

This Program Announcement expires on August 14, 2001.

## BIOENGINEERING RESEARCH PARTNERSHIPS

Release Date: December 1, 2000 (Supercedes November 30, 1999 version)

PA NUMBER: PA-01-024

National Cancer Institute

National Eye Institute

National Heart, Lung, and Blood Institute

National Human Genome Research Institute

National Institute on Aging

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 and Craniofacial 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

Letter of Intent Receipt Dates: January 16, 2001 and July 13, 2001

Application Receipt Dates: February 16, 2001 and August 14, 2001

## PURPOSE

Participating Institutes and Centers (ICs) of the National Institutes of Health (NIH) invite applications for R01 awards to support Bioengineering Research Partnerships (BRPs) for basic multidisciplinary research addressing important biological or medical research problems. A BRP is a multidisciplinary research team applying an integrative, systems approach to develop knowledge and/or methods to prevent, detect, diagnose, or treat disease or to understand health

and behavior. The partnership must include appropriate bioengineering expertise in combination with basic and/or clinical investigators. A BRP may propose discovery-driven, developmental, non-hypothesis-driven, design-directed, or hypothesis-driven research at universities, national laboratories, medical schools, large or small businesses, or other public and private entities.

On October 29, 1998, NIH issued the related program announcement (PA) PAR-99-009 (<http://grants.nih.gov/grants/guide/pa-files/PAR-99-009.html>) for Bioengineering Research Grants (BRGs). The BRGs differ from the BRP applications in the expectation that the research will be performed in a single laboratory or by a small number of investigators.

## HEALTHY PEOPLE 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This program announcement is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" on the Internet at <http://www.health.gov/healthypeople/>.

## ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit, public and private organizations such as universities, colleges, hospitals, national laboratories, industrial research organizations, large or small businesses, units of state and local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible to apply, but BRP collaborative projects may include work at a foreign site when the expertise at the foreign site is not present in the United States. 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 NIH R01 regular research grant. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total requested project period for a competitively-reviewed application may not exceed five years.

In accordance with NIH policy (<http://grants.nih.gov/grants/guide/notice-files/not98-030.html>), investigators planning to submit an application in response to this PA that requests \$500,000 or more in direct costs for any year are advised that agreement for acceptance of both any such

new application and/or any subsequent amended application must be obtained from a NIH research institute or center prior to submittal. Instructions for obtaining this agreement are provided in the section titled APPLICATIONS EXCEEDING \$500,000 PER YEAR DIRECT COSTS.

Since most budget requests associated with BRP applications are expected to exceed \$250,000 per year direct costs, the modular grant concept will not be used for this program announcement. Detailed budgets are required for BRP applications.

## FUNDS AVAILABLE

For any grant, the maximum total costs to be awarded in any year is \$2 million. The number of awards and level of support will depend on the number of applications of high scientific merit that are received and the availability of funds. Funding in subsequent years will be contingent upon satisfactory progress during the preceding year(s) and the availability of funds. Applicants are encouraged to discuss budget requests with NIH scientific and financial contacts listed under INQUIRIES prior to submission. The initial period of support for a BRP award may be up to five years. The award may be competitively renewed for a second period up to five years. NIH does not envision more than one renewal period.

## BACKGROUND

Many of today's biomedical problems are too complex to be solved by biologists or clinicians alone. Partners are needed in many disciplines including physics, mathematics, chemistry, computer sciences, and engineering. Bioengineering integrates principles from a diversity of technical and biomedical fields. The creativity of interdisciplinary teams is resulting in new basic understandings, novel products, and innovative technologies for addressing biomedical problems. Bioengineering also crosses the boundaries of many scientific disciplines, and thus partnerships between academia, Federal laboratories, and industry are encouraged.

Recognizing the increasing importance of bioengineering in public health, the NIH established the Bioengineering Consortium (BECON) in 1997 as a central focus for NIH bioengineering research. Each subsequent year, BECON has held two-day symposia on emerging topics of interest related to bioengineering including bioengineering (1998), bioimaging, (1999), and nanotechnology (2000). Summaries of the presentations and the conclusions of these symposia are available on the Internet at [http://www.nibib.nih.gov/becon/becon\\_symposia.htm](http://www.nibib.nih.gov/becon/becon_symposia.htm).

Discussions and recommendations of symposia participants aided the formulation of the BRP and BRG program announcements. Both the BRP and BRG PAs recognize that applications for bioengineering projects most often focus on technology development rather than on proving or disproving scientific hypotheses. Therefore, the NIH review criteria for bioengineering applications submitted in response to these PAs have been modified to ensure that these applications are evaluated appropriately and fairly.

