

Tobacco Settlement Act (Act 2001-77) and Act 2002-149 - Excerpts Related to the Commonwealth Universal Research Enhancement Program

IMPORTANT NOTE: Chapter 9 of Act 2001-77, which was enacted in 2001, authorized the establishment of the Commonwealth Universal Research Enhancement Program (CURE). Act 2002-149, which was enacted in 2002, amended the definition of infrastructure that was contained in Act 2001-77. Act 2002-149's definition of infrastructure is cited below, followed by Chapter 9 of Act 2001-77.

ACT 2002-149

THE DEFINITION OF INFRASTRUCTURE CONTAINED IN ACT 2002-149, AS SHOWN BELOW, REPLACES THE PREVIOUS DEFINITION OF INFRASTRUCTURE CONTAINED IN ACT 2001-77.

"Infrastructure." Office equipment and supplies, nonprofessional personnel, laboratory or building construction or renovations, used to conduct research.

ACT 2001-77

CHAPTER 9

COMMONWEALTH UNIVERSAL RESEARCH ENHANCEMENT

Section 901. Scope.

This chapter deals with Commonwealth universal research enhancement efforts.

Section 902. Definitions.

The following words and phrases when used in this chapter shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Advisory committee." The Health Research Advisory Committee established in section 903(b).

"Applicant." Any of the following located in this Commonwealth:

(1) A person.

(2) An institution.

(3) An entity established under the act of August 24, 1951 (P.L.1304, No.315), known as the Local Health Administration Law.

"Biomedical research." Comprehensive research pertaining to the application of the natural sciences to the study and clinical practice of medicine at an institution, including biobehavioral research related to tobacco use.

"Clinical research." Patient-oriented research which involves direct interaction and study of the mechanisms of human disease, including therapeutic interventions, clinical trials, epidemiological and behavioral studies and the development of new technology.

"Department." The Department of Health of the Commonwealth.

"Health services research." Any of the following:

(1) Research on the promotion and maintenance of health, including biobehavioral research.

(2) Research on the prevention and reduction of disease.

(3) Research on the delivery of health care services to reduce health risks and transfer research advances to community use.

"Infrastructure." Equipment, supplies, nonprofessional personnel, laboratory or building construction or renovations, or the development, acquisition or maintenance of technology, including training, used to conduct research.

"Institution." Any of the following located in this Commonwealth:

- (1) A nonprofit entity that conducts research.
- (2) A hospital that conducts research and is established under the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.
- (3) An institution of higher education that conducts research.

"NIH." The National Institutes of Health.

"Peer review." A process approved by the Department of Health or the National Institutes of Health in which a review panel which includes the applicant's professional peers reviews and evaluates research grant applications using a rating system of scientific and technical merit.

"Research." Biomedical, clinical and health services research which may include infrastructure.

"Secretary." The Secretary of Health of the Commonwealth.

Section 903. Health research program.

(a) Program establishment.--

(1) There is established in the department a health research program which shall be known as the Commonwealth Universal Research Enhancement Program.

Appropriations from the fund to the department shall be used to fund research projects and related infrastructure by eligible applicants. This includes:

- (i) biomedical research;
- (ii) clinical research; and
- (iii) health services research.

(2) Funds appropriated for the program may be used to conduct peer reviews and performance reviews.

(b) Advisory committee.--

(1) There is hereby established in the department the Health Research Advisory Committee.

(2) The committee is comprised of the following:

- (i) The secretary or a designee, who shall serve as chairperson.
- (ii) Four members appointed by the Governor.
- (iii) One member appointed by the President pro tempore of the Senate and one member appointed by the Minority Leader of the Senate.
- (iv) One member appointed by the Speaker of the House of Representatives and one member appointed by the Minority Leader of the House of Representatives.

(3) Members appointed to the committee by the Governor must possess expertise in health care or research, with representation by institution-based research specialists, practicing clinicians, clinical investigators and public health professionals.

(4) Terms are as follows:

- (i) The secretary shall serve ex officio.
- (ii) A member under paragraph (2)(ii) shall serve a term of six years.
- (iii) A member under paragraph (2)(iii) shall serve a term of four years but may be removed at the pleasure of the appointing authority.
- (iv) A member under paragraph (2)(iv) shall serve a term of two years but may be removed at the pleasure of the appointing authority.
- (v) An appointment to fill a vacancy shall be for the period of the unexpired term or until a successor is appointed and qualified.

