and have a background in legal issues related to biotechnology, stem cell research, in vitro fertilization or health law; 1 of whom shall be a representative of the {Biotechnology Center of Excellence Corporation}, and 1 of whom shall be a person with a background in economic development; 1 person to be appointed by the minority leader of the house who shall be a member of the public]. In making appointments pursuant to this Act the appointing authorities shall give due consideration to the ethnic and racial composition of the [council].

(b) The [council] shall make recommendations to the [general court] and the [governor] regarding proposed changes to this Act, or any other state law, or any regulations promulgated pursuant thereto, necessary to promote biotechnology in this state.

(c) The [council] shall investigate the implementation of this Act and the conduct of research, including but not limited to, issues relative to the age, race, ethnicity and insurance status of the donor. The investigation shall also include an analysis of ways to encourage disproportionately impacted populations' participation in, and benefit from, research conducted pursuant to this Act. Nothing in this section shall authorize the [council] to obtain individually identifiable patient or donor study participant information.

(d) The [council] shall submit an annual report of its findings, conclusions, proposals and recommendations as provided in subsections (b) and (c) not later than [December 31]. The report shall also include an update on the current state of pre-implantation embryo research relating to human embryonic stem cell research in this state. The report shall be submitted to the [governor, the president of the senate, the speaker of the house, the house and senate chairs of the joint committee on economic development and emerging technologies, the clerk of the senate and the clerk of the house].

(e) The [council] shall meet periodically, but not less than [twice each year]. All meetings shall be public.

(f) The [council] shall keep a public record of all meetings, votes and other business.

(g) Members of the [council] shall be appointed for terms of [3 years] or until a successor is appointed. Members shall be eligible to be reappointed and shall serve without compensation. A chairman of the council shall be elected annually from the membership. The [department] shall provide administrative support to the [council] as requested.

(h) In the event of a vacancy on the [council], the original appointing authority shall, within [60 days of the occurrence of a vacancy], appoint a new member consistent with subsection (a) to fulfill the remainder of the unexpired term.

Section 11. [*Regulations*.]

(a) The [department] shall enforce this Act and may adopt regulations, in a manner consistent with this Act, and with the advice of the [biomedical research advisory council], relating to the administration and enforcement of this Act; but the [department] shall not propose or implement any regulation or rule which would have the purpose or effect of inhibiting, delaying or otherwise obstructing research or clinical applications proposed or undertaken pursuant to subsection (a) or (b) of section 4. The regulations shall be consistent with the findings and declarations of the [legislature] as stated in section 2.

(b) Before the adoption, amendment or repeal of any regulation pursuant to this Act, the [department] shall hold a public hearing in accordance with this [insert citation]. Notwithstanding [insert citation], at least [90 days] before a public hearing the [department] shall:

(I) publish notice of its proposed action in at least [1 major newspaper] in the following metropolitan areas [insert areas], in at least [1 biotechnology newspaper or trade journal], in at least [1 medical journal published in the state], and in such additional newspapers or trade, industry, or professional publications as the [department] may select;

(II) notify any institution holding a certificate of registration issued pursuant to this Act;

(III) notify any person, institution or group which has filed a written request pursuant to this section for notice of any regulatory proceeding; such a request shall be renewed at least [annually], and delivering or mailing a copy of the notice to the last known address of

the person, institution or group required to be notified shall constitute sufficient notice under this section;

(IV) file a copy of the notice with the [joint committee on economic development and emerging technologies] and the [joint committee on state administration and regulatory oversight]; and

(V) file a copy of the notice with the [state secretary]. The notice required by this section shall refer to the statutory authority pursuant to which the regulatory action is predicated; and shall specify the date, time and place of the public hearing, the manner in which data, views or arguments may be submitted to the agency by any interested person, institution, or group, and the express terms or the substance of the proposed regulations.

(c) No regulation promulgated by the [department] pursuant to this Act shall be exempt from the hearing requirement or be considered an emergency regulation pursuant to [insert citation].

(d) The [joint committee on state administration and regulatory oversight of the general court], in this subsection called the [committee], shall have authority to review regulations proposed or adopted pursuant to this Act. The [committee] shall consult with the [joint committee on economic development and emerging technologies] in performing this review. The [committee] may hold public hearings concerning a proposed or existing regulation and may submit to the [department] comments concerning the merit and appropriateness of the regulations to be promulgated and an opinion whether the regulations are authorized by, and consistent with, this Act. The [department] shall respond in writing within [10 days] to the [committee's] written questions relevant to the [committee's] review of a proposed or existing regulation. The [department] shall provide to the [committee], without charge, copies of all public records in the agency's custody relating to the regulation or action in question within [10 days] of a request by the [committee]. The [committee] may issue a report with proposed changes to a proposed or existing regulation and shall transmit this report to the [department]. If the [department] does not adopt the proposed changes contained in the [committee's] report, the [department] shall notify the [committee] in writing of the reasons why it did not adopt the changes either at the time it adopts a proposed regulation or within [21 days] of receiving the [committee's] report on an existing regulation.