## RESEARCH GOALS AND OBJECTIVES

One objective of this program announcement is to encourage research in selected basic bioengineering areas. Bioengineering is defined as follows: Bioengineering integrates physical, engineering, and computational science 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 biologicals, materials, processes, implants, devices, and informatics approaches for the prevention, diagnosis, and treatment of disease, for patient rehabilitation, and for improving health.

A second objective is to encourage collaborations and partnerships among the scientific and biomedical disciplines. Each BRP should bring together the necessary basic science and engineering and/or clinical expertise to focus on a significant area of bioengineering research within the mission of the NIH. In addition to the benefits to be derived from the research, the collaborations and partnerships can create opportunities for transdisciplinary communication and training for a new generation of scientists capable of interacting across traditional technical boundaries.

## BIOENGINEERING RESEARCH AREAS

Applications for BRP 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 NIH research institutes and centers (ICs). Bioengineering areas of particular relevance to the mission of ICs are listed below. This list is not all-inclusive.

Behavioral science

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 analytical tools  
Imaging, molecular imaging, and image-guided methods  
Nanotechnology and microtechnology  
Informatics, databases, and computational methods  
Computational modeling and simulation  
Medical implants, biomembranes, sensors and devices  
Optics  
Complex biological systems  
Organ culture systems and organogenesis  
Rehabilitation and prostheses  
Cell and tissue engineering and biomaterials  
Tissue regeneration  
Integrative physiology  
Drug bioavailability  
Telemedicine  
Computer-assisted diagnosis and procedures

#### BRP ORGANIZATIONAL STRUCTURE, LEADERSHIP, AND MANAGEMENT

An organizational structure that clearly defines the partnership and justifies relationships among the various components must be developed and described in the application. The BRP size, structure, and mode of operation should match the needs and scope of the proposed research.

The BRP Principal Investigator (PI) is responsible for management, staffing, and resource allocation and for administering the award in accordance with NIH policies. The PI has the responsibility and authority to use BRP funds in the most productive way to achieve the goals defined at the time of the award. To accomplish this task, the PI should adjust funding among BRP participants to support new partners or to reduce support to old partners as needed.

#### BRP PI MEETING

BRP PIs will meet annually to share results, to ensure that the NIH has a coherent view of the advances in these fields, and to have an opportunity for collective problem solving among the PIs. The cost of participating in this annual meeting should be included in the BRP budget.

#### 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 subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or 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" published in the "NIH Guide for Grants and Contracts" on August 2, 2000 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html>).

Recent revisions relate to NIH-defined Phase III clinical trials and require: a) all applications or proposals and/or protocols to provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) all investigators to report accrual and to conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

#### 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 on the Internet at <http://grants.nih.gov/grants/guide/notice-files/not98-024.html>.

#### URLS IN NIH GRANT APPLICATIONS OR APPENDICES

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary for the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

#### LETTER OF INTENT

Prospective applicants are asked to submit by the deadlines given on the first page of this announcement a letter of intent that includes a descriptive title of the proposed research; the name, address, telephone number, and e-mail address of the Principal Investigator; the identities of other key personnel and participating institutions; and the number and title of the PA. Although the letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, this information is useful to NIH staff to plan the BRP review process.

The letter of intent is to be sent via email to [BRP2@od.nih.gov](mailto:BRP2@od.nih.gov). An acknowledgement of receipt will be provided.

#### APPLICATIONS EXCEEDING \$500,000 PER YEAR DIRECT COSTS

In accordance with NIH policy (<http://grants.nih.gov/grants/guide/notice-files/not98-030.html>), an applicant planning to submit a proposal that requests \$500,000 or more in direct costs for any year must contact program staff at a research institute or center for approval before submitting the application; i.e., as plans for the study are being developed. The applicant must identify the institute or center and the staff member who agreed to accept assignment of the application in the cover letter that transmits the proposal. A list of scientific contacts for each of the NIH IC's is available on the Internet at [http://www.nibib.nih.gov/becon/becon\\_contacts.htm](http://www.nibib.nih.gov/becon/becon_contacts.htm).

#### APPLICATION PROCEDURES

Applicants are strongly advised to contact IC scientific staff listed under INQUIRIES to discuss the responsiveness of their plans to the intent of this PA and the relevance of their proposed work to the institute's mission before preparing a detailed research application. Detailed information on research missions and programs for each NIH institute and center is available on the individual IC's Web sites which can be accessed through the NIH Homepage at <http://www.nih.gov>. Since a BRP award may include funds from several NIH ICs, applicants may be directed to contact staff in more than one institute or center.

Applications are to be submitted on the grant application form PHS 398 (rev. 4/98). 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, Telephone: (301) 435-0714, Email: [grantsinfo@nih.gov](mailto:grantsinfo@nih.gov). Application kits are also available on the Internet at <http://grants.nih.gov/grants/forms.htm>.

