

National Center for Research Resources
National Institutes of Health
Department of Health and Human Services

Biomedical Technology Guidelines

- # Biomedical Technology Resource Center Grants
- # Research Project Grants
- # Shared Instrumentation Grants
- # Small Business Grants

An Administrative Document Issued by the National Center for Research Resources (NCRR).

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INTRODUCTION

he National Center for Research Resources (NCRR) is a "catalyst for discovery" for the National Institutes of Health (NIH)-supported investigations throughout the Nation by providing a broad range of technologies, research models and resources that contribute to major scientific breakthroughs. The NCRR supports primary research to create and develop these critical resources, models and technologies, promotes resource sharing and collaborations within and across scientific disciplines, enhances research competitiveness through institutional development, increases student and public understanding of the health sciences, and provides career development for biomedical investigators to address new and emerging research needs.

The four areas administered and managed by NCRR are:

- # Biomedical Technology
- # Clinical Research
- # Comparative Medicine
- # Research Infrastructure

The Biomedical Technology (BT) area of NCRR makes the newest and most advanced technologies and techniques accessible to the biomedical research communities. BT supports research to discover, create, develop and disseminate innovative technologies for a broad spectrum of research activities. It also provides research institutions opportunities to obtain advanced, high-cost instruments to be shared by groups of researchers supported by the NIH. Research supported by the BT area is multidisciplinary and transcends the interests of any single NIH Institute. The BT area is essential to the mission of the NIH to advance research that leads to better health for all humanity.

Through research support, new and innovative developments in advanced technologies -- high-performance computing, synchrotron radiation, mass spectrometry and nuclear magnetic resonance imaging and spectroscopies—are rapidly advancing knowledge in many biomedical fields, including structural biology, neuroscience, drug design, and clinical diagnosis.

Current areas of emphasis include, but are not limited to, bioinformatics, biomedical engineering, high performance computing, modeling/simulation methodologies, technologies for the study of molecular and cellular structure and function, neurosciences research technologies, and advanced imaging and spectroscopy.

The BT area supports the following grant funding mechanisms: Biomedical Technology Resource Center Grants (P41); Investigator-initiated Biomedical Research Project Grants (R01); Resource-related Research Project Grants (R24); Shared Instrumentation Grants (S10); Innovative Biomedical Technology Grants (R21); Small Business Innovative Research (SBIR) Grants (R43, R44); Small Business Technology Transfer (STTR) Grants (R41, R42); Academic Research Enhancement Award (AREA) Grants (R15), and Conference Grants (R13), as well as cooperative agreements and contracts.

GUIDELINES FOR THE BIOMEDICAL TECHNOLOGY PROGRAM of the National Center for Research Resources, National Institutes of Health

I. BIOMEDICAL TECHNOLOGY RESOURCE CENTER PROGRAM (P41)

A. General Description:

A major emphasis of the BT area is directed to the research and development (R&D) as well as collaborative activities at Biomedical Technology Resource Centers. These centers are located across the country, primarily at major academic institutions. The Biomedical Technology Resource Center Program (P41) is designed to provide a multi-disciplinary technological infrastructure primarily for NIH-funded researchers. The program accomplishes this end through support of a combination of research, development, collaborative research, service, and information dissemination activities involving a wide range of technologies. These BT Centers provide state-of-the-art experimental and computational resources to a wide range of biomedical researchers, particularly those supported by NIH. Each center functions as both a technological resource and an intellectual resource, with an infrastructure that permits staff scientists to react rapidly and effectively to emerging biomedical research opportunities. Resource centers provide major, complex, expensive technologies that are difficult for single institutions to acquire and support. While the primary goal of the P41 Resource Grant is to facilitate sophisticated research and development activities targeting biomedical applications, the multidisciplinary environment of each center stimulates innovation and collaboration among physical scientists, engineers, and biomedical scientists. The centers also make their technologies available to a user community of biomedical researchers.

