BIOENGINEERING RESEARCH GRANTS

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P.T.

National Cancer Institute
National Center for Research Resources
National Eye Institute
National Human Genome Research Institute
National Heart, Lung, and Blood Institute
National Institute on Aging
National Institute on Alcohol Abuse and Alcoholism
National Institute of Allergy and Infectious Diseases
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institute of Child Health and Human Development
National Institute on Drug Abuse
National Institute on Deafness and Other Communication Disorders
National Institute of Dental Research
National Institute of Diabetes and Digestive and Kidney Diseases
National Institute of Environmental Health Sciences
National Institute of General Medical Sciences
National Institute of Mental Health
National Institute of Neurological Disorders and Stroke
National Institute of Nursing Research
National Library of Medicine

PURPOSE

Participating Institutes and Centers (ICs) of the National Institutes of Health (NIH) invite applications for Bioengineering Research Grants (BRG) to support basic bioengineering research whose outcomes are likely to advance health or health-related research within the mission of the NIH. A BRG application should propose to apply basic bioengineering design-directed or hypothesis-driven research to an important medical or biological research area.

In parallel with this program announcement (PA), NIH is issuing a PA for Bioengineering Research Partnerships (BRP). BRP applications differ from BRG applications in that they will be funded as R24 awards that support an interdisciplinary group of Partners who work together applying an integrative, multidisciplinary, systems approach to a significant area of basic bioengineering research.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This PA, Bioengineering Research Grants (BRG), is related to all priority areas. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001- 00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Tel: 202-512-1800).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as principal investigators.

MECHANISM OF SUPPORT

The mechanism of support will be the research project grant (R01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total requested project period may not exceed five years and applicants should apply for the length of time appropriate for the work proposed, typically three to five years.

An applicant planning to submit an application requesting $500,000 or more in direct costs for any year is advised that he or she must contact IC program staff, listed under INQUIRIES, before submitting the application, i.e., as plans for the study are being developed. Furthermore, the applicant must obtain agreement from IC staff that the IC will accept the application for consideration for award. Finally, the applicant must identify, in a cover letter sent with the application, the staff member and IC who agreed to accept assignment of the application. This

policy requires an applicant to obtain agreement for acceptance of both any such application and any subsequent amendment. Refer to the NIH Guide for Grants and Contracts, March 20, 1998 (http://www.nih.gov/grants/guide/notice-files/not98-030.html).

RESEARCH OBJECTIVE

Background

Bioengineering brings a perspective that is valuable for many of today's biological problems. Bioengineering integrates principles from a diversity of fields. The creativity of interdisciplinary teams is resulting in new basic understanding, novel products and innovative technologies. Bioengineering also crosses the boundaries of academia, science, medicine, and industry.

Recognizing the increasing importance of bioengineering in public health, NIH established the Bioengineering Consortium (BECON) as a central focus for NIH bioengineering research. BECON organized a two-day Bioengineering Symposium on February 27-28, 1998. A summary of the presentations and the conclusions of the panels are included in the full report, which is available on the Internet at http://www.nibib.nih.gov/. The discussions and recommendations of symposium participants aided in the formulation of the BRP and BRG PAs. For example, both the BRP and BRG PAs recognize that applications for bioengineering projects are often focused on technology development rather than on proving or disproving a scientific hypothesis. Therefore, the NIH review criteria for bioengineering proposals in response to these PAs have been modified to ensure that these proposals are evaluated appropriately and fairly.

Objectives and Scope

The objective of this program announcement is to encourage research in basic bioengineering areas. Bioengineering is defined as follows: Bioengineering integrates physical, chemical, or mathematical sciences and engineering principles for the study of biology, medicine, behavior, or health. It advances fundamental concepts, creates knowledge from the molecular to the organ systems level, and develops innovative biologics, materials, processes, implants, devices, and informatics approaches for the prevention, diagnosis, and treatment of disease, for patient rehabilitation, and for improving health.

Areas of Bioengineering Research for a BRG

Applications for BRG awards should focus on an area of bioengineering research where progress is likely to make a significant contribution to improving human health. It is likely that these areas will be of interest to many ICs. For example, materials science may be relevant to the ultimate development of artificial organs and thus a research initiative in materials science would be of interest to many ICs even though it is not clear at the outset which organ or which IC will benefit from advances in the field. Similarly, bioinformatics may provide analysis and modeling tools for large sets of biological data, facilitate home-based devices, and create networks to help manage chronic diseases. Imaging may be applied to monitoring of cellular processes, elucidation of developmental processes in the organism, identification and localization of disease, developing virtual reality training tools, and monitoring therapeutic interventions. Micro- and nano-fabrication and fluidics may be applied to creating in vivo sensors, biochemical analysis systems, imaging systems, and surgical devices.

Bioengineering areas of particular relevance to the mission of ICs are identified below. This list is not intended to be exclusive.

Bioengineering Research Areas

- Biomechanics
- Bioprocessing
- Bioelectrics, Ion Channels, and Organ Function
- Clinical Medicine, Therapeutics and Drug Delivery
- Combinatorial Approaches to Chemistry, Materials, Genes, and Therapeutics
- Functional Genomics including Microarray Technology, Integrated Systems, and Analysis Tools
- Imaging
- Nanotechnology
- Informatics and Computational Methods
- Medical Implants, Biomembranes, Sensors and Devices
- Complex Biological Systems
- Organ Culture Systems and Organogenesis
- Rehabilitation, Prostheses
- Cell and Tissue Engineering and Biomaterials
- Tissue Regeneration
- Integrative Physiology
- Drug Bioavailability

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH supported medical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided that inclusion is inappropriate with respect to the health of the subjects of the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and the NIH Guide for Grants and Contracts, Vol. 23, No. 11, March 18, 1994 (http://www.nih.gov/grants/guide/1994/94.03.18/notice-nih-guideline008.html).