Follow the PHS 398 instructions for "Preparing Your Application" with the following modifications and additions:

1. Page limitations have been increased to a maximum of 40 pages from the usual 25 page limit for sections A-D of the "Research Plan" of an application. This 40 page limit is an absolute maximum. Applicants are encouraged to be concise and use fewer pages.
2. Description Page - The institution leading the BRP and any other participating institutions must be identified. The description should provide a clear indication of the area of bioengineering research that will be the focus of the BRP, the planned multidisciplinary approach, the specific milestones to be achieved, and timelines for achievement for the first year and additional years of the grant.
3. An organization chart (OC) that clearly defines the partnership and relationships among its various components must be included with the application. A program plan (PP) should accompany the OC and list major tasks with a timeline of expected milestones for the entire project period. The OC and PP must not exceed one page each. This information should be included in the Research, Design, and Methods section of the application.
4. BRP Budget Items - A separate budget for each partner at a subcontract/consortium institution, and when appropriate for clarity, for each partner within the grantee institution must be included. Include a summary budget for all BRP participants with partners at non-grantee institutions shown as consortium arrangements.

The NIH ICs will not provide annual support in excess of \$2 million total cost for any year. Direct cost inflationary increases following the first year may be included, but the total cost maximum request level of \$2,000,000 per year must be observed.

The PI is expected to devote a minimum of 25% effort to the BRP. The percent effort requested for other personnel should be limited to time devoted specifically to BRP Partner activities and not to other research activities. Information documenting the level of effort on BRP activities should be included in the application. The need for all requested personnel costs should be thoroughly justified. The percent effort of the BRP PI should be justified in the context of the PI's other responsibilities. Administrative support (a secretary or an administrative assistant) may be requested for the BRP office only for matters directly pertaining to the BRP.

There will be an annual BRP PI meeting at a date and location to be determined by NIH staff. Applicants should include travel funds specifically for these meetings in the BRP budget request.

Applicants may request and justify other travel funds in addition to the funds required for the annual PI meeting. Travel funds could be used to promote collaboration among BRP partners at different institutions or at a distant site, be used for travel of external advisors to the BRP site, and/or be used for BRP partners to attend scientific meetings essential to the progress of the BRP and for which other funds are not available.

Other expenses can be requested including costs necessary for the central administration and fiscal management of the BRP including relevant and reasonable costs for reprints, graphics, and publications.

With regard to projected funding by source, some BRP applicants may anticipate or receive commitments for significant funding from other than NIH sources; e.g., from a collaborating company. In this case, applications should describe the source, annual amount, and use of the other funding.

5. Other Support - Provide a complete listing of current and pending support for the Principal Investigator, Co-Investigator(s), and other key personnel for grantee and partnering organizations.

6. Resources - The application should describe the equipment and facilities available for the proposed BRP.

If the BRP entails an institutional commitment of resources across boundaries in the institution or anticipates the provision of institutional resources, include letters from appropriate senior-level individuals describing their agreements to support those commitments.

Where appropriate, describe the shared facilities to be established including specific major research instruments and plans for the development of instruments. Describe plans for maintaining and operating the facilities including staffing, provisions for user fees, and plans for ensuring access to outside users. Distinguish between existing facilities and those still to be developed.

7. Research Plan

A. Specific Aims - Describe the specific aims in the selected area of bioengineering research and the goals for the first year and for the long term. Delineate the design principle(s) supporting the research to be performed and/or the hypothesis(-es) to be tested. Describe the expected applications of the bioengineering research that will improve human health. One page is recommended.

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

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

D. Research Design and Methods - A BRP should focus on a systems approach in a significant area of bioengineering research. Describe an overall research plan that is sufficiently long term (five to ten years) to justify organizing a BRP and adaptable enough to permit change as the research proceeds. Clearly indicate current activities, why a BRP is necessary, and what unique opportunities will be provided by the proposed BRP. Explain the integrative-engineering approach and why such an approach is essential to the proposed research. If the proposed BRP research is closely related to ongoing research or an existing center, explain how the research activities of the BRP will complement but not overlap existing research. Describe the contributions of each partner and how these will be integrated and organized to accomplish the specific aims of the project. Provide a tentative sequence or timetable for the project. If appropriate to the project, state quantitative milestones corresponding to timetable events. Include a description of how the data will be collected, analyzed, and interpreted. Discuss major technical challenges and possible alternative approaches to achieve the aims. Describe plans for enhancing the abilities and opportunities for investigators and trainees to work across disciplinary boundaries. Describe how the data and technological advances will be disseminated to other investigators, and if relevant, how the technology developed (intellectual property) will be transferred to the commercial sector for product development.