A central aspect of any BT Resource Center is the combination of core technology R&D and collaborative research. While resource staff is critical for the development of the technology itself and its application to biomedical problems, collaborative research involving carefully selected segments of the user community is an important driving force leading to new avenues of technology development. Research is the major Resource Center activity—involving core technology development and collaborative research. In addition, a Resource Center serves the research needs of a significant community of users, whose research depends on access to the particular resource technologies. Service activities make use of established resource technology rather than directly impelling its further development.

In addition to providing direct service functions to the biomedical research community, BT Resource Centers engage in training activities and in active dissemination of information about the core technology and its applications.

1. Technological Research and Development:

The Resource Center technology must be dynamically evolving and an important area for R&D in its own right. The technological R&D or core component consists of investigations in the technology that are at the cutting edge of the technological field with a goal of increasing its usefulness in biomedical research. A minimum of three technological research projects constitute the core section of the resource grant application.

For example, these projects may involve development of new or significant modification of existing instruments or methods; development of new computer algorithms and related software or new methods to prepare samples for instrumental analysis; or development of innovative applications through the integration of existing technologies. Technological R&D is most effective when it responds to emerging needs of the biomedical research community.

2. Collaborative Research:

In concert with investigators from other regional and national institutions, Resource Center staff should continuously develop new, significant applications of the resource technology in the biomedical sciences. This is best accomplished through high-quality collaborative research projects that are closely related to core technology development. These projects involve experts in the technology, usually resource personnel, working jointly with investigators outside the resource who have expertise in a particular biomedical discipline. Such efforts should lead to joint publications and, in some cases, patents. The collaborations should drive the technological R&D and the technology should significantly advance the frontiers of the collaborative research projects.

3. Service:

Providing biomedical investigators access to a Resource's technology constitutes the service activity. This includes making available specialized instrumentation, equipment, software and techniques, and offering consultation and technical assistance in their use. Service is characterized by a routine operation of resource equipment or methods in which Resource Center personnel have little intellectual role and generally do not share in the intellectual property of the data or samples nor in authorship on resulting papers or patents. The Resource Center, however, is expected to be acknowledged in papers resulting from all projects, including service research projects. While service is one of the key elements of the Resource, the P41 mechanism is not intended to support centers that are predominantly service oriented.

4. Training:

Special training in the use of a Resource Center's technologies is provided to collaborators and service users of the resource. Routine training and education on the technology/methodology are provided through hands-on laboratory experience, seminars, and lectures on a regular basis. Short courses, symposia, and workshops on appropriate topics that bring together researchers, often from multidisciplinary areas, are important in introducing the national research community to the potential application of the Resource's technology in biomedical research. Training can be offered periodically, often in conjunction with meetings that the user community is likely to attend.

5. Dissemination:

This activity involves informing the scientific community about the resource's technology or accomplishments by publishing articles, books, patents, newsletters, annual reports, special issues of technical journals; issuing press releases; presenting research results at meetings; conducting conferences; distributing software products, or transferring technologies to industry where they will be distributed widely. In resources that are developing software, emphasis should be placed on producing portable, well-documented, user-friendly software, and making it readily available to the user community. The resource center is expected to maintain an up-to-date Web site for the purpose of dissemination of the technology.

6. Advisory Committee:

The advisory committee is appointed by the principal investigator (PI) and advises the P.I.on future directions for the Resource particularly in planning additional grant applications and in setting priorities for allocation of Resource facilities. The committee chair should be knowledgeable about the Resource's technology and the science it serves, but should not be a member of the Resource staff or a major user of the resource. Other committee membership should be balanced among scientists knowledgeable about the Resource's technology, experts in its application to biomedical research problems and users of the technology. Committee members should be from the geographical regions served and membership should be rotated periodically. The committee chair and a majority of members should be from outside the host institution. The advisory committee should meet at least annually at the Resource Center and prepare a written report of its recommendations. This report must be supplied as part of the Resource's annual progress report and must be available for NIH staff review during site visits.

