Stricken language would be deleted from and underlined language would be added to the law as it existed prior to this session of the General Assembly.

State of Arkansas
86th General Assembly
Regular Session, 2007

A Bill

HOUSE BILL 2806

By: Representative Bond

For An Act To Be Entitled

AN ACT TO ESTABLISH THE REGENERATIVE MEDICINE ENHANCEMENT ACT; AND FOR OTHER PURPOSES.

Subtitle

AN ACT TO ESTABLISH THE REGENERATIVE MEDICINE ENHANCEMENT ACT.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Arkansas Code Title 20, Chapter 8, is amended to add an additional subchapter to read as follows:

20-8-501. Short title.

This subchapter shall be known and may be cited as the "Regenerative Medicine Enhancement Act".

20-8-502. Legislative findings.

The General Assembly finds and declares that:

(1) 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;

(2) 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

(3) It is 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 subchapter. It shall further be the policy of this state to prohibit human reproductive cloning.

20-8-503. Definitions.

As used in this subchapter:

(1) "Asexual" means not initiated by the union of an oocyte and a sperm;

(2) "Council" means the Biomedical Research Advisory Council;

(3) "Department" means the Department of Health and Human Services;

(4)(A) "Donated to research" means 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.

(B) However, 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 fourteen (14) days of development;

(5) "Embryo" means an organism of the species homo-sapiens whether formed by fertilization, somatic cell nuclear transfer, parthenogenesis, or other means;

(6) "Employee" means an individual who performs services for and under the control and direction of an employer for wages or other remuneration;

(7) "Fertilization" means the process whereby the male and female gametes unite to form an embryo;

(8) "Gamete" means a sperm or oocyte;

(9) "Human adult stem cell" means an undifferentiated cell found in a differentiated tissue that can renew itself and differentiate to yield

specialized cell types;

(10) “Human reproductive cloning” means 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;

(11) “In vitro” means in an artificial environment, referring to a process or reaction occurring therein, as in a test tube or culture medium;

(12) "In vitro fertilization” means an assisted reproduction technique in which fertilization is accomplished outside of the human body;

(13) “Informed consent” means the written consent for the donation of gametes or embryos used for research conducted pursuant to this subchapter which complies with the requirements of an 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;

(14) “Institution” means a corporation, association, partnership, nonprofit organization, or other legal entity which conducts research authorized by this subchapter;

(15) “Institutional review board” means a board that has a minimum of five (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;

(16) “Manager” means an individual to whom an institution conducting research pursuant to this subchapter 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;

(17) “Parthenogenesis” means the development of an egg without fertilization;

(18) “Parthenote” means the product of egg development without fertilization;

(19) “Person” means a natural person, corporation, association, partnership, or other legal entity;

(20) "Placental cells" means cells obtained from the placenta;

(21)(A) "Pre-implantation embryo" means 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 fourteen (14) days of development.

(B) However, the length of time shall not include any interval in which the development has been suspended, such as through freezing;

(22) "Public body" means:

(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 subdivisions (22)(A) - (D) of this section;

(23) "Public institutional review board" means a board established pursuant to § 20-8-507(a) that has a minimum of five (5) members who meet regularly to review research applying the standards of 45 C.F.R. Part 46 or 21 C.F.R. Parts 50 and 56 as they existed on January 1, 2007, as may be amended from time to time;

(24) "Retaliatory action" means 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;

(25) "Somatic cell" means a nongamete cell obtained from a living or deceased human being;

(26) "Somatic cell nuclear transfer" means the technique in which the nucleus of an oocyte is replaced with the nucleus of a somatic cell;

(27) "Umbilical cord cells" means cells derived from an

umbilical cord;

(28) "Uterine-like environment" means a replicate of the uterus used for the purpose of sustaining an embryo through birth and creating a human being;

(29) "Uterus" means a uterus or fallopian tube; and

(30) "Valuable consideration" means 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.

20-8-504. 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) of this section shall only be conducted upon the written approval of a 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 institutional review board or by the hospital or institution for which the institutional review board acts.

20-8-505. Disposition of 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 of Health and Human Services 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 two (2) documents, in multiple languages as determined by the department:

(1) 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 of this pamphlet and provide any other treatment information which may be specific to the patient's treatment; and

(2) 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 of this form 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 informed consent only under circumstances that provide the prospective patient reasonable opportunity to consider whether or not to receive the 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.

20-8-506. Public bank for collecting and storing umbilical cord blood and placental tissue donated by maternity patients at participating hospitals.

(a) The Department of Health and Human Services, in partnership with the University of Arkansas for Medical Sciences, 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 § 20-8-504.