SUBMISSION OF APPLICATIONS

The title and number of this program announcement must be typed on line 2 of the face page of the application form, and the YES box must be marked. Submit a signed, typewritten original of the application, including the Checklist, 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)

Applications must be received by the application deadline dates given on the first page of this solicitation. If an application is received after that date, it will be returned to the applicant without review.

#### APPENDICES

Applicants are advised that the 40-page application should contain all relevant information. Appendix materials should not be submitted with the application. Reviewers are not obligated to read appended materials. Applicants who wish to send appendices should wait until they receive notification that the application has been assigned to an Initial Review Group. At that time, they should contact the Scientific Review Administrator of the committee to which their application is assigned to receive further instructions.

#### REVISED APPLICATIONS

The Center for Scientific Review (CSR) will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantive revision of an application already reviewed, but such an application must include an introduction addressing the previous critique.

#### REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by CSR staff and for responsiveness by program staff of the IC to which an application is assigned. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration.

Applications that are complete and responsive will be evaluated for scientific and technical merit by Scientific Review Groups of the CSR. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit (generally the top half of applications under review) may be discussed, assigned a priority score, and receive a second-level review by the appropriate national advisory council or board.

## REVIEW CRITERIA

The NIH review criteria have been adapted to ensure that the BRP application is evaluated appropriately. The score should reflect the overall impact that the BRP award could have on the selected area of bioengineering research based on consideration of the five criteria given below. The emphasis on each criterion can vary from one application to another depending on the nature of the application and its relative strengths. An application need not be strong in all categories to be judged likely to have major technical or scientific impact and thus deserve a high priority score. For example, an investigative partnership may propose to perform important work that by its nature is not innovative but is essential to advance a field.

A BRP may propose discovery-driven, developmental, non-hypothesis-driven, design-directed, of hypothesis-driven research at universities, national laboratories, medical schools, large or small businesses, or other public and private entities. The review criteria include:

1. Significance. If the specific aims of the BRP 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? Will the technological advances have a significant impact on human health?

2. Approach. Are the BRP engineering, scientific and clinical approaches and methods adequately developed, well integrated, and appropriate to the aims of the project? Does the application address potential problem areas and consider alternative strategies? Is a timetable with adequate research milestones proposed? Are appropriate specifications and evaluation procedures provided for assessing technological progress?

Is the proposed partnership adequate for the research? Is the partnership strategy well-planned and documented? Is there evidence that the partners from academia or industry can work together effectively, have an impact on achieving the research goals, and disseminate the technology developed? Do they describe arrangements that facilitate the fruitful participation of a

partner at a distant site? If partnership with industry or small business is included, does this positively affect the research goals and technology dissemination?

3. Innovation. Does the BRP propose new approaches, explore new research paradigms, or represent new concepts that combine engineering, physical, and clinical sciences? Will the proposed approaches or concepts solve current scientific or technical problems in novel ways?

4. Investigators. Is the PI capable of coordinating and managing the proposed BRP? Are the investigators (partners) appropriately trained in their disciplines and capable of conducting the proposed interdisciplinary work?

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 within the partnership? Is there evidence of institutional support? Does the partnership create potential opportunities to foster transdisciplinary communication and training across traditional scientific and technical boundaries?

In addition to these five review criteria, applicants must demonstrate adequate provisions for the protection of human subjects, humane care and use of animals, safety of the research environment, and compliance 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

BRP applications will compete for available funds with all other recommended applications. Funding decisions will be based on the quality of the proposed research as determined by peer review, availability of funds, and the institute's programmatic priority for the focus of the proposed research.

#### INQUIRIES

Inquiries concerning this PA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Inquiries or contacts concerning institute-specific scientific or financial issues should be directed to the NIH BECON scientific or financial contacts listed at the following Web site:

[http://www.nibib.nih.gov/becon/becon\\_contacts.htm](http://www.nibib.nih.gov/becon/becon_contacts.htm). These scientific contacts can also be used to obtain permission to submit applications that request more the \$500,000 of direct costs in any year.

Inquiries regarding general programmatic issues or notices of intent should be directed to:

Dr. Richard E. Swaja  
Office of Extramural Research  
1 Center Drive – Room 152  
Bethesda, MD 20892-0152  
TEL: 301-402-2725  
FAX: 301-496-0232  
E-mail: [swajad@od.nih.gov](mailto:swajad@od.nih.gov)

Inquiries concerning review issues should be directed to:

Dr. Eileen Bradley  
Center for Scientific Review  
6701 Rockledge Drive  
Bethesda, MD 20892  
TEL: 301-435-1179  
FAX: 301-480-2241  
E-mail: [bradleye@csr.nih.gov](mailto:bradleye@csr.nih.gov)

#### 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, 93.361, and 93.879.

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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[Return to Volume Index](#)

[Return to NIH Guide Main Index](#)