Regenerative Medicine Research Fund (RMRF)

Public Act No. 14-98

Key: [] denotes text that was deleted in the legislation; _____ denoted new text that was added to the legislation

- Sec. 32. Subsection (a) of section 19a-32d of the 2014 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2014*):
- (a) As used in sections 19a-32d to 19a-32g, inclusive, <u>as amended by this act</u>, and section 4-28e, <u>as amended by this act</u>:
- (1) "Embryonic stem cell research oversight committee" means a committee established in accordance with the National Academies' Guidelines for Human Embryonic Stem Cell Research, as amended from time to time.
- (2) "Cloning of a human being" means inducing or permitting a replicate of a living human being's complete set of genetic material to develop after gastrulation commences.
- (3) "Gastrulation" means the process immediately following the blastula state when the hollow ball of cells representing the early embryo undergoes a complex and coordinated series of movements that results in the formation of the three primary germ layers, the ectoderm, mesoderm and endoderm.
- (4) "Embryonic stem cells" means cells created through the joining of a human egg and sperm or through nuclear transfer that are sufficiently undifferentiated such that they cannot be identified as components of any specialized cell type.
- (5) "Nuclear transfer" means the replacement of the nucleus of a human egg with a nucleus from another human cell.
- (6) "Eligible institution" means (A) a nonprofit, tax-exempt academic institution of higher education, (B) a hospital that conducts biomedical research, or (C) any entity that conducts biomedical research or [embryonic or human adult stem cell] <u>regenerative</u> medicine research.
- (7) "Regenerative medicine" means the process of creating living, functional tissue to repair or replace tissue or organ function lost due to aging, disease, damage or congenital defect. Regenerative medicine includes basic stem cell research.
- Sec. 33. Section 19a-32e of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2014*):

- (a) There is established the ["Stem Cell Research Fund"] "Regenerative Medicine Research Fund", which shall be a separate, nonlapsing account within the General Fund. The fund may contain any moneys required or permitted by law to be deposited in the fund and any funds received from any public or private contributions, gifts, grants, donations, bequests or devises to the fund. [The Commissioner of Public Health may] The chief executive officer of Connecticut Innovations, Incorporated, (1) shall make grants-in-aid from the fund in accordance with the provisions of subsection (b) of this section, and (2) may enter into agreements with other entities, including, but not limited to, the government of any state or foreign country for the purpose of advancing research collaboration opportunities for recipients of grants-in-aid under this section.
- (b) [Not later than June 30, 2006, the Stem Cell] The Regenerative Medicine Research Advisory Committee established pursuant to section 19a-32f, as amended by this act, shall develop an application for grants-in-aid under this section for the purpose of conducting [embryonic or human adult stem cell] regenerative medicine research and may receive applications from eligible institutions for such grants-in-aid. Jon and after said date. The Stem Cell The Regenerative Medicine Research Advisory Committee shall require any applicant for a grant-in-aid under this section to conduct [stem cell] regenerative medicine research to submit (1) a complete description of the applicant's organization, (2) the applicant's plans for [stem cell] regenerative medicine research and proposed funding for such research from sources other than the state, [of Connecticut,] and (3) proposed arrangements concerning financial benefits to the state [of Connecticut] as a result of any patent, royalty payment or similar rights developing from any [stem cell] proposed research made possible by the awarding of such grant-inaid. [Said committee shall direct the Commissioner of Public Health] The Regenerative Medicine Research Advisory Committee shall direct the chief executive officer of Connecticut Innovations, Incorporated, with respect to the awarding of such grants-inaid after considering recommendations from the [Stem Cell] Regenerative Medicine Research Peer Review Committee established pursuant to section 19a-32g, as amended by this act.
- (c) Commencing with the fiscal year ending June 30, 2006, and for each of the [nine] thirteen consecutive fiscal years thereafter, until the fiscal year ending June 30, [2015] 2019, not less than ten million dollars shall be available from the [Stem Cell] Regenerative Medicine Research Fund for grants-in-aid to eligible institutions for the purpose of conducting [embryonic or human adult stem cell research, as directed by the Stem Cell Research Advisory Committee established pursuant to section 19a-32f] regenerative medicine research. Any balance of such amount not used for such grants-in-aid during a fiscal year shall be carried forward for the fiscal year next succeeding for such grants-in-aid.

