42 USC Sec. 285r 01/22/02

-EXPCITE-

TITLE 42 - THE PUBLIC HEALTH AND WELFARE

CHAPTER 6A - PUBLIC HEALTH SERVICE

SUBCHAPTER III - NATIONAL RESEARCH INSTITUTES

Part C - Specific Provisions Respecting National Research
Institutes

subpart 18 - national institute of biomedical imaging and
bioengineering

-HEAD-

Sec. 285r. Purpose of the Institute
-STATUTE-

# (a) In general

The general purpose of the National Institute of Biomedical

Imaging and Bioengineering (in this section referred to as the

''Institute'') is the conduct and support of research, training,

the dissemination of health information, and other programs with

respect to biomedical imaging, biomedical engineering, and

associated technologies and modalities with biomedical applications

(in this section referred to as ''biomedical imaging and bioengineering'').

- (b) National Biomedical Imaging and Bioengineering Program
- (1) The Director of the Institute, with the advice of the Institute's advisory council, shall establish a National Biomedical Imaging and Bioengineering Program (in this section referred to as the ''Program'').
- (2) Activities under the Program shall include the following with respect to biomedical imaging and bioengineering:
  - (A) Research into the development of new techniques and devices.
  - (B) Related research in physics, engineering, mathematics, computer science, and other disciplines.
  - (C) Technology assessments and outcomes studies to evaluate the effectiveness of biologics, materials, processes, devices, procedures, and informatics.
    - (D) Research in screening for diseases and disorders.
  - (E) The advancement of existing imaging and bioengineering modalities, including imaging, biomaterials, and informatics.

- (F) The development of target-specific agents to enhance images and to identify and delineate disease.
- (G) The development of advanced engineering and imaging technologies and techniques for research from the molecular and genetic to the whole organ and body levels.
- (H) The development of new techniques and devices for more effective interventional procedures (such as image-guided interventions).
- (3)(A) With respect to the Program, the Director of the Institute shall prepare and transmit to the Secretary and the Director of NIH a plan to initiate, expand, intensify, and coordinate activities of the Institute with respect to biomedical imaging and bioengineering. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The Director of the Institute shall periodically review and revise the plan and shall transmit any revisions of the plan to the Secretary and the Director of NIH.
- (B) The plan under subparagraph (A) shall include the recommendations of the Director of the Institute with respect to

#### the following:

- (i) Where appropriate, the consolidation of programs of the National Institutes of Health for the express purpose of enhancing support of activities regarding basic biomedical imaging and bioengineering research.
- (ii) The coordination of the activities of the Institute with related activities of the other agencies of the National Institutes of Health and with related activities of other Federal agencies.

## (c) Membership

The establishment under section 284a of this title of **an** advisory council for the Institute is subject to the following:

- (1) The number of members appointed by the Secretary shall be 12.
  - (2) Of such members -
  - (A) six members shall be scientists, engineers, physicians, and other health professionals who represent disciplines in biomedical imaging and bioengineering and who are not officers or employees of the United States; and

- (B) six members shall be scientists, engineers, physicians, and other health professionals who represent other disciplines and are knowledgeable about the applications of biomedical imaging and bioengineering in medicine, and who are not officers or employees of the United States.
- (3) In addition to the ex officio members specified in section 284a(b)(2) of this title, the ex officio members of the advisory council shall include the Director of the Centers for Disease Control and Prevention, the Director of the National Science Foundation, and the Director of the National Institute of Standards and Technology (or the designees of such officers).
- (d) Authorization of appropriations
- (1) Subject to paragraph (2), for the purpose of carrying out this section:
  - (A) For fiscal year 2001, there is authorized to be appropriated **an** amount equal to the amount obligated by the National Institutes of Health during fiscal year 2000 for biomedical imaging and bioengineering, except that such amount shall be adjusted to offset any inflation occurring after October

1, 1999.

- (B) For each of the fiscal years 2002 and 2003, there is authorized to be appropriated **an** amount equal to the amount appropriated under subparagraph (A) for fiscal year 2001, except that such amount shall be adjusted for the fiscal year involved to offset any inflation occurring after October 1, 2000.
- (2) The authorization of appropriations for a fiscal year under paragraph (1) is hereby reduced by the amount of any appropriation made for such year for the conduct or support by any other national research institute of any program with respect to biomedical imaging and bioengineering.

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(July 1, 1944, ch. 373, title IV, Sec. 464z, as added Pub. L. 106-580, Sec. 3(a), Dec. 29, 2000, 114 Stat. 3089.)

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### EFFECTIVE DATE

Pub. L. 106-580, Sec. 4, Dec. 29, 2000, 114 Stat. 3092, provided that: ''This Act (enacting this subpart, amending section 281 of this title, and enacting provisions set out as notes under this

section and section 201 of this title) takes effect October 1, 2000, or upon the date of the enactment of this Act (Dec. 29, 2000), whichever occurs later.''

#### FINDINGS

Pub. L. 106-580, Sec. 2, Dec. 29, 2000, 114 Stat. 3088, provided that: ''The Congress makes the following findings:

- ''(1) Basic research in imaging, bioengineering, computer science, informatics, and related fields is critical to improving health care but is fundamentally different from the research in molecular biology on which the current national research institutes at the National Institutes of Health ('NIH') are based. To ensure the development of new techniques and technologies for the 21st century, these disciplines therefore require an identity and research home at the NIH that is independent of the existing institute structure.
- ''(2) Advances based on medical research promise new, more effective treatments for a wide variety of diseases, but the development of new, noninvasive imaging techniques for earlier detection and diagnosis of disease is essential to take full

advantage of such new treatments and to promote the general improvement of health care.

- ''(3) The development of advanced genetic and molecular imaging techniques is necessary to continue the current rapid pace of discovery in molecular biology.
- ''(4) Advances in telemedicine, and teleradiology in particular, are increasingly important in the delivery of high quality, reliable medical care to rural citizens and other underserved populations. To fulfill the promise of telemedicine and related technologies fully, a structure is needed at the NIH to support basic research focused on the acquisition, transmission, processing, and optimal display of images.
- ''(5) A number of Federal departments and agencies support imaging and engineering research with potential medical applications, but a central coordinating body, preferably housed at the NIH, is needed to coordinate these disparate efforts and facilitate the transfer of technologies with medical applications.
  - ''(6) Several breakthrough imaging technologies, including

magnetic resonance imaging ('MRI') and computed tomography ('CT'), have been developed primarily abroad, in large part because of the absence of a home at the NIH for basic research in imaging and related fields. The establishment of a central focus for imaging and bioengineering research at the NIH would promote both scientific advance and United States economic development.

- ''(7) At a time when a consensus exists to add significant resources to the NIH in coming years, it is appropriate to modernize the structure of the NIH to ensure that research dollars are expended more effectively and efficiently and that the fields of medical science that have contributed the most to the detection, diagnosis, and treatment of disease in recent years receive appropriate emphasis.
- ''(8) The establishment of a National Institute of Biomedical Imaging and Bioengineering at the NIH would accelerate the development of new technologies with clinical and research applications, improve coordination and efficiency at the NIH and throughout the Federal Government, reduce duplication and waste, lay the foundation for a new medical information age, promote

economic development, and provide a structure to train the young researchers who will make the pathbreaking discoveries of the next century.''

ESTABLISHMENT OF INSTITUTE AND ADVISORY COUNCIL

Pub. L. 106-580, Sec. 3(b)-(d), Dec. 29, 2000, 114 Stat. 3091,

provided that:

- ''(b) Use of Existing Resources. In providing for the establishment of the National Institute of Biomedical Imaging and Bioengineering pursuant to the amendment made by subsection (a) (enacting this subpart), the Director of the National Institutes of Health (referred to in this subsection as 'NIH') -
  - ''(1) may transfer to the National Institute of Biomedical

    Imaging and Bioengineering such personnel of NIH as the Director

    determines to be appropriate;
  - $^{\prime\prime}(2)$  may, for quarters for such Institute, utilize such facilities of NIH as the Director determines to be appropriate; and
  - ''(3) may obtain administrative support for the Institute from the other agencies of NIH, including the other national research

institutes.

- ''(c) Construction of Facilities. None of the provisions of this Act (enacting this subpart, amending section 281 of this title, and enacting provisions set out as notes under this section and section 201 of this title) or the amendments made by the Act may be construed as authorizing the construction of facilities, or the acquisition of land, for purposes of the establishment or operation of the National Institute of Biomedical Imaging and Bioengineering.
- ''(d) Date Certain for Establishment of Advisory Council. Not later than 90 days after the effective date of this Act (Dec. 29, 2000) under section 4 (set out above), the Secretary of Health and Human Services shall complete the establishment of an advisory council for the National Institute of Biomedical Imaging and Bioengineering in accordance with section 406 of the Public Health Service Act (section 284a of this title) and in accordance with section 464z of such Act (as added by subsection (a) of this section) (this section).''