B. Criteria for Consideration for a Resource Grant:

The five activities—technological R&D, collaborative research, service, training and dissemination—must be present in a Biomedical Technology Resource Center.

The technological capabilities of the Resource Center must be state-of-the-art and not broadly available by other means. The projects served by the new technology must be broad in scope and involve a variety of biomedical research areas. The resource is expected to serve investigators in a wide geographical region, and preferably across the nation.

C. Funding Plan of a Resource:

The BT Resource Center Program provides support for the establishment and initial user operations of a resource. Continued support depends primarily upon the merit of the technology R&D and its application to important biomedical problems. Resources are not intended to serve selected users or laboratories on a permanent basis. Long-term collaborative and service users are expected to acquire separate funding for their technology needs either directly or through shared support of the resource. Costs of routine service activities should also be shared, for example, through joint grant support, institutional funding, or a charge back system. For details on how to report Program income obtained through a charge back system see section 3c.

D. Types of Resource Grants Currently Supported:

A *Biomedical Technology Resources* directory is available in paper and electronic forms to assist scientists in learning about the types of Resource Centers supported by the program. Copies of this directory may be obtained from the Office of Science Policy, National Center for Research Resources, National Institutes of Health, One Rockledge Centre, Suite 5046, 6705 Rockledge Drive, Bethesda, Maryland 20892-7965 or by accessing the NCRR Web site: http://www.ncrr.nih.gov/biotech.htm.

The absence of a particular technology from among those currently supported does not necessarily mean that the Program would not consider an application for a grant in that technology. The Program is responsible for supporting the initiation of cutting-edge technologies with the potential for having a major impact on biomedical research. The Program currently supports the following technological areas:

- Bioengineering
- Flow Cytometry
- Informatics
- Integrated Technologies
- Isotopes and Particles
- Laser Applications
- Magnetic Resonance Imaging (Structure and Function)
- Magnetic Resonance Spectroscopy
- Mass Spectrometry

- Optical and Electron Microscopy
- Simulation and Computing
- Synchrotron Radiation
- X-ray (excluding synchrotrons)

E. Instructions for Applicants:

1. Eligibility:

Eligibility for Biomedical Technology Resource Center Grants is limited to those institutions located in the United States. Both profit and nonprofit organizations are eligible for support.

2. Coordination with NIH Program Staff Required to Develop Applications:

For both new resource grant applications and competing continuations, prospective grantees are required to discuss the proposed resource grant application and the proposed budget with NCRR Program staff well in advance of the application deadline. These discussions provide applicants with a clearer understanding of current Program policies, priorities, and any newly instituted guidelines and special situations, such as the inclusion of consortia, subcontracts, etc. Applications that do not meet the BT Resource Center guidelines will be returned without review.

For ALL requests over \$500,000 in annual total cost, applicants are advised that they must contact the Program Staff as they begin to develop their application plans. Applications received without prior staff contact may be delayed in the review process or returned to the applicant without review. For further information, please refer to http://www.nih.gov/grants/guide/notice-files/not98-030.html.

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Studies using vertebrate animals or human subjects in core, collaborative, or service projects require assurances and review by the Institutional Animal Care and Use Committee (IACUC) or Institutional Review Board (IRB), respectively, and must be in compliance with Public Health Service (PHS) policy (for animal welfare) and HHS regulations (for human subjects). This includes studies involving volunteers. Applications without IACUC and/or IRB approval will be deferred for a later cycle. Other assurances are required and are discussed in the instructions for completion of Form PHS 398.

3. Application Form:

The current version of Form PHS 398, Application for Research Grant, should be used for resource grant applications. Application kits should be available within each institution's sponsored research office. If necessary, an application kit may be requested from the Division of Extramural Outreach and Information Resource, Office of Extramural Research, National Institutes of Health, 6701 Rockledge Drive, Suite 6095, Bethesda, Maryland 20892-7910; Tel:(301) 435-0714; e-mail: grantsinfo@nih.gov. Forms are also available on the NIH Web site: http://www.nih.gov/grants/funding/phs398/phs398.html.