(b) Notwithstanding any general or special law to the contrary, all licensed hospitals shall inform pregnant patients under their care, not later than thirty (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 subchapter 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 subchapter may reach an 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 the 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.

20-8-507. Public Institutional Review Board.

(a) The University of Arkansas for Medical Sciences 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 fifty (50) full-time employees for review of that institution's experimentation, study, and procedures for the purposes of conducting research pursuant to this subchapter.

(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 University of Arkansas for Medical Sciences 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.

20-8-508. Creation or use of pre-implantation embryos in relation to human embryonic stem cell research to the extent that the 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 the research conflicts with the sincerely-held religious practices or beliefs of the employee.

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

(1) 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 subchapter or of another institution conducting the research with whom the employee's institution has a contractual relationship, that the employee reasonably believes is in violation of this subchapter; or

(2) Objects to or refuses to participate in any activity, policy, or practice that the employee reasonably believes is in violation of this subchapter.

(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 the confidential disclosure is made by the employee directly to and exclusively with the Office of the Attorney General or the Department of Health and Human Services. The department shall not publicly disclose any confidential information but shall submit the information to the Attorney General immediately.

(d) Any employee aggrieved by a violation of this section may, within two (2) years, file a complaint with the Attorney General, who may bring an action in the name of Arkansas against the institution alleged to have violated this section. Within ninety (90) days of receiving a complaint, the Attorney General shall notify the complainant in writing as to whether he or she intends to bring an action in the name of the State of Arkansas. If the Attorney General declines to bring an action based on the complaint filed, the aggrieved employee may, within one (1) year, institute a civil action in circuit court. A party to that action may claim a jury trial. All remedies

available in common law tort actions are available to prevailing plaintiffs. These remedies are in addition to any legal or equitable relief provided in this subchapter. The circuit court may:

(1) Issue temporary restraining orders or preliminary or permanent injunctions to restrain the continued violation of this section;

(2) Reinstate the employee to the same position held before the retaliatory action or to an equivalent position;

(3) Reinstate full fringe benefits and seniority rights to the employee;

(4) Compensate the employee for three (3) times the lost wages, benefits, and other remuneration and interest thereon; and

(5) Order payment by the institution of reasonable costs and attorneys' fees.

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

(f) An employee shall not be assessed attorney's fees under subsection (e) of this section 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) of this section shall be deemed a waiver by the plaintiff of the rights and remedies available to the plaintiff, 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 subchapter.

20-8-509. Human reproductive cloning.

(a) Human reproductive cloning is 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 subchapter 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) of this section shall be punished by imprisonment for not less than five (5) years nor more than ten (10) years or by imprisonment for not more than ten (10) years or by a fine of not more than one million dollars ($1,000,000). In addition to the penalty, and at the discretion of the circuit court, a person who is found to have knowingly violated this section and derives a personal financial profit from the violation may be ordered to pay all or part of any of the profits to the state as damages.

(e) A person who is found to have knowingly violated subsection (b) or subsection (c) of this section shall be punished by imprisonment for not less than one (1) year nor more than two (2) years or by imprisonment for not more than five (5) years or by a fine of not more than one hundred thousand dollars ($100,000).

20-8-510. Biomedical Research Advisory Council.

(a) The Biomedical Research Advisory Council is created. The council shall consist of the following fifteen (15) members:

(1) One (1) of whom shall be the Director of the Department of

Health and Human Services or his or her designee;

(2) One (1) of whom shall be the Director of the Division of Health of the Department of Health and Human Services, or his or her designee;

(3) One (1) of whom shall be a scientist designated by the Dean of the University of Arkansas for Medical Sciences, 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;

(4) One (1) of whom shall be a physician licensed to practice in this state who shall be appointed by the Governor;

(5) One (1) of whom shall be designated by the Dean of the University of Arkansas for Medical Sciences, who shall have experience in medical ethics;

(6) Four (4) persons to be appointed by the President Pro Tempore of the Senate as follows:

(A) One (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;

(B) One (1) of whom shall be a physician licensed to practice in the state;

(C) One (1) of whom shall have experience in medical ethics; and

(D) One (1) of whom shall be a member of the Arkansas Bar with a background in legal issues related to biotechnology, stem cell research, in vitro fertilization or health law;

(7) One (1) person to be appointed by the minority leader of the senate who shall be a member of the public;

(8) Four (4) persons to be appointed by the Speaker of the House of Representatives as follows:

(A) One (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;

(B) One (1) of whom shall be a member of the Arkansas Bar

and have a background in legal issues related to biotechnology, stem cell research, in vitro fertilization or health law;

(C) One (1) of whom shall be a representative of a biotechnology corporation; and

(D) One (1) of whom shall be a person with a background in economic development;

(9) One (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 subchapter, 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 Assembly and the Governor regarding proposed changes to this subchapter, 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 subchapter 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 subchapter. 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) of this section not later than December 31 of each year. 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 Pro Tempore of the Senate, and the Speaker of the House of Representatives.