Investigators may obtain copies from these sources or from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

NIH POLICY AND GUIDELINES ON THE INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://www.nih.gov/grants/guide/notice-files/not98-024.html.

Investigators may obtain copies from these sources or from the program staff listed under INQUIRIES who may also provide additional relevant information concerning the policy.

APPLICATION PROCEDURES

Applicants are strongly encouraged to contact program staff listed under INQUIRIES early in application development with any questions regarding the responsiveness of their proposal to the goals of this PA. An applicant may suggest in a cover letter the IC or ICs believed to be most appropriate to support the proposed research.

Applications are to be submitted on the grant application form PHS 398 (rev.5/95) and will be accepted on the standard receipt dates indicated in the application kit. Application kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, Tel: (301) 435-0714, email: grantsinfo@nih.gov. The PHS 398 application kit is also available on the Internet at http://www.nih.gov/grants/funding/funding.htm. Follow the PHS 398 instructions for "Preparing Your Application" with modifications and additions as described in the sections below.

Annual Meeting.

Each year, the NIH will convene a meeting of the PIs of the BRPs and BRGs to share substantive results, to help the NIH to maintain a view of the advances in these fields and have an opportunity for collective problem solving. The cost for the PI to participate in the annual meeting may be built into the BRG budget.

Research Plan.

A. Specific Aims. Describe the specific aims in the selected area of bioengineering research. The proposed design principle(s) or hypothesis (-es) must be clearly defined. If possible, include the expected applications of the bioengineering research that will improve human health or health-related research. One page is recommended.

B. Background and Significance. Briefly describe the area of bioengineering research that is the focus of the BRG. Critically evaluate existing knowledge and approaches that have been or are being directed in the area and specifically describe how the BRG approach will advance the field. State concisely the importance and health relevance of the proposed research to the Specific Aims.

C. Preliminary Studies and Rationale. Preliminary studies are not required for BRG applications, but applicants with preliminary results should describe them. In the absence of preliminary results, applicants should describe the rationale, scientific and engineering basis for the proposal.

D. Research Design and Methods. A BRG should focus on a significant area of bioengineering research where advances are likely to affect human health or health-related research. If the proposed BRG research is closely related to ongoing research, explain how the research activities of the BRG will complement but not overlap existing research. Provide a tentative sequence or timetable for the project. Include how the data will be collected, analyzed, and interpreted.

The number and title of this program announcement must be typed in Section 2 on the face page of the application and the YES box must be checked.

Submit a signed, typewritten original of the application, including the Checklist, and appendices, and five signed photocopies in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the NIH Center for Scientific Review (CSR). Incomplete applications will be returned to the applicant without further consideration. Applications that are complete will be evaluated for scientific and technical merit by Scientific Review Groups (SRGs) of the CSR. As part of the initial merit review, all applications may be subjected to standard NIH streamlined review procedures; nevertheless, each application will receive a written critique.

Review criteria

The NIH review criteria have been adapted to ensure that a BRG application is evaluated appropriately. The score should reflect the overall impact that the BRG award could have on the selected area of bioengineering research based on consideration of the five criteria, with the

emphasis on each criterion varying from one application to another, depending on the nature of the application and its relative strengths. Note that an application need not be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward. The review criteria are:

(1) Significance. If the Specific Aims of the BRG are achieved, will they provide significant advances in the selected area of bioengineering research? Is the research likely to have a significant impact on other areas of research?

(2) Approach. Are the BRG approaches and methods adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

(3) Innovation. Does the BRG propose new approaches or explore new research paradigms or new concepts that will affect bioengineering, basic or clinical sciences? Are extant approaches or concepts applied to new scientific problems in novel ways?

(4) Investigators. Are the PI and key personnel appropriately trained in their disciplines and capable of conducting the proposed research?

(5) Environment. Does the scientific and technological environment in which the work will be done contribute to the probability of success? Does the proposed research take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of other support that will contribute to the success of the research?

In addition to these five review criteria, applicants must demonstrate adequate provisions for the protection of human and animal subjects, the safety of the research environment, and conformance with the "NIH Guidelines for the Inclusion of Women and Minorities as Subjects in Clinical Research," and "NIH Policy And Guidelines On The Inclusion Of Children As Participants In Research Involving Human Subjects."

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

- Quality of the proposed research as determined by peer review
- Availability of funds
- Institute's priority for area of proposed research

INQUIRIES

The opportunity to clarify any issues or questions regarding an application is welcome.

Questions regarding BRG scientific issues, management issues, or issues on cores related to participating ICs may be directed to:

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AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.394, 93.395, 93.396, 93.306, 93.867, 93.172, 93.837, 93.838, 93.839, 93.866, 93.273, 93.855, 93.856, 93.846, 93.864, 93.865, 93.929, 93.279, 93.173, 93.121, 93.847, 93.848, 93.849, 93.113, 93.821, 93.859, 93.862, 93.242, 93.853, 93.854, 93.361, and 93.879. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285). Awards will be administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74 and Part 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or, in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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