

Health Research Program



In June of 2001, then Governor Ridge signed into law the Tobacco Settlement Act, called Act 2001-77, which authorized the Department of Health to establish a health research program called the Commonwealth Universal Research Enhancement Program, also known as CURE.

Chapter 9 of Act 2001-77 specifies the requirements for the administration of the CURE program. Chapter 7 details the provisions of the Department's Tobacco Prevention and Cessation Program, which is the only other ongoing program administered by the Department using Tobacco Settlement funds.

THE GOAL OF CURE

To support broad based health research for the purpose of discovering new scientific knowledge that can be applied toward improving the health of all Pennsylvanians.



The goal of the health research program is to create opportunities for broad-based health research for the purpose of discovering new scientific knowledge that can be applied toward improving the health of all Pennsylvanians.

Although the source of the funds is the Tobacco Settlement monies, the legislature did not intend that these funds focus only on tobacco-related health research issues. Instead, they intended that the funds be used to support broad based research on any health-related issue.

DISTRIBUTION OF HEALTH RESEARCH FUNDS

- Research
- Infrastructure
- 2% of funds for:
 - Peer review
 - Performance review



Health Research funds must be used for research and research infrastructure.

- For the 2001-2002 grants, there were four types of research infrastructure projects possible: building/laboratory construction and/or renovation, equipment, research training programs, and technology transfer projects to commercialize research results.
- For the 2002-03 and subsequent year grants, research infrastructure projects only include building/laboratory construction and/or renovation projects.

Other than research and research infrastructure, the only other authorized use of these funds is to cover the costs of peer review and performance review. All other costs, including staff salaries and Advisory Committee costs are covered by the Commonwealth's general fund.

WHAT RESEARCH WILL BE FUNDED?

- Biomedical research
- Clinical research
- Health services research



The authorizing legislation defines three major types of health research as eligible for funding:

1. Biomedical research is 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.
2. Clinical research is 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.
3. Health services research includes research on the promotion and maintenance of health, including biobehavioral research, research on the prevention and reduction of disease, and research on the delivery of health care services to reduce health risks and transfer research advances to community use.

TYPES OF FUNDS

- **Formula** Based on funds received from NIH and NCI
- **Nonformula** Competitive bid



There are two types of funds available for health research—formula and nonformula funds. Formula funds are awarded to institutions that received funding from the National Institutes of Health (NIH) or the National Cancer Institute (NCI), while nonformula funds are awarded as a result of a competitive bidding process.

CHAPTER 9 BREAKDOWN OF FUNDS

➤ Section 906 research funds:

Section 906 (a) - 70% for formula grants, based on NIH funds received
Section 906 (b) & (c) - 30% for nonformula grants, awarded via peer review

➤ Section 908 (b) provides further breakdown of Section 906 (a) formula funds:

Section (1) - 20% to Univ. of Penn and 20% to Univ. of Pitt
Section (2) - 17% to Penn State University
Section (3) - 43% to other eligible institutions

➤ Section 909 research funds:

Formula funds awarded to institutions based on NCI funds received



Most of the health research funds are awarded for formula grants. Two separate appropriations are made: (1) Section 906 includes both formula and nonformula funds, while Section 909 includes only formula funds.

Section 906 of Chapter 9 of Act 2001-77 allocates funds to health research as follows: 70% of funds are allotted for formula grants based on the amount of funds institutions have received from NIH during the preceding three years and 30% of funds are allotted for nonformula grants, which are awarded through a peer review process.

Section 908 (b) further breakdowns Section 906 (a) formula funds as follows. Twenty percent is awarded to institutions that receive more than \$175,000,000 as an average amount from the National Institutes of Health (NIH) during the preceding three federal fiscal years. The Universities of Pennsylvania and Pittsburgh qualify to receive this percentage of Section 906 (a) formula funds. Seventeen percent is awarded to institutions that receive more than \$60,000,000 from NIH and \$175,000,000 in federally sponsored research and development funds as reported by the National Science Foundation. The Pennsylvania State University qualifies to receive this percentage of Section 906 (a) formula funds. The remaining funds (43%) are allotted to other institutions that receive three years of NIH awards.

Section 909 are formula funds that are awarded to institutions that received three years of National Cancer Institute (NCI) funds.

ELIGIBILITY FOR FORMULA FUNDS

- Universities, hospitals, or non-profit entities that conduct research and are located in Pennsylvania
- Grant dollars based on NIH/NCI funds



Only hospitals, universities and non-profit organizations that conduct research, are located in Pennsylvania, and have received funding from the National Institutes of Health (NIH) are eligible for formula funds. The amount of formula funds that an organization may receive is based on a formula specified in the Act and depends on how much money they successfully garnered from both the NIH and the National Cancer Institute (NCI) over the past three years.