(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 three (3) years or until a successor is appointed. Members shall be eligible to be reappointed and shall serve without compensation. A chair of the council

shall be elected annually from the membership. The Department of Health and Human Services shall provide administrative support to the council as requested.

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

20-8-511. Rules.

(a) The Department of Health and Human Services shall enforce this subchapter and may adopt rules, in a manner consistent with this subchapter, and with the advice of the Biomedical Research Advisory Council, relating to the administration and enforcement of this subchapter; but the department shall not propose or implement any rule which would have the purpose or effect of inhibiting, delaying, or otherwise obstructing research or clinical applications proposed or undertaken pursuant to § 20-8-504(a) or (b). The rules shall be consistent with the findings and declarations of the General Assembly as stated in § 20-8-502.

(b) Before the adoption, amendment, or repeal of any rule pursuant to this subchapter, the department shall hold a public hearing in accordance with this subchapter. Notwithstanding the Arkansas Administrative Procedure Act § 25-15-201 et seq., at least ninety (90) days before a public hearing the department shall:

(1) Publish notice of its proposed action in at least one (1) major newspaper, in at least one (1) biotechnology newspaper or trade journal, in at least one (1) medical journal, and in additional newspapers or trade, industry, or professional publications as the department may select;

(2) Notify any institution holding a certificate of registration issued pursuant to this subchapter;

(3) Notify any person, institution, or group which has filed a written request pursuant to this section for notice of any regulatory proceeding. The 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;

(4) File a copy of the notice with the House and Senate

Committees having jurisdiction over technology issues and the Legislative Council; and

(5) File a copy of the notice with the Secretary of State. 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 rules.

(c) No rule promulgated by the department pursuant to this subchapter shall be exempt from the hearing requirement or be considered an emergency rule pursuant to the Administrative Procedure Act § 25-15-201 et seq.

(d) The Legislative Council shall have authority to review rules proposed or adopted pursuant to this subchapter. The Legislative Council shall consult with the House and Senate Committees having jurisdiction over technology issues in performing this review. The Legislative Council may hold public hearings concerning a proposed or existing rule and may submit to the department comments concerning the merit and appropriateness of the rules to be promulgated and an opinion whether the rules are authorized by and are consistent with this subchapter. The department shall respond in writing within ten (10) days to the Legislative Council's written questions relevant to the Legislative Council's review of a proposed or existing rules. The department shall provide to the Legislative Council, without charge, copies of all public records in the agency's custody relating to the rule or action in question within ten (10) days of a request by the Legislative Council. The Legislative Council may issue a report with proposed changes to a proposed or existing rule and shall transmit this report to the department. If the department does not adopt the proposed changes contained in the Legislative Council's report, the department shall notify the Legislative Council in writing of the reasons why it did not adopt the changes either at the time it adopts a proposed rule or within twenty-one (21) days of receiving the Legislative Council's report on an existing rule.

(e) The circuit court shall have jurisdiction to consider any claim challenging the validity of a rule issued pursuant to this section. Any institution holding a certificate of registration to conduct research pursuant to this subchapter and aggrieved by a rule 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 circuit court shall consider any rule that would have the effect of prohibiting or discontinuing research authorized pursuant to this subchapter 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 thirty (30) days after submission of an application from the applicant institution, if the institution:

(1) Pays a fee of not more than two hundred dollars ($200) to the department; and

(2) 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) of this section.

(g) No research authorized pursuant to § 20-8-504(b) 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 three (3) years from the date of issuance. The department shall notify all holders of certificates of registration under this section at least sixty (60) days before the expiration of the certificate of registration. If an institution that is issued a certificate of registration under this subchapter 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 ninety (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 (h) of this section.

(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 subchapter, 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 Secretary of State.

(l) The department shall keep an official record of anyone convicted of violating § 20-8-509(a), (b), or (c). 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 § 20-8-509(a), (b), or (c).

(m) The department shall revoke any certificate of registration, shall not renew the certificates and shall deny any future application for a certificate of registration for any institution that knowingly and willfully permits or assists a violation of § 20-8-509(a), 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 subchapter if it is determined, after an opportunity for an adjudicatory proceeding conducted pursuant to the Arkansas Administrative Procedure Act § 25-15-201 et seq. that the institution has:

(A) Violated § 20-8-504(b);

(B) Violated § 20-8-505;

(C) Knowingly and willfully permitted or assisted a violation of § 20-8-509(b) or (c);

(D) Knowingly violated subsection (f) of this section, if applicable;

(E) Failed to submit an annual report to the department pursuant to subsection (i) of this section;

(F) Employed a person identified in the annual notice by

the department pursuant to subsection (l) of this section; or

(G) Knowingly implemented a decision by an institutional review board to authorize research prohibited by this subchapter.