Required information, in addition to that requested in the Form PHS 398 instructions, is listed below, by section. Neither a site visit nor an applicant interview is guaranteed as part of the review of the resource grant application. **The written application should be complete and stand on its own.**

Form Pages 4-5: The budget should be completed as described in the instruction sheet for Application for a Public Health Service Grant (Form PHS 398). Funds may be requested for technological R&D, training, dissemination, advisory committee meetings (in the consultant costs) and the Resource's expenses associated with collaborative and service projects. Graduate student and postdoctoral support can be requested only if they are active participants in a core research project. The level of the requested budget should be clearly supported by the research plan. The outside investigators of collaborative and service projects must derive support for their projects from sources outside the Resource Center.

The budget justification beginning on PHS Form Page 5 should include a detailed justification for key personnel. The percentage effort for each of the staff on research should be specified for a) each of the core projects, b) collaboration, and c) service in the budget justification.

A detailed justification should also be supplied for the equipment requested for the Resource. Appropriate price quotes should be included for major items of equipment costing more than \$25,000. An evaluation of alternative instruments or manufacturers should be included along with a discussion of the proposed procurement plan. Similar justifications should be provided for any

subcontractual or consortium arrangements. Use continuation pages as needed.

A budget ceiling of \$700,000 per year in direct cost, excluding equipment cost, and a budget ceiling of \$500,000 in equipment for the duration of the requested project are placed on BT Resource Center Grants. In applications where the budget request exceeds the BT Program's budget ceilings, scientific reasons for exceeding the ceiling must be provided in the application. In addition, applicants must obtain a written waiver from the Director of the NCRR Biomedical Technology area to these ceilings and include it in their application. The waiver must be requested well in advance of submission of the application. Major equipment purchases (more than \$500,000 over the course of the project period) often require support from other sources when the BT Program is unable to fund the entire request. Plans for such shared funding should be detailed in the application. Applications exceeding these ceilings (\$700,000 in direct costs per budget period and/or \$500,000 total in equipment for the duration of the requested award) will be returned without review if approval from the NCRR BT Director has not been granted prior to submission.

In accordance with NCRR policy, the recurring direct costs (direct costs excluding equipment) requested for the first year of a competitive renewal application cannot exceed the final non-competing year's budget direct recurring costs budget by more than 20 percent. Where this policy may significantly limit the Program scope of the proposed research, the applicant may request a waiver of the 20 percent ceiling. A letter, clearly justifying the request for a waiver, must be submitted to the NCRR BT Director well in advance of the application receipt date. The waiver to the ceiling must be approved in writing by the BT Director before the center's competing renewal application is submitted and accepted.

Section 6, Biographical Sketches, no more than two pages each, should be included for key personnel for whom salary support is requested in the application and for each of the principal collaborators.

Section 9, Research Plan, A-D: The page limitation specified in the PHS 398 for items A-D of the Research Plan does not apply, but applicants are reminded to be succinct as well as complete. The length of the application should be consistent with the scope of the proposed research and the number of collaborative and service projects. It is important to be concise, but there should be sufficient information about each core, collaborative, and service project to permit its evaluation.

Section 9, Research Plan C: Preliminary Studies/Progress Report should include a plan that states long-term goals and overall objectives for the resource and a projected timetable for technology development. Information on factors and events contributing to the decision to create the resource and on comparable resources elsewhere should be presented. Applicants should explain in detail what makes this particular resource "unique" in terms of its intellectual and technological capabilities. For competing continuation or supplemental applications, a brief summary of the Resource Center's progress should be included. Include copies of the Resource Center's most

recent annual progress report and minutes of the most recent Advisory Committee meeting in the Appendix.

Section 9, Research Plan D: Research Design and Methods should include a discussion of the proposed research in each of the three major resource activities: technological R&D, collaborative research, and service. Indicate the relative emphasis to be given to these activities and explain the proposed division of effort. Plans for training and dissemination should also be presented.