(e) The [superior court department of the trial court] shall have jurisdiction to consider any claim challenging the validity of a regulation issued pursuant to this section. Any institution holding a certificate of registration to conduct research pursuant to this Act, and aggrieved by a regulation promulgated by the [department], may bring a civil action presenting its claim. In any such civil action, in determining whether a preliminary injunction shall issue, the [court] shall consider any regulation that would have the effect of prohibiting or discontinuing research authorized pursuant to this Act to be an irreparable injury to the institution bringing the claim.

(f) The [department] shall issue a certificate of registration authorizing an institution to conduct human embryonic stem cell research within [30 days] after submission of an application from the applicant institution, if the institution:

(I) pays a fee of not more than [$200] to the [department]; and

(II) provides documentation to the [department] demonstrating that the institution has an [institutional review board] or provides a copy of a contract between the institution and either a private or public institutional review board which shall review the institution's experimentation, study and procedures involving human embryonic stem cell research. Any institution which submits an application and meets the requirements for a certificate of registration pursuant to this section shall not have the certificate of registration unreasonably withheld. A certificate may be withheld if the [department] determines that the applicant institution has violated subsection (m).

(g) No research authorized pursuant to subsection (b) of section 4 shall be conducted at any institution that does not have a valid certificate of registration issued pursuant to this section.

(h) All certificates of registration issued in accordance with this section shall be valid for a term of [3 years] from the date of issuance. The [department] shall notify all holders of certificates of registration under this section at least [60 days] before the expiration of the certificate of registration. If an institution that is issued a certificate of registration under this Act makes timely and sufficient application for a renewal, its certificate of registration shall not expire until its application has been finally determined by the [department]. Before the assessment of a civil administrative penalty pursuant to this section, the [department] shall notify the holder of the certificate of registration that it has [90 days] after the date of expiration within which to submit an application for renewal during which time the [department] shall waive any applicable penalties pursuant to this subsection.

(i) An institution holding a certificate of registration shall submit an annual report to the [department] providing a summary of the research approved during each calendar year and a statement representing that the research was reviewed in accordance with this Act, if applicable.

(j) The [department] shall certify its receipt of annual reports from institutions holding a certificate of registration.

(k) The [department] shall keep an official record of the names of all institutions holding a certificate of registration and of all money received and disbursed by it. A duplicate of this record shall be open for public inspection in the [office of the state secretary].

(l) The [department] shall keep an official record of anyone convicted of violating subsection (a), (b) or (c) of section 9. The [department] shall annually send notice of the names of those violators to all institutions issued a certificate of registration. No such institution shall knowingly employ a person whom the department has identified as having been convicted of a violation of said subsection (a), (b) or (c) of said section 9.

(m) The [department] shall revoke any certificate of registration, shall not renew such certificate and shall deny any future application for a certificate of registration for any institution that knowingly and willfully permits or assists a violation of subsection (a) of section 9, whether or not the violation is committed by an employee of that institution.

(n) (1) The [department] may discipline an institution conducting research pursuant to this Act if it is determined, after an opportunity for an adjudicatory proceeding conducted pursuant to [insert citation], that the institution has:

(I) violated subsection (b) of section 4;

(II) violated section 5;

(III) knowingly and willfully permitted or assisted a violation of subsection (b) or (c) of section 9;

(IV) knowingly violated subsection (f) of this section, if applicable;

(V) failed to submit an annual report to the [department] pursuant to subsection (i);

(VI) employed a person identified in the annual notice by the [department] pursuant to subsection (l); or

(VII) knowingly implemented a decision by an [institutional review board] to authorize research prohibited by this Act.

(2) The [department] may, after an opportunity for an adjudicatory proceeding conducted pursuant to [insert citation], upon determination that an institution conducting research pursuant to this Act has violated this subsection undertake the following actions:

(I) for violating (n)(1)(III) of this subsection -- revoke or refuse to renew such certificate of registration or assess upon the holder a civil administrative penalty not to

exceed [$250,000] and may require the holder to submit to additional oversight as a condition or retention, or future consideration of reinstatement of the certificate of registration;

(II) for violating clause (n)(1),(I), (II), (IV),(VI) or (VII)), assess upon the holder a civil administrative penalty not to exceed [$100,000]; or

(III) for a first violation of (n)(I)(V)(1) censure a holder; and for each subsequent violation of (n)(I)(V), suspend such certificate of registration until compliance with subsection (I), and impose a civil administrative penalty, as determined by the [department] not to exceed [$1,000].

(3) An institution sanctioned under this subsection may be subject to such other sanctions or punishment as may be provided by law. The [department] shall promulgate such rules and regulations not inconsistent with [insert citation] and this Act as necessary for the filing of charges and the conduct of proceedings.

Section 12. [*Recommendations about Proposed Regulations to Administer and Enforce this Act*.] Notwithstanding any general or special law to the contrary, the [biomedical research advisory council] established under this Act may, from time to time, make recommendations to the [commissioner of public health] about proposed regulations for the administration and enforcement of this Act.

Section 13. [*Investigating the Feasibility of Permitting Certain Companies to Use an Alternative Method to Get Approval to Conduct Embryonic Stem Cell Research*.] Notwithstanding any general or special law to the contrary, the [biomedical research advisory council] established under this Act shall investigate the feasibility of permitting companies whose stock is publicly traded to use an alternative method of approval in lieu of having to acquire the approval of an [institutional review board] before conducting embryonic stem cell research pursuant to this Act. The investigation shall include a recommendation as to whether the approval of a duly appointed [bioethical advisory board] is a suitable alternative to the approval of an [institutional review board]. The [council] shall complete its investigation, and submit its recommendations, if any, to the [joint committee on economic development and emerging technologies] not later than [insert date].

Section 14. [*Investigating the Appropriate and Suitable Manner for Disposing Pre-Implantation Embryos Which Have Been Abandoned by the People who Contributed the Genetic Material from Which the Embryos were Created*.] Notwithstanding any general or special law to the contrary, the [biomedical research advisory council] established under this Act shall investigate an appropriate and suitable manner of disposing pre-implantation embryos which have been abandoned by the people who contributed the genetic material from which the embryos were created. The investigation shall include an analysis of the feasibility of granting the [commissioner of public health], upon a declaration by a court of competent jurisdiction that the embryos have been abandoned, the authority to accept legal custody of the embryos and to provide consent to their use for purposes of biomedical research or medical care or treatment. The [council] shall complete its investigation, and submit its recommendations, if any, to the [joint committee on economic development and emerging technologies] not later than [insert date].

Section 15. [*Investigating the Optimum Method by Which a Public Placental and Umbilical Cord Blood Bank Should be Established at the {State University Medical School} or Other Appropriate Institution*]. Notwithstanding any general or special law to the contrary, the [biomedical research advisory council] established under this Act shall investigate the optimum

method by which a public placental and umbilical cord blood bank should be established at the [state university medical school] or other appropriate institution. The investigation shall include an analysis of establishing a public umbilical cord blood bank for the purpose of collecting and storing umbilical cord blood and placental tissue that is donated to research by maternity patients and an analysis establishing a public umbilical cord blood bank for the collection and storage of umbilical cord blood and cells and placental tissue and cells and making the same available to the person depositing the blood or cells and their designees for individual medical research and treatment. The investigation shall also include a recommendation on an appropriate fee structure for participation in the public placental and umbilical cord blood bank. The [council] shall analyze the need for eligibility requirements to ensure equal access to the bank for all citizens of this state and the costs associated with the operation and maintenance of the public placental and umbilical cord blood bank, including the need for, and appropriateness of, public funding. Finally, the [council] shall make recommendations as to the need for regulations or protocols to govern donations to the bank and the release and use of banked cells, tissue or blood. The [council] shall report its findings, together with any proposed legislation, to the [house and senate chairs of the joint committee on economic development and emerging technologies and to the house and senate chairs of the joint committee on health care financing] not later than [insert date].

Section 16. [*Appointment of Biomedical Research Advisory Council*.] Notwithstanding any general or special law to the contrary, the members of the [biomedical research advisory council] established under this Act shall be appointed not later than [insert date]. If, as of [insert date], the [council] shall consist of fewer than [15 members], the [attorney general] shall appoint such members, not later than [insert date] so that the [council] consists of [15 members].

Section 17. [*Investigating the Optimum Method by Which a Public Institutional Review Board Should be Established at the {State University Medical School}*]. Notwithstanding any general or special law to the contrary, the [biomedical research advisory council] established under this Act shall investigate the optimum method by which a [public institutional review board] should be established at the [state university medical school]. The [council] shall report its findings, together with any proposed legislation, to the [house and senate chairs of the joint committee on economic development and emerging technologies and to the house and senate chairs of the joint committee on healthcare financing] not later than [insert date].

Section 18. [*Analyzing and Investigating the Feasibility of Establishing an Institute for Regenerative Medicine at the {State University Medical School}*]. Notwithstanding any general or special law to the contrary, the [president of the state university] or their designee, shall appoint a [commission] to analyze and investigate the feasibility of establishing an [Institute for Regenerative Medicine] at the [state university medical school]. The analysis and investigation shall include the potential cost of establishing such an institute as well as the potential scientific, economic and social benefits such an institute may have upon this state. The [commission] shall submit a final report detailing its recommendations, if any, including any proposed legislation, to the [house and senate chairs of the joint committee on economic development and emerging technologies] and to the [house and senate chairs of the joint committee on healthcare financing] not later than [insert date].

Section 19. [*Date for Establishing the Public Institutional Review Board*.] The [public institutional review board] to be established pursuant to this Act shall be established not later than [120 days] after the effective date of this Act.

Section 20. [*Deadline for Complying with this Act*.] Any institution which on the effective date of this Act is conducting human embryonic stem cell research in this state shall have [180 days from the effective date] to come into compliance with this Act.

Section 21. [*Severability*.] [Insert severability clause.]

Section 22. [*Repealer*.] [Insert repealer clause.]

Section 23. [*Effective Date.*] [Insert effective date.]