Sec. 34. Section 19a-32f of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2014*):

- (a) (1) There is established a [Stem Cell] Regenerative Medicine Research Advisory Committee. The committee shall consist of the Commissioner of Public Health, or the commissioner's designee, the chief executive officer of Connecticut Innovations, Incorporated, or the chief executive officer's designee, and eight members who shall be appointed as follows: Two by the Governor, one of whom shall [be nationally recognized as an active investigator in the field of stem cell research and one of whom shall have background and experience in the field of bioethics] have background and experience in stem cell or regenerative medicine research and one of whom shall have background and experience in business or financial investments; one each by the president pro tempore of the Senate and the speaker of the House of Representatives, who shall have background and experience in private sector [stem cell] regenerative medicine research and development; one each by the majority leaders of the Senate and House of Representatives, who shall be academic researchers specializing in [stem cell] regenerative medicine research; one by the minority leader of the Senate, who shall have background and experience in either private or public sector [stem cell] regenerative medicine research and development or related research fields, including, but not limited to, embryology, genetics or cellular biology; and one by the minority leader of the House of Representatives, who shall have background and experience in [business or financial investments] the field of bioethics. Members shall serve for a term of four years commencing on October first, except that members first appointed by the Governor and the majority leaders of the Senate and House of Representatives shall serve for a term of two years. No member may serve for more than two consecutive four-year terms. [and no member may serve concurrently on the Stem Cell Research Peer Review Committee established pursuant to section 19a-32g. All initial appointments to the committee shall be made by October 1, 2005. Any vacancy shall be filled by the appointing authority.
- (2) [On and after July 1, 2006, the advisory committee] The Regenerative Medicine Research Advisory Committee shall include eight additional members who shall be appointed as follows: Two by the Governor, [one of whom shall be nationally recognized as an active investigator in the field of stem cell research and one of whom shall have background and experience in the field of ethics] who shall have backgrounds and experience in business or financial investments; one each by the president pro tempore of the Senate and the speaker of the House of Representatives, who shall have background and experience in private sector [stem cell] regenerative medicine research and development; one each by the majority leaders of the Senate and House of Representatives, who shall be academic researchers specializing in [stem cell] regenerative medicine research; one by the minority leader of the Senate, who shall have background and experience in either private or public sector [stem cell] regenerative medicine research and development or related research fields, including, but not limited to, embryology, genetics or cellular biology; and one by the minority leader of the House of Representatives, who shall have background and experience in business, [or financial investments] law or ethics. Members shall serve for a term of four

years, except that (A) members first appointed by the Governor and the majority leaders of the Senate and House of Representatives pursuant to this subdivision shall serve for a term of two years and three months, and (B) members first appointed by the remaining appointing authorities shall serve for a term of four years and three months. No member appointed pursuant to this subdivision may serve for more than two consecutive four-year terms. [and no such member may serve concurrently on the Stem Cell Research Peer Review Committee established pursuant to section 19a-32g.] All initial appointments to the committee pursuant to this subdivision shall be made by July 1, 2006. Any vacancy shall be filled by the appointing authority.