The following five areas should be addressed:

Technological Research and Development: The technological R&D projects to be conducted must be presented in detail. For each project describe the background, objectives, rationale, methods and procedures, significance, and facilities available to conduct the project. For competing continuation applications, new activities should be specifically identified. If research activities involve support at more than one location through a consortium/contractual arrangement, the application should provide a separate description, detailed budget and budget justification for the consortium/contractual component(s).

The continued development of innovative technology and the steady infusion of new areas of technological R&D are important considerations in reviewing competing continuation proposals. Long-term support depends strongly on the Resource's commitment to the introduction and application of new technology and serving biomedical investigators from an array of institutions on a regional or national basis.

Collaborative Research: Collaborative projects enable non-core researchers to interact with the Resource staff to pursue areas of common interest which further the Resource's research objectives. These projects are selected for the impact they will make on the technological field as well as for advancing the frontiers of biology and medicine.

For each collaborative project, describe the specific objectives: the rationale for the proposed approach to the problem, methods, and procedures to be used; the significance of the proposed work; and the impact of the expertise of the Center's core staff along with the technology developed at the Center on the collaborative project. Provide literature citations. The collaborator's name, institution and funding status of the project including principal investigator, grant number, and project period dates, and also the source of funds should accompany the description of the project. Collaborative projects that have already been peer-reviewed will be evaluated on how they clearly advance and stimulate technological resource development as well as advancing the frontiers of biomedical science. Those that have not been peer-reviewed should include more detail and will be evaluated for scientific merit of the research proposed. New applications should have at least four relevant collaborative projects, three of which are with investigators outside the

Resource Center's host institution. In competing renewals, the number of collaborative projects is expected to increase significantly, with the majority being from the outside the host research institution.

Service: A representative sample of (no more than 20) research projects to be served by the resource should be presented. Each project should be described in sufficient detail to allow the reviewers to evaluate the need for the resource technology in the proposed project. The user's name and institution and funding status of the project (including principal investigator, grant number, funding source, and term) should accompany the description of the project. In competing renewals, the Resource Center should strive to provide the major portion of its service to the outside research community. If a charge back system that results in program income is planned, a description of how costs are to be shared by the users should be included. Additionally, special administrative requirements that apply to program income must be observed. Program income means gross income earned by the recipient that is directly generated by a supported activity or earned as a result of the award (additional information is available in 45 CSR 74.2 and 74.24, which can be obtained by searching the Code of Federal Regulations at http://www.access.gpo.gov/nara/cfr/cfr-table-search.html). An estimate of the amount and source of program income expected to be generated as a result of the BT Center award must be included on the "Checklist Page" of all competing and noncompeting continuation applications. Net program income earned during a budget period must be reported on the long-form Financial Status Report (except for program income earned as a result of inventions, to which special rules apply). Cost incident to the generation of program income may be deducted from gross income to determine program income, provided these costs have not been charged to the award.

Program income earned during the project period shall be retained by the BT Center award recipient and, in accordance with the terms and conditions of the award, used in the following way:

A. The first \$25,000 earned during a budget period is added to funds committed to the project or program, and used to further eligible project or program objectives;

B. Any amount over \$25,000 earned during a budget period is to be deducted from the total project or program allowable costs in determining the net allowable costs on which the Federal share of costs is based. NCRR may offset a future award by this amount or reauthorize it for expenditure on a future award.

All publications that result from utilization of the Biomedical Technology Resource Grant must acknowledge NCRR grant support.

Training: Plans for training activities should be presented. Examples of appropriate

training activities include: special training on resource facilities to collaborators and service users of the resource on an individual basis; routine training and education on the technology/methodology through hands-on laboratory experience, seminars and lectures on a regular basis; short courses, symposia and workshops on appropriate topics that bring together researchers in multidisciplinary areas from academic institutions, hospitals and industry for discussions on the use of the resource's technology in biomedical research.

Funds to support courses given for credit may not be requested. Individuals involved in the training experiences may not be paid a stipend nor may the training experience be a requirement for receipt of an academic degree.