(2) The department may, after an opportunity for an adjudicatory proceeding conducted pursuant to the Arkansas Administrative Procedure Act, § 25-15-201 et seq., and upon determination that an institution conducting research pursuant to this subchapter has violated this subsection (n), undertake the following actions:

(A) For violating subdivision (n)(1)(C) of this section, revoke or refuse to renew the certificate of registration or assess upon the holder a civil administrative penalty not to exceed two hundred fifty thousand dollars ($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;

(B) For violating subdivision (n)(1)(A), (B), (C), (D) or (E) of this section, assess upon the holder a civil administrative penalty not to exceed one hundred thousand dollars ($100,000); or

(C) For a first violation of subdivision (n)(1)(E) censure a holder; and for each subsequent violation of subdivision (n)(1)(E), suspend the certificate of registration until compliance with subdivision (n)(1), and impose a civil administrative penalty, as determined by the department not to exceed one thousand dollars ($1,000).

(3) An institution sanctioned under this subsection (n) may be subject to such other sanctions or punishment as may be provided by law. The department shall promulgate such rules not inconsistent with Administrative Procedure Act, § 25-25-201 et seq., and this subchapter as necessary for the filing of charges and the conduct of proceedings.

20-8-512. Recommendations about Proposed Regulations to Administer and Enforce this Act.

The Biomedical Research Advisory Council established under this subchapter may, from time to time, make recommendations to the Director of the Department of Health and Human Services about proposed regulations for the administration and enforcement of this subchapter.

20-8-513. Investigating the Feasibility of Permitting Certain

Companies to Use an Alternative Method to Get Approval to Conduct Embryonic Stem Cell Research. (a) The Biomedical Research Advisory Council established under this subchapter 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 subchapter. The investigation shall include a recommendation as to whether the approval of an appointed bioethical advisory board is a suitable alternative to the approval of an institutional review board.

(b) The council shall complete its investigation and submit its recommendations, if any, to the the House and Senate Committees having jurisdiction over technology issues not later than October 1, 2008.

20-8-514. 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 subchapter 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 Director of the Department of Health and Human Services, 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 House and Senate Committees having jurisdiction over technology issues not later than October 1, 2008.

20-8-515. Investigating the Optimum Method by Which a Public Placental and Umbilical Cord Blood Bank Should be Established at the University of Arkansas for Medical Sciences or Other Appropriate Institution.

The Biomedical Research Advisory Council established under this subchapter shall investigate the optimum method by which a public placental

and umbilical cord blood bank should be established at the University of Arkansas for Medical Sciences 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 them 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 Committees having jurisdiction over technology issues not later than October 1, 2008.

20-8-516. Appointment of Biomedical Research Advisory Council.

Notwithstanding any law to the contrary, the members of the Biomedical Research Advisory Council established under this subchapter shall be appointed not later than thirty (30) days after the effective date of this section. If, as of that date, the council shall consist of fewer than fifteen (15) members, the Attorney General shall appoint the members, not later forty-five (45) days after the effective date of this section so that the council consists of fifteen (15) members.

20-8-517. Investigating the Optimum Method by Which a Public Institutional review board Should be Established at the University of Arkansas for Medical Sciences.

Notwithstanding any general or special law to the contrary, the Biomedical Research Advisory Council established under this subchapter shall

investigate the optimum method by which a public institutional review board should be established at the University of Arkansas for Medical Sciences. The council shall report its findings, together with any proposed legislation, to the House and Senate Committees having jurisdiction over technology issues not later than October 1, 2008.

20-8-518. Analyzing and Investigating the Feasibility of Establishing an Institute for Regenerative Medicine at the University of Arkansas for Medical Sciences.

The President of the University of Arkansas System shall appoint a commission to analyze and investigate the feasibility of establishing an institute for regenerative medicine at the University of Arkansas for Medical Sciences. The analysis and investigation shall include the potential cost of establishing an institute as well as the potential scientific, economic and social benefits 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 Committees having jurisdiction over technology issues not later than October 1, 2008.

20-8-519. Date for Establishing the Public Institutional review board.

The public institutional review board to be established pursuant to this subchapter shall be established not later than one hundred twenty (120) days after the effective date of this subchapter.

20-8-520. Deadline for Complying with this Act.

Any institution that on the effective date of this subchapter is conducting human embryonic stem cell research in this state shall have one hundred eighty (180) days from the effective date to come into compliance with this subchapter.