- [(b) The Commissioner of Public Health, or the commissioner's designee, shall serve as the chairperson of the committee and shall schedule the first meeting of the committee, which shall be held no later than December 1, 2005.]
- (b) The chief executive officer of Connecticut Innovations, Incorporated, or the chief executive officer's designee, shall serve as chairperson of the Regenerative Medicine Research Advisory Committee.
- (c) All members appointed to [the] <u>said advisory</u> committee shall work to advance [embryonic and human adult stem cell] <u>regenerative medicine</u> research. Any member who fails to attend three consecutive meetings or who fails to attend fifty per cent of all meetings held during any calendar year shall be deemed to have resigned from [the] <u>said advisory</u> committee.
- (d) Notwithstanding the provisions of any other law, it shall not constitute a conflict of interest for a trustee, director, partner, officer, stockholder, proprietor, counsel or employee of any eligible institution, or for any other individual with a financial interest in any eligible institution, to serve as a member of [the] said advisory committee. All members shall be deemed public officials and shall adhere to the code of ethics for public officials set forth in chapter 10. Members may participate in the affairs of [the] said advisory committee with respect to the review or consideration of grant-in-aid applications, including the approval or disapproval of such applications, except that no member shall participate in the affairs of [the] said advisory committee with respect to the review or consideration of any grant-in-aid application filed by such member or by any eligible institution in which such member has a financial interest, or with whom such member engages in any business, employment, transaction or professional activity.
- (e) The [Stem Cell] <u>Regenerative Medicine</u> Research Advisory Committee shall (1) develop, in consultation with [the Commissioner of Public Health] <u>Connecticut Innovations, Incorporated</u>, a donated funds program to encourage the development of funds other than state appropriations for [embryonic and human adult stem cell] <u>regenerative medicine</u> research in [this] <u>the</u> state, (2) examine and identify specific ways

to improve and promote for-profit and not-for-profit [embryonic and human adult stem cell] regenerative medicine research and [related] research in related areas in the state, including, but not limited to, identifying both public and private funding sources for such research, maintaining existing [embryonic and human adult stem-cell-related] regenerative medicine-related businesses, recruiting new [embryonic and human adult stem-cell-related regenerative medicine-related businesses to the state and recruiting scientists and researchers in such field to the state, (3) [establish and] administer [, in consultation with the Commissioner of Public Health, a stem cell] a regenerative medicine research grant program [which] that shall provide grants-in-aid to eligible institutions for the advancement of [embryonic or human adult stem cell] regenerative medicine research in [this] the state pursuant to section 19a-32e, as amended by this act, [and] (4) monitor the [stem cell] regenerative medicine research conducted by eligible institutions that receive such grants-in-aid, and (5) prepare a comprehensive strategic plan for the Regenerative Medicine Research Fund, established pursuant to section 19a-32e, as amended by this act, and grants-in-aid made from said fund that shall include, but need not be limited to, identification of specific methods or strategies to (A) achieve the scientific and economic development objective of said fund, (B) build innovation capacity, and (C) sustain investments of moneys received by said fund.

(f) [Connecticut Innovations, Incorporated shall serve as administrative staff of the committee and shall assist the committee in (1) developing the application for the grants-in-aid authorized under subsection (e) of this section, (2) reviewing such applications, (3) preparing and executing any assistance agreements or other agreements in connection with the awarding of such grants-in-aid, and (4) performing such other administrative duties as the committee deems necessary Connecticut Innovations, Incorporated, shall serve as administrator of the Regenerative Medicine Research Fund and shall, in consultation with the Regenerative Medicine Research Advisory Committee: (1) Develop the application for the grants-in-aid authorized under subsection (b) of section 19a-32e, as amended by this act; (2) review such applications; (3) review recommendations of the Regenerative Medicine Research Advisory Committee, established pursuant to section 19a-32g, as amended by this act; (4) prepare and execute any assistance agreements or other agreements in connection with the awarding of such grants-in-aid; (5) develop performance metrics and systems to collect data from recipients of such grants-in-aid; (6) collect information from such recipients concerning each recipient's employment statistics, business accomplishments and performance outcomes, peer review articles and papers published, partnerships and collaborations with other entities, licenses, patents and invention disclosures, scientific progress as it relates to the commercialization of intellectual property funded by such grants-in-aid, efforts to commercialize such intellectual property, and other funds received for research; and (7) performing such other administrative duties as the Regenerative Medicine Research Advisory Committee deems necessary.

- Sec. 35. Section 19a-32g of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2014*):
- (a) (1) There is established a [Stem Cell] <u>Regenerative Medicine</u> Research Peer Review Committee. [The] <u>Said peer review</u> committee shall consist of five members. [appointed by the Commissioner of Public Health. All]
- (2) On and before September 30, 2014, all members appointed by the Commissioner of Public Health to the committee shall (A) have demonstrated knowledge and understanding of the ethical and medical implications of [embryonic and human adult stem cell] regenerative medicine research or related research fields, including, but not limited to, embryology, genetics or cellular biology, (B) have practical research experience in [human adult or embryonic stem cell] regenerative medicine research or related research fields, including, but not limited to, embryology, genetics or cellular biology, and (C) work to advance [embryonic and human adult stem cell] regenerative medicine research. Members shall serve for a term of four years commencing on October first, except that three members first appointed by the Commissioner of Public Health shall serve for a term of two years. No member may serve for more than two consecutive four-year terms and no member may serve concurrently on the [Stem Cell] Regenerative Medicine Research Advisory Committee established pursuant to section 19a-32f, as amended by this act. All initial appointments to [the] said peer review committee shall be made by October 1, 2005. Any member who fails to attend three consecutive meetings or who fails to attend fifty per cent of all meetings held during any calendar year shall be deemed to have resigned from [the] said peer review committee.
- [(2) The Commissioner of Public Health may appoint such additional members to the Stem Cell Research Peer Review Committee as the commissioner deems necessary for the review of applications for grants-in-aid, provided the total number of Stem Cell Research Peer Review Committee members does not exceed fifteen. Such additional members shall be appointed as provided in subdivision (1) of this subsection, except that such additional members shall serve for a term of two years from the date of appointment.]
- (3) On and after October 1, 2014, each member appointed by the Commissioner of Public Health pursuant to subdivision (2) of this subsection may serve to the conclusion of his or her current term at which time members shall be appointed by the chief executive officer of Connecticut Innovations, Incorporated, as follows: Members appointed to said peer review committee shall: (A) Have demonstrated knowledge and understanding of the ethical and medical implications of regenerative medicine research or research in a related field, including, but not limited to, embryology, genetics or cellular biology; (B) have practical research experience in regenerative medicine research or research in a related field, including, but not limited to,

embryology, genetics or cellular biology; and (C) work to advance regenerative medicine research. Members shall serve for a term of four years, except that three members first appointed by the chief executive officer of Connecticut Innovations, Incorporated, shall serve for a term of two years. No member may serve for more than two consecutive four-year terms and no member may serve concurrently on the Regenerative Medicine Research Advisory Committee established pursuant to section 19a-32f, as amended by this act. Any member who fails to attend three consecutive meetings or who fails to attend fifty per cent of all meetings held during any calendar year shall be deemed to have resigned from said peer review committee.

- (b) All members shall be deemed public officials and shall adhere to the code of ethics for public officials set forth in chapter 10. No member shall participate in the affairs of the committee with respect to the review or consideration of any grant-in-aid application filed by such member or by any eligible institution in which such member has a financial interest, or with which such member engages in any business, employment, transaction or professional activity.
- (c) Prior to the awarding of any grants-in-aid for [embryonic or human adult stem cell] regenerative medicine research pursuant to section 19a-32e, as amended by this act, the [Stem Cell] Regenerative Medicine Research Peer Review Committee shall review all applications submitted by eligible institutions for such grants-in-aid and make recommendations to the [Commissioner of Public Health and the Stem Cell] Regenerative Medicine Research Advisory Committee established pursuant to section 19a-32f, as amended by this act, with respect to the ethical and scientific merit of each application.
- (d) [Peer review committee members] Members of the Regenerative Medicine Research Peer Review Committee may receive compensation from [the Stem Cell Research Fund, established pursuant to section 19a-32e,] Connecticut Innovations, Incorporated, for reviewing grant-in-aid applications submitted by eligible institutions. [pursuant to subsection (c) of this section.] The rate of compensation shall be established by the [Commissioner of Public Health in consultation with the Department of Administrative Services and the Office of Policy and Management] board of directors of Connecticut Innovations, Incorporated.
- (e) The <u>Regenerative Medicine Research</u> Peer Review Committee shall establish guidelines for the rating and scoring of such applications. [by the Stem Cell Research Peer Review Committee.]
- (f) All members of [the] <u>said peer review</u> committee shall become and remain fully cognizant of the National Academies' Guidelines for Human Embryonic Stem Cell Research, as amended from time to time, and shall utilize said guidelines to evaluate each grant-in-aid application. [The committee may make recommendations to the Stem

Cell Research Advisory Committee and the Commissioner of Public Health concerning the adoption of said guidelines, in whole or in part, in the form of regulations adopted pursuant to chapter 54.]

Sec. 36. Section 32-41aa of the 2014 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2014*):

For the purpose of this section and sections 32-41bb to 32-41dd, inclusive, as amended by this act:

- [(1) "Administrative costs" means the costs paid or incurred by the administrator, including, but not limited to, peer review costs, professional fees, allocated staff costs and other out-of-pocket costs attributable to the administration and operation of the Connecticut Bioscience Innovation Fund.]
- [(2)] (1) "Administrator" means Connecticut Innovations, Incorporated, in its capacity as administrator of the Connecticut Bioscience Innovation Fund established pursuant to section 32-41cc, as amended by this act.
- [(3)] (2) "Advisory committee" means the Bioscience Innovation Advisory Committee established pursuant to section 32-41bb, as amended by this act.
- [(4)] (3) "Early-stage business" means a business that has been in operation for not more than three years and is developing or testing a product or service that is (A) not yet available for commercial release, or (B) commercially available in a limited manner, including, but not limited to, market testing of prototypes and clinical trials.
- [(5)] (4) "Eligible recipient" means a duly accredited college or university, a nonprofit corporation or a for-profit start-up or early-stage business.
- [(6)] (5) "Financial assistance" means any and all forms of grants, extensions of credit, loans or loan guarantees, equity investments or other forms of financing.
- [(7)] (6) "Return on investment" means any and all forms of principal or interest payments, guarantee fees, returns on equity investments, royalties, options, warrants and debentures and all other forms of remuneration to the administrator in return for any financial assistance offered or provided.
- Sec. 37. Subsection (e) of section 32-41bb of the 2014 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2014*):
- (e) Notwithstanding any provision of the general statutes, it shall not constitute a conflict of interest for a trustee, director, partner, officer, manager, shareholder, proprietor, counsel or employee of an eligible recipient, or any individual with a

financial interest in an eligible recipient, to serve as a member of the advisory committee, provided such trustee, director, partner, officer, manager, shareholder, proprietor, counsel, employee or individual shall abstain from deliberation, action or vote by the advisory committee in specific respect to such eligible recipient. <u>All members of the advisory committee shall be deemed public officials and shall adhere to the code of ethics for public officials set forth in chapter 10.</u>

Sec. 38. Subsections (d) and (e) of section 32-41cc of the 2014 supplement to the general statutes are repealed and the following is substituted in lieu thereof (*Effective October 1, 2014*):

- (d) The Connecticut Bioscience Innovation Fund shall be used (1) to provide financial assistance to eligible recipients as may be approved by the advisory committee pursuant to subsection (e) of this section, and (2) for the repayment of state bonds in such amounts as may be required by the State Bond Commission. [, and (3) to pay or reimburse the administrator for administrative costs pursuant to subsection (j) of this section.] Such financial assistance shall be awarded to further the development of bioscience, biomedical engineering, health information management, medical care, medical devices, medical diagnostics, pharmaceuticals, personalized medicine and other related disciplines that are likely to lead to an improvement in or development of services, therapeutics, diagnostics or devices that are commercializable and designed to advance the coordination, quality or efficiency of health care and lower health care costs, and that promise, directly or indirectly, to lead to job growth in the state in these or related fields.
- (e) All expenditures from the Connecticut Bioscience Innovation Fund, except for [administrative costs reimbursed to the administrator pursuant to subsection (j) of this section and] amounts required for the repayment of state bonds in such amounts as may be required by the State Bond Commission, shall be approved by the advisory committee. Any such approval shall be (1) specific to an individual expenditure to be made, (2) for budgeted expenditures with such variations as the advisory committee may authorize at the time of such budget approval, or (3) for a financial assistance program to be administered by staff of the administrator, subject to limits, eligibility requirements and other conditions established by the advisory committee at the time of such program approval.

Sec. 39. Subsections (j) and (k) of section 32-41cc of the 2014 supplement to the general statutes are repealed and the following is substituted in lieu thereof (*Effective October 1, 2014*):

[(j) Administrative costs shall be paid or reimbursed to the administrator from the Connecticut Bioscience Innovation Fund, provided the total of such administrative costs in any fiscal year shall not exceed five per cent of the total amount of the allotted

funding for such fiscal year as determined in the operating budget prepared pursuant to subsection (i) of this section. Nothing in sections 32-41aa and 32-41bb and this section shall require the administrator to risk or expend the funds of Connecticut Innovations, Incorporated in connection with the administration of the Connecticut Bioscience Innovation Fund.]

[(k)] (j) Not later than April 15, 2014, and annually thereafter, the administrator shall provide a report of the activities of the Connecticut Bioscience Innovation Fund to the advisory committee for its review and approval. Upon its approval, the advisory committee shall provide such report, in accordance with the provisions of section 11-4a, to the joint standing committees of the General Assembly having cognizance of matters relating to finance, revenue and bonding, appropriations, commerce, public health and higher education. Such report shall contain available information on the status and progress of the operations and funding of the Connecticut Bioscience Innovation Fund and the types, amounts and recipients of financial assistance awarded and any returns on investment.

Sec. 40. Subsection (c) of section 4-28e of the 2014 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2014*):

- (c) (1) For the fiscal year ending June 30, 2001, disbursements from the Tobacco Settlement Fund shall be made as follows: (A) To the General Fund in the amount identified as "Transfer from Tobacco Settlement Fund" in the General Fund revenue schedule adopted by the General Assembly; (B) to the Department of Mental Health and Addiction Services for a grant to the regional action councils in the amount of five hundred thousand dollars; and (C) to the Tobacco and Health Trust Fund in an amount equal to nineteen million five hundred thousand dollars.
- (2) For the fiscal year ending June 30, 2002, and each fiscal year thereafter, disbursements from the Tobacco Settlement Fund shall be made as follows: (A) To the Tobacco and Health Trust Fund in an amount equal to twelve million dollars, except in the fiscal years ending June 30, 2014, and June 30, 2015, said disbursement shall be in an amount equal to six million dollars; (B) to the Biomedical Research Trust Fund in an amount equal to four million dollars; (C) to the General Fund in the amount identified as "Transfer from Tobacco Settlement Fund" in the General Fund revenue schedule adopted by the General Assembly; and (D) any remainder to the Tobacco and Health Trust Fund.
- (3) For each of the fiscal years ending June 30, 2008, to June 30, 2012, inclusive, the sum of ten million dollars shall be disbursed from the Tobacco Settlement Fund to the [Stem Cell] Regenerative Medicine Research Fund established by section 19a-32e, as amended by this act, for grants-in-aid to eligible institutions for the purpose of conducting embryonic or human adult stem