Each year the Department obtains a list of grants awarded to Pennsylvania institutions by the NIH. Each institution is then asked to certify that they meet the eligibility requirements for formula funds and to verify the accuracy of the NIH awards to their institution. After the process is complete the Department computes the amount that each institution is eligible to receive.

HEALTH RESEARCH ADVISORY COMMITTEE

9 Members

- Secretary of Health, Chairperson
- 4 Governor appointees
- 4 Legislature appointees



All research funded by the Health Research Program must be consistent with research priorities that are established by the Department in conjunction with the Health Research Advisory Committee.

The Committee consists of 9 members, including the Secretary of Health who chairs the Committee.

Four members are appointed by the Governor and serve a term of 6 years. The Governor's appointees must possess expertise in health care or research and include institution-based research specialists, practicing clinicians, clinical investigators and public health professionals.

Two members are appointed by the House of Representatives for terms of 2 years each, and two members are appointed by the Senate for terms of 4 years each.

The names and photographs of the current Advisory Committee members may be viewed on the CURE website.

COMMITTEE RESPONSIBILITIES

- Recommends research priorities
- Recommends evaluation & accountability

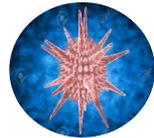
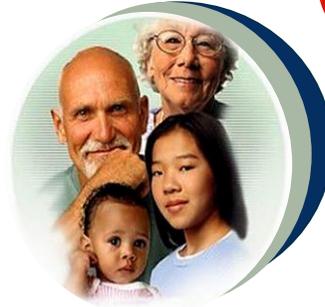
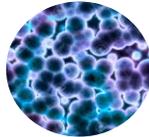


All committee meetings are open to the public. Meeting notices are published in the Pennsylvania Bulletin and advertised in the local paper in accordance with the Sunshine law. Meeting notices and minutes are posted on the CURE website.

The Advisory Committee provides recommendations to the Department of Health regarding the research priorities, evaluation and accountability procedures, and related issues.

RESEARCH PRIORITIES

- National Health Objectives
- Health Disparities



In developing the research priorities, the Department and the Advisory Committee must consider the national health promotion and disease prevention objectives, as applied to Pennsylvania. Staff provides the Committee with the health data showing how the state compares to the national health objectives on the key health indicators.

Act 2001-77 requires that the research priorities 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.

RESEARCH PRIORITIES

- Biomedical
- Clinical
- Health services



Separate research priorities are established for formula and nonformula grants.

The research priorities for formula grants are very broad – they are the same as the three allowable categories of research – biomedical, clinical and health services.

They are broad because formula grants are awarded to over 25 institutions, some of which are focused on only one health problem such as cancer. If the priorities for the formula grants were limited to areas that were outside the expertise of these focused research organizations, they would be unable to utilize the funds.

The research priorities for the nonformula funds are narrower than the priorities for the formula funds, and they have changed each year.

Because nonformula grants are selected by a peer review process, the Advisory Committee recommended that the number of topics be limited to one or two topics each year in order to limit peer review costs.

RESEARCH GRANT REQUIREMENTS

- Grant application
- Consistent with research priorities
- Maximum of 4 years
- Annual and final progress & financial reports
- Performance review



Regardless of the type of grant, formula or nonformula, applicants must submit a grant application, which specifies the research methodology.

The research projects must be consistent with the research priorities.

Grantees receive one payment of the grant funds at the beginning of the grant and are required to invest the funds in secure, low-risk investments. The grantees must use both the grant funds and the income earned from investments for the research that is proposed in the approved grant application.

Grants cannot exceed four years. Grantees must submit an annual progress and financial report and a final progress and financial report. All grants are subject to a performance review upon completion.

REQUEST FOR APPLICATIONS (RFA'S)

- Formula RFA restricted to eligible applicants
- Nonformula RFA open to applications from any PA-based entities



Each year, after the research priorities are established and the formula has been calculated, the Department sends a Request for Applications (RFA) to institutions that are eligible for formula funds (between 26-41 organizations).

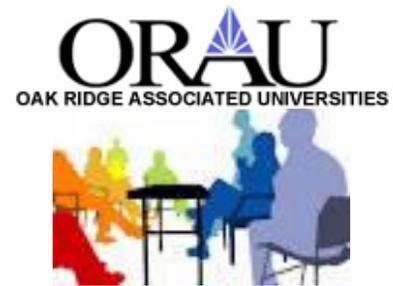
A separate RFA is issued for the nonformula funds. The RFA solicits research proposals which address the research priorities recommended for the nonformula funds for the year. Any person or entity that is located in Pennsylvania, including for-profit organizations, may apply for nonformula grants.