Dissemination: Plans for dissemination of the Resource's technology, expertise or accomplishments must be presented. Appropriate dissemination activities involve informing the scientific community about the Resource's technology or accomplishments by: publishing articles, books, patents, newsletters, annual reports, special issues of technical journals, world wide web pages, and press releases, presenting research results at meetings; conducting conferences; distributing software products; and transferring technologies to industry where they will be distributed widely.

In resources that are developing software, emphasis should be placed on producing portable, well-documented, user-friendly software, making it readily available to the user community and providing user support. All dissemination activities must acknowledge NCRR grant support.

4. Administrative, Management, and Fiscal Aspects:

A separate section on resource organizational structure should address the following:

Organizational Structure: Describe the organizational structure of the Resource. Indicate how the Resource will relate to the administrative structure of the grantee institution.

Resource Staff Responsibilities: Describe how the principal investigator and the proposed resource staff will be organized with respect to the resource activities: technological R&D, collaborative research, provision of service, training, dissemination and general resource administration. Describe the scientific and technical expertise of the staff who will operate, maintain, and develop the Resource capabilities.

Resource Operating Procedure: Describe operating procedures and policies planned for the Resource. Include criteria and mechanisms to review applications

for the use of the resource and for scheduling. Also describe methods for selecting collaborative research and service projects. Include samples of the form to be filled out by the collaborators and users and the instructions on how they are to acknowledge support provided by the Resource in any resulting publications.

Support of Service and Collaborative Projects: Direct support from resource funds for collaborative or user activities is not allowed. For competing continuation applications, when applicable, present a plan for sharing costs for routine service and long-term collaborative projects with funds from outside the resource grant. For resources with a substantial amount of service anticipated, describe fee-for-services. Include instructions on how users are to acknowledge support provided by the Resource in any resulting publications.

Resource Advisory Committee: Describe the role of the resource advisory committee. For example, explain the committee's role in advising on instrument purchases, reviewing collaborative and service projects for merit and appropriateness, and allocating instrument time. The scientific disciplines to be represented by the advisory committee should be provided. Names of committee members should also be included, if already appointed, accompanied by a brief description of their qualifications. An executive committee, perhaps a local subcommittee of the advisory committee, may be included as an adjunct to the full advisory committee as well as a medical committee if there is substantial involvement of human subjects in research projects. Funds may be requested in the consultant category of the budget to support the costs related to a resource advisory committee.

Deadlines for submission of all new **and competing continuation** resource grants are: **February 1, June 1, and October 1.**

F. Guidelines for Review:

The following guidelines are intended to assist members of study sections in their review of resource grant applications, as well as to provide guidance to potential applicants. In addition, NCRR BT Program Staff attend the review to present and interpret program guidelines.

1. Resource Plan: The five components -- technological R&D, collaborative research, service, training and dissemination -- should be clearly described. Absence of sufficient detail in the written proposal on one or more of these will be sufficient basis for the application to be returned without review.

R&D is the major resource activity. Research projects are divided into two categories: core technological R&D and collaborative. The emphasis placed on each research category depends on the goals of the Resource and the stage of development of the resource technology and should reflect a balance in terms of the advanced technological needs of the scientific community. While service is one of the key elements of the Resource, the P41 grant mechanism was not designed to support service-only centers.

New applicants are expected to have active R&D core and collaborative research projects at the time of application and to detail their plans for expanding these and adding the service, training, and dissemination components if not yet established. Investigators submitting continuing competing applications are expected to have all five components in place at the time of application.

a. Technological Research and Development:

The reviewers should evaluate whether the resource technology is dynamically evolving, state-of-the-art, an important area for R&D in its own right, and likely to advance the frontiers of biomedical research. The resource technology should not be broadly available by other means. An element of high risk (and potentially high payoff) may be present in one or more of the core projects and is appropriate for this component. Investigators should, however, present alternative approaches to solving technological problems in the event that their main conceptual thrust should prove unfