

- obtain informed consent from all human subjects;
- inform subjects of the identity of the sponsoring agency;
- inform subjects that the project involves classified research;
- obtain approval by an “independent panel of non-governmental experts and citizen representatives, all with the necessary security clearances” that reviews scientific merit, risk-benefit tradeoffs, and ensures subjects have enough information to make informed decisions to give valid consent; and
- maintain permanent records of the panel’s deliberations and consent procedures.

This memorandum implements these recommendations with some modifications. For classified research, it prohibits waiver of informed consent and requires researchers to disclose that the project is classified. For all but minimal risk studies, it requires researchers to inform subjects of the sponsoring agency. It also requires permanent recordkeeping.

The memorandum also responds to the Advisory Committee’s call for a special review process for classified human subjects research. It requires that institutional review boards for secret projects include a non-governmental member, and establishes an appeals process so that any member of a review board who believes a project should not go forward can appeal the boards’ decision to approve it.

Finally, this memorandum sets forth additional steps to ensure that classified human research is rare. It requires the heads of Federal agencies to disclose annually the number of secret human research projects undertaken by their agency. It also prohibits any agency from conducting secret human research without first promulgating a final rule applying the Federal Policy for the Protection of Human Subjects, as modified in this memorandum, to the agency.

These steps, set forth in detail below, will preserve the government’s ability to conduct any necessary classified research involving human subjects while ensuring adequate protection of research participants.

1. *Modifications to the Federal Policy for the Protection of Human Subjects as it Affects Classified Research.* All agencies that may conduct or support classified research that is subject to the 1991 Federal Policy for the Protection of Human Subjects (“Common Rule”) (56 Fed. Reg. 28010–28018) shall promptly jointly publish in the Federal Register the following proposed revisions to the Common Rule as it affects classified research. The Office for Protection from Research Risks in the Department of Health and Human Services shall be the lead agency and, in consultation with the Office of Management and Budget, shall coordinate the joint rulemaking.

(a) The agencies shall jointly propose to prohibit waiver of informed consent for classified research.

(b) The agencies shall jointly propose to prohibit the use of expedited review procedures under the Common Rule for classified research.

(c) The joint proposal should request comment on whether all research exemptions under the Common Rule should be maintained for classified research.

(d) The agencies shall jointly propose to require that in classified research involving human subjects, two additional elements of information be provided to potential subjects when consent is sought from subjects:

(i) the identity of the sponsoring Federal agency. Exceptions are allowed if the head of the sponsoring agency determines that providing this information could compromise intelligence sources or methods and that the research involves no more than minimal risk to subjects. The determination about sources and methods is to be made in consultation with the Director of Central Intelligence and the Assistant to the President for National Security Affairs. The determination about risk is to be made in consultation with the Director of the White House Office of Science and Technology Policy.

(ii) a statement that the project is “classified” and an explanation of what classified means.

(e) The agencies shall jointly propose to modify the institutional review board (“IRB”) approval process for classified human subjects research as follows:

(i) The Common Rule currently requires that each IRB “include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.” For classified research, the agencies shall define “not otherwise affiliated with the institution,” as a nongovernmental member with the appropriate security clearance.

(ii) Under the Common Rule, research projects are approved by the IRB if a “majority of those (IRB) members present at a meeting” approved the project. For classified research, the agencies shall propose to permit any member of the IRB who does not believe a specific project should be approved by the IRB to appeal a majority decision to approve the project to the head of the sponsoring agency. If the agency head affirms the IRB’s decision to approve the project, the dissenting IRB member may appeal the IRB’s decisions to the Director of OSTP. The Director of OSTP shall review the IRB’s decision and approve or disapprove the project, or, at the Director’s discretion, convene an IRB made up of nongovernmental officials, each with the appropriate security clearances, to approve or disapprove the project.

(iii) IRBs for classified research shall determine whether potential subjects need access to classified information to make a valid informed consent decision.

2. *Final Rules.* Agencies shall, within 1 year, after considering any comments, promulgate final rules on the protection of human subjects of classified research.

3. *Agency Head Approval of Classified Research Projects.* Agencies may not conduct any classified human research project subject to the Common Rule unless the agency head has personally approved the specific project.

4. *Annual Public Disclosure of the Number of Classified Research Projects.* Each agency head shall inform the Director of OSTP by September 30 of each year of the number of classified research projects involving human subjects underway on that date, the number completed in the previous 12-month period, and the number of human subjects in each project. The Director of OSTP shall report the total number of classified research projects and participating subjects to the President and shall then report to the congressional armed services and intelligence committees and further shall publish the numbers in the Federal Register.

5. *Definitions.* For purposes of this memorandum, the terms “research” and “human subject” shall have the meaning set forth in the Common Rule. “Classified human research” means research involving “classified information” as defined in [former] Executive Order 12958.

6. *No Classified Human Research Without Common Rule.* Beginning one year after the date of this memorandum, no agency shall conduct or support classified human research without having proposed and promulgated the Common Rule, including the changes set forth in this memorandum and any subsequent amendments.

7. *Judicial Review.* This memorandum is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any other persons.

8. The Secretary of Health and Human Services shall publish this memorandum in the Federal Register.

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§ 6602. Congressional declaration of policy

(a) Principles

In view of the foregoing, the Congress declares that the United States shall adhere to a national policy for science and technology which includes the following principles:

(1) The continuing development and implementation of strategies for determining and

achieving the appropriate scope, level, direction, and extent of scientific and technological efforts based upon a continuous appraisal of the role of science and technology in achieving goals and formulating policies of the United States, and reflecting the views of State and local governments and representative public groups.

(2) The enlistment of science and technology to foster a healthy economy in which the directions of growth and innovation are compatible with the prudent and frugal use of resources and with the preservation of a benign environment.

(3) The conduct of science and technology operations so as to serve domestic needs while promoting foreign policy objectives.

(4) The recruitment, education, training, retraining, and beneficial use of adequate numbers of scientists, engineers, and technologists, and the promotion by the Federal Government of the effective and efficient utilization in the national interest of the Nation's human resources in science, engineering, and technology.

(5) The development and maintenance of a solid base for science and technology in the United States, including: (A) strong participation of and cooperative relationships with State and local governments and the private sector; (B) the maintenance and strengthening of diversified scientific and technological capabilities in government, industry, and the universities, and the encouragement of independent initiatives based on such capabilities, together with elimination of needless barriers to scientific and technological innovation; (C) effective management and dissemination of scientific and technological information; (D) establishment of essential scientific, technical and industrial standards and measurement and test methods; and (E) promotion of increased public understanding of science and technology.

(6) The recognition that, as changing circumstances require periodic revision and adaptation of this subchapter, the Federal Government is responsible for identifying and interpreting the changes in those circumstances as they occur, and for effecting subsequent changes in this subchapter as appropriate.

(b) Implementation

To implement the policy enunciated in subsection (a) of this section, the Congress declares that:

(1) The Federal Government should maintain central policy planning elements in the executive branch which assist Federal agencies in (A) identifying public problems and objectives, (B) mobilizing scientific and technological resources for essential national programs, (C) securing appropriate funding for programs so identified, (D) anticipating future concerns to which science and technology can contribute and devising strategies for the conduct of science and technology for such purposes, (E) reviewing systematically Federal science policy and programs and recommending legislative amendment thereof when needed. Such elements should include an advisory mecha-

nism within the Executive Office of the President so that the Chief Executive may have available independent, expert judgment and assistance on policy matters which require accurate assessments of the complex scientific and technological features involved.

(2) It is a responsibility of the Federal Government to promote prompt, effective, reliable, and systematic transfer of scientific and technological information by such appropriate methods as programs conducted by nongovernmental organizations, including industrial groups and technical societies. In particular, it is recognized as a responsibility of the Federal Government not only to coordinate and unify its own science and technology information systems, but to facilitate the close coupling of institutional scientific research with commercial application of the useful findings of science.

(3) It is further an appropriate Federal function to support scientific and technological efforts which are expected to provide results beneficial to the public but which the private sector may be unwilling or unable to support.

(4) Scientific and technological activities which may be properly supported exclusively by the Federal Government should be distinguished from those in which interests are shared with State and local governments and the private sector. Among these entities, cooperative relationships should be established which encourage the appropriate sharing of science and technology decisionmaking, funding support, and program planning and execution.

(5) The Federal Government should support and utilize engineering and its various disciplines and make maximum use of the engineering community, whenever appropriate, as an essential element in the Federal policymaking process.

(6) Comprehensive legislative support for the national science and technology effort requires that the Congress be regularly informed of the condition, health and vitality, and funding requirements of science and technology, the relation of science and technology to changing national goals, and the need for legislative modification of the Federal endeavor and structure at all levels as it relates to science and technology.

(c) Procedures

The Congress declares that, in order to expedite and facilitate the implementation of the policy enunciated in subsection (a) of this section, the following coordinate procedures are of paramount importance:

(1) Federal procurement policy should encourage the use of science and technology to foster frugal use of materials, energy, and appropriated funds; to assure quality environment; and to enhance product performance.

(2) Explicit criteria, including cost-benefit principles where practicable, should be developed to identify the kinds of applied research and technology programs that are appropriate for Federal funding support and to determine the extent of such support. Particular attention should be given to scientific and techno-

logical problems and opportunities offering promise of social advantage that are so long range, geographically widespread, or economically diffused that the Federal Government constitutes the appropriate source for undertaking their support.

(3) Federal promotion of science and technology should emphasize quality of research, recognize the singular importance of stability in scientific and technological institutions, and for urgent tasks, seek to assure timeliness of results. With particular reference to Federal support for basic research, funds should be allocated to encourage education in needed disciplines, to provide a base of scientific knowledge from which future essential technological development can be launched, and to add to the cultural heritage of the Nation.

(4) Federal patent policies should be developed, based on uniform principles, which have as their objective the preservation of incentives for technological innovation and the application of procedures which will continue to assure the full use of beneficial technology to serve the public.

(5) Closer relationships should be encouraged among practitioners of different scientific and technological disciplines, including the physical, social, and biomedical fields.

(6) Federal departments, agencies, and instrumentalities should assure efficient management of laboratory facilities and equipment in their custody, including acquisition of effective equipment, disposal of inferior and obsolete properties, and cross-servicing to maximize the productivity of costly property of all kinds. Disposal policies should include attention to possibilities for further productive use.

(7) The full use of the contributions of science and technology to support State and local government goals should be encouraged.

(8) Formal recognition should be accorded those persons whose scientific and technological achievements have contributed significantly to the national welfare.

(9) The Federal Government should support applied scientific research, when appropriate, in proportion to the probability of its usefulness, insofar as this probability can be determined; but while maximizing the beneficial consequences of technology, the Government should act to minimize foreseeable injurious consequences.

(10) Federal departments, agencies, and instrumentalities should establish procedures to insure among them the systematic interchange of scientific data and technological findings developed under their programs.

(Pub. L. 94-282, title I, § 102, May 11, 1976, 90 Stat. 460.)

§ 6603. Sense of Congress on innovation acceleration research

(a) Sense of Congress on support and promotion of innovation in the United States

It is the sense of Congress that each Federal research agency should strive to support and promote innovation in the United States through high-risk, high-reward basic research projects that—

- (1) meet fundamental technological or scientific challenges;
- (2) involve multidisciplinary work; and
- (3) involve a high degree of novelty.

(b) Sense of Congress on setting annual funding goals for basic research

It is the sense of Congress that each Executive agency that funds research in science, technology, engineering, or mathematics should set a goal of allocating an appropriate percentage of the annual basic research budget of such agency to funding high-risk, high-reward basic research projects described in subsection (a).

(c) Report

Each Executive agency described in subsection (b) shall submit to Congress each year, together with documents submitted to Congress in support of the budget of the President for the fiscal year beginning in such year (as submitted pursuant to section 1105 of title 31), a report describing whether a funding goal as described in subsection (b) has been established, and if such a goal has been established, the following:

- (1) A description of such funding goal.
- (2) Whether such funding goal is being met by the agency.

(3) A description of activities supported by amounts allocated in accordance with such funding goal.

(d) Definitions

In this section:

(1) Basic research

The term “basic research” has the meaning given such term in the Office of Management and Budget Circular No. A-11.

(2) Executive agency

The term “Executive agency” has the meaning given such term in section 105 of title 5.

(Pub. L. 110-69, title I, § 1008, Aug. 9, 2007, 121 Stat. 581.)

CODIFICATION

Section was enacted as part of the America COMPETES Act, also known as the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science Act, and not as part of the National Science and Technology Policy, Organization, and Priorities Act of 1976 which comprises this chapter.

SUBCHAPTER II—OFFICE OF SCIENCE AND TECHNOLOGY POLICY

§ 6611. Establishment of Office

There is established in the Executive Office of the President an Office of Science and Technology Policy (hereinafter referred to in this subchapter as the “Office”).

(Pub. L. 94-282, title II, § 202, May 11, 1976, 90 Stat. 463.)

SHORT TITLE

For short title of this subchapter as the “Presidential Science and Technology Advisory Organization Act of 1976”, see section 201 of Pub. L. 94-282, set out as a Short Title note under section 6601 of this title.

HIGH-RESOLUTION INFORMATION SYSTEM ADVISORY BOARD

Pub. L. 102-245, title V, § 501, Feb. 14, 1992, 106 Stat. 22, authorized the Director of the Office of Science and