The program maintains a mailing list for the nonformula RFA. Requests to be placed on the RFA mailing list can be emailed to ra-healthresearch@pa.gov.

NONFORMULA GRANT SELECTION

➤ 2-step process:

1. Peer review
2. DOH Final Review Committee



Nonformula grants are selected by a 2-stage review process, as required by Act 2001-77. The first stage is peer review of the scientific and technical merit of the proposed research. The Department contracts with Oak Ridge Associated Universities to manage the peer review process. Peer reviewers are scientists, researchers, and physicians who have expertise in the proposed research topic. They are selected from outside of Pennsylvania to minimize the potential for conflict of interest. A separate peer review panel is established for each research priority. Proposals are then ranked by the average of the panel members' final scores.

The second stage of review is conducted by the DOH Final Review Committee, which is comprised of Departmental staff. The selection of research grants to be funded is based on the rankings developed from the peer review panels. In making these awards, the Department must use the criteria specified in Act 2001-77: 1) avoid unnecessary duplication; 2) ensure relevance to the appropriate research priority; 3) encourage collaboration between applicants; and 4) provide for the development of a complementary statewide research program.

ANNUAL REPORT

- Act 2001-77 Requirements
 - Awards and expenditures
 - Principal investigator
 - Participating researchers
 - Research project title and purpose
 - Expected outcomes and benefits
 - Detailed summary of research completed



One of the requirements of Act 2001-77 is an annual report to the legislature.

According to the act, the annual report must include information on the amount of the awards made and expenditures, the name and address of the principal investigator and the names and employers of participating researchers. For each research project, the report also must include the project's title, purpose, expected outcomes and benefits, and a detailed summary of research completed.

The reporting period for the annual report is the state fiscal year.



The process of compiling the annual report begins with the grant application. The Department designed the RFA's to capture most of the information needed for the annual report to the legislature. To ease the reporting burden on grantees, staff copies this information from each grant application into the grantee's annual reporting form. This individualized report is provided to grantees 2-3 months prior to the due date of the report, giving grantees ample time to prepare their reports. Grantees correct outdated information in the report and provide a report of grant expenditures and summary of progress made on the research projects.

The annual report is posted on the CURE website and provided to the committee chairs and minority chairs of the Senate and House health and appropriations committees.

ACCOUNTABILITY/EVALUATION

- Performance Review
 - Information reviewed:
 - Research proposals
 - Annual progress reports
 - Final progress reports



Built into Act 2001-77 is an accountability and evaluation process called performance review. All research projects, upon completion or sooner if needed, are subject to a performance review. The Department contracts with Oak Ridge Associated Universities (ORAU) to manage the performance review process. ORAU recommends peer reviewers for approval by the Department. The peer reviewers read the research proposals, annual progress reports and final progress reports and then rate the progress achieved and outcomes of the research as outstanding, favorable or unfavorable. The reviewers also describe strengths and weaknesses of the research and make recommendations for future direction.



PERFORMANCE REVIEW

1. Progress made in achieving goals
2. Extent of clinical activities
3. Peer-review publications, patents, licenses
4. Changes in risks, diseases, outcomes
5. Discoveries, new drugs, prevention methods
6. Other necessary information



Section 910 of the Act 2001-77 specifies the information that grantees must submit for the performance review. These items include:

- (1) progress made in achieving expected research goals and objectives;
- (2) extent of clinical activities initiated and completed;
- (3) number of peer-reviewed publications and the number of licenses and patents filed;
- (4) any changes in risk factors, services provided, incidence of disease or other outcome measures;
- (5) any major discoveries, new drugs or new prevention, diagnosis or treatment modalities; and
- (6) any other information deemed necessary by the Department.

PERFORMANCE REVIEW

- Additional Criteria:
 - Leveraged additional research funds
 - Enhanced research capacity
 - Collaboration and commercialization



The Health Research Advisory Committee provided advice to the Department on the performance review process. They recommended that the performance review process include a consideration of these additional criteria:

- Did the grant leverage additional funds?
- Did the grant build/enhance research capacity at the institution?
- Did the grant lead to collaboration with research partners outside the institution or did it lead to the commercial development of research products?

CONSEQUENCES OF UNFAVORABLE REVIEW

- Penalties for “unfavorable” reviews
- Reduction in or ineligibility for future funding



Grantees are provided with copies of the performance review report and are asked to prepare a response explaining how they plan to address any weaknesses or recommendations identified by the reviewers.

Grants receiving consecutive overall ratings of “unfavorable” are subject to funding impacts, according to the Act. The recommended funding impacts increase through consecutive years of “unfavorable” overall ratings.

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