(5) The committee shall meet as needed, but at least twice a year, to fulfill the purposes provided for in this chapter. A majority of the members of the committee constitutes a quorum. A majority of the members of the committee has authority to act upon any matter properly before it. The committee is authorized to establish rules

for its operation and shall hold public hearings, as necessary, to obtain public input and make recommendations to the department regarding research priorities, evaluation and accountability procedures and related issues. Meetings of the committee shall be conducted under 65 Pa.C.S. Ch. 7 (relating to open meetings).

(6) Members shall receive no payment for their services. Members who are not employees of State government shall be reimbursed for necessary and reasonable expenses incurred in the course of their official duties.

Section 904. Department responsibilities.

The department has the following powers and duties:

(1) Administer the health research program established under this chapter.

(2) Establish, in conjunction with the Health Research Advisory Committee, the research priorities of the Commonwealth. In developing these research priorities, the national health promotion and disease prevention objectives established by the United States Department of Health and Human Services, as applied to this Commonwealth, shall be considered. The priorities shall include the identification of critical research areas, disparities in health status among various Commonwealth populations, expected research outcomes and benefits and disease prevention and treatment methodologies. The priorities shall be reviewed annually and revised as necessary.

(3) Except as provided in section 905(f) and (g), review applications and award research grants to applicants consistent with the priorities established under paragraph (2). Research grants may be awarded for a period not to exceed four years for each project.

(4) Develop and implement peer review procedures to be used for the review of grant applications for projects funded pursuant to section 906(2) and (3).

(5) Publish an annual report on all research funded under this chapter. The report shall include:

(i) the aggregate amount of research grants awarded to each applicant;

(ii) the name and address of each principal investigator that received a grant;

(iii) the project title and purpose;

(iv) the name and employer of each participating researcher;

(v) the expected research outcomes and benefits;

(vi) the amount of each research grant awarded;

(vii) an anticipated disbursement schedule by fiscal year for each grant awarded;

(viii) a report of expenditures by grant by fiscal year; and

(ix) a detailed summary of the research completed that year.

(6) The report under paragraph (5) shall be provided to the chair and minority chair of the Public Health and Welfare Committee and the chair and minority chair of the Appropriations Committee of the Senate and the chair and minority chair of the Health and Human Services Committee and the chair and minority chair of the Appropriations Committee of the House of Representatives no later than November 30, 2002, and annually thereafter. The annual report shall be made available for public inspection and posted on the department's publicly accessible World Wide Web site.

Section 905. Peer review procedures.

(a) Peer review required.--Except for infrastructure and for projects funded under section 906(1), research funded under this chapter shall be peer reviewed and selected in accordance with this section.

(b) Prior peer review.--Research which has received peer review by the National Institutes of Health, the Centers for Disease Control or another Federal agency may be approved and ranked for funding by the department consistent with the priorities established under section 904(2).

(c) Department peer review.--Research which has not received peer review as provided in subsection (b) shall be subject to peer review by the department in accordance with subsection (d) prior to being considered for funding under section 906(2) and (3).

(d) Peer review panels.--The department shall establish peer review panels in various disciplines, as necessary, to review research grant proposals which are consistent with the priorities established under section 904(2). A panel shall be composed of at least three nationally recognized physicians, scientists or researchers from the same or similar discipline as the research grant proposal under review. Members of a peer review panel may be residents of other states. In no case shall a member of a peer review panel be an employee of an applicant whose grant proposal is under its review.

(e) Panel review factors.--A review panel shall determine eligibility for grant funding based on the highest-ranked peer review scores through a rating system consistent with Federal rating standards as developed by the department. A panel shall review and rank research projects eligible for funding in a manner which recognizes scientific and technical merit on the basis of scientific need, scientific method, research design, adequacy of the facility and qualifications of the research personnel.

(f) Ethical standards.--No research funded under this chapter shall be permitted until a memorandum of understanding between the applicant and the secretary has been executed specifying that the research to be performed and all individuals performing such research shall be subject to Federal ethical and procedural standards of conduct as prescribed by the NIH on the date the memorandum of understanding is executed. Research funded under this act shall observe the Federal ethical and procedural standards regulating research and research findings, including publications and patents, which are observed under NIH extramural funding requirements and NIH grants policy statements and applicable sections of 45 CFR Pt. 74 (relating to uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with States, local governments and Indian tribal governments) and Pt. 92 (relating to uniform administrative requirements for grants and cooperative agreements to State and local governments).

(g) Ethics Advisory Board.--

(1) The Ethics Advisory Board shall be composed of six individuals who are not officers or employees of the Commonwealth. The secretary shall make appointments to the board from among individuals with qualifications and experience to provide advice and recommendations regarding ethical matters in research. The members of the board shall include one attorney, one ethicist, one practicing physician, one theologian, one scientist with experience in biomedical research and one scientist with experience in behavioral research. In no case shall a member of the board be an officer, director, employee or paid consultant of an applicant whose grant proposal is under review.

(i) A majority of the board shall consist of four members.

(ii) Members of the board shall serve at the pleasure of the secretary.

(iii) The secretary shall designate an individual from among the members of the board to serve as the chair of the board.

(iv) A member of the board shall receive no payment for service but shall be reimbursed by the department for necessary and reasonable expenses incurred in the course of the member's official duties.

(v) An annual report setting forth a summation of the board activities as well as each board decision shall be submitted no later than November 30 of each year

to the chair and minority chair of the Public Health and Welfare Committee of the Senate and to the chair and minority chair of the Health and Human Services Committee of the House of Representatives and shall be made available to the public.

(2) The board shall be convened by the secretary to advise and make recommendations when a research project may be denied due to ethical considerations, consistent with the standards set forth in subsection (f) that are in effect on the date the board is convened.

(i) The department shall notify the research applicant of the initiation of an ethics review. The applicant shall have the opportunity to provide comment on the ethical considerations of the project to the board. The board may receive other comments or information to assist in its review.

(ii) The board shall have access to all relevant information possessed by the department regarding the research project.

(iii) Within 60 days of initiating its review, the board shall submit to the secretary a report with its findings and recommendations regarding the ethical considerations of the research project.

(3) Funding for a research project under this chapter shall be denied by the secretary based on a finding of improper ethical considerations by a majority of the board.

(4) As used in this subsection, the following words and phrases shall have the meanings given to them in this paragraph:

"Board." The Ethics Advisory Board.

"Ethical considerations." Matters concerning whether the proposed conduct of or subject of the research is medically, sociologically and legally moral and proper.

(h) Final selection.--Based on the procedures set forth in this section and the rankings established by the relevant peer review panel, the department shall award research grants to selected applicants. In making these awards, the department shall avoid unnecessary duplication, ensure relevance to the appropriate research priority, encourage collaboration between applicants and provide for the development of a complementary Statewide research program.

Section 906. Use of funds.

Research projects conducted under this section shall be consistent with the priorities established under section 904(2). Funds under this section shall be allocated for the following purposes:

(1) Seventy percent of the funds appropriated under this section shall be used to fund research pursuant to section 908.

(2) Fifteen percent of the funds appropriated under this section shall be used to fund clinical and health services research projects by eligible applicants.

(3) Fifteen percent of the funds appropriated under this section shall be used to fund other research projects by eligible applicants.

Section 907. Applications.

(a) General rule.--An application for a research grant under section 906 must include all of the following, as applicable:

(1) The name and address of the applicant.

(2) The identification of participating researchers.

(3) The description of the purpose and methodology of the research project.

(4) An accounting of proposed expenditures, to include salary expenses, capital equipment and construction or renovation.

- (5) The expected research outcomes and benefits.
- (6) An explanation of the project's evaluative procedures.
- (7) A list of other proposed funding sources being sought by the applicant for the research project.
- (8) Any other information deemed necessary by the department.

(b) Report.--An applicant receiving a research grant under this chapter shall report annually to the department on the progress of the research project or as often as the department deems necessary. The results of the research and other information deemed necessary by the department shall be reported to the department upon conclusion of the research project in accordance with section 910.

(c) Limitations.

(1) An applicant for a research grant under section 906 may not expend more than 50% of its grant for infrastructure.

(2) The award of a research grant shall not constitute an entitlement derived from the Commonwealth or a claim on any funds of the Commonwealth.

Section 908. National Institutes of Health funding formula.

(a) Eligibility.--An institution that conducts research in this Commonwealth and has received funding from the National Institutes of Health during each of the three immediately preceding Federal fiscal years shall be eligible to receive a grant pursuant to section 906(1). For one year from the effective date of this act, an institution that has immediately succeeded, by asset acquisition, the research function of another institution that received National Institutes of Health funding during any of the four immediately preceding fiscal years shall be considered eligible to receive a grant pursuant to section 906(1).

(b) Fund distribution.--Funds under this section shall be distributed to eligible institutions as follows:

(1) Twenty percent shall be distributed to each institution that receives more than \$175,000,000 as an average amount from the National Institutes of Health during the three immediately preceding Federal fiscal years.

(2) Seventeen percent shall be distributed to each institution that receives more than \$175,000,000 in federally sponsored research and development obligations in the immediately available preceding Federal fiscal year as reported by the National Science Foundation and receives more than \$60,000,000 as an average amount from the National Institutes of Health during the three immediately preceding Federal fiscal years.

(3) The remaining funds shall be distributed to eligible institutions based on the percentage calculated by dividing an institution's average award from the National Institutes of Health for the three immediately preceding Federal fiscal years by the sum of the average annual award from the National Institutes of Health for all Pennsylvania-based eligible institutions during the three immediately available preceding Federal fiscal years.

(4) An institution is not eligible to receive funds under more than one paragraph of this subsection.

(c) Additional requirements.--An institution that receives \$400,000 or more pursuant to this section shall include the following information with its application under section 907(a):

(1) A plan for the timely licensure or commercial development of research results conducted under this section, including its management of intellectual property.

(2) Standard forms of agreement developed by the institution for use in the licensing of research results.

(3) A plan to establish affiliations, exchanges, partnerships or other cooperative efforts with postsecondary educational institutions to provide programs to train students and health professionals in the biomedical field.

(4) A description of the training opportunities provided for researchers employed by the institution relating to the licensing and commercial development of research.

(5) Outreach efforts directed toward informing businesses and business organizations regarding recent developments in research being conducted by the institutions.

(6) A plan for collaboration with an applicant, an institution, a regional biomedical research center under Chapter 17 or a for-profit corporation or other business entity to participate in the development of research.

Section 909. National Cancer Institute funding formula.

(a) Eligibility.--An institution that conducts research in this Commonwealth and has received funding from the National Cancer Institute during each of the three immediately preceding Federal fiscal years shall be eligible to receive a grant under this section.

(b) Fund distribution.--Funds shall be distributed to an eligible institution based on the percentage calculated by dividing that institution's average award from the National Cancer Institute for the three immediately available preceding Federal fiscal years by the sum of the average annual award from the National Cancer Institute for all Pennsylvania-based eligible institutions during the three immediately available preceding Federal fiscal years.

(c) Ineligibility.--An institution that receives funding pursuant to section 908(b)(1) and (2) shall be ineligible for funding under this section.

(d) Requirements.--An institution that receives a grant pursuant to this section shall comply with all applicable requirements of this chapter.

Section 910. Accountability procedures.

(a) Requirements.--An applicant that receives a research grant under this chapter shall be subject to a performance review by the department upon completion of a research project or more often as deemed necessary by the department. The performance review shall be based on an evaluation process developed by the department in consultation with the advisory committee. Information shall be submitted by research grant recipients and shall include, as applicable, the following:

(1) The progress made in achieving expected research goals and objectives.

(2) The extent of clinical activities initiated and completed, detailing the number of treatment, prevention and diagnostic studies; the number of hospitals and health care professionals; the number of subjects relative to targeted goals; and the extent of penetration of the studies throughout the region or this Commonwealth.

(3) The number of peer-reviewed publications and the number of licenses and patents filed, including commercial development opportunities.

(4) Any changes in risk factors, services provided, incidence of disease, death from disease, stage of disease at the time of diagnosis or other relevant measures of the outcome, impact and effectiveness of the research being conducted.

(5) Any major discoveries, new drugs and new approaches for prevention, diagnosis and treatment which are attributable to the completed research project.

(6) Any other information deemed necessary by the department.

(b) Penalty.--Notwithstanding any other provision of this chapter, an applicant that receives an unfavorable review by the department under subsection (a) may be subject to a reduction in or ineligibility for research grant funding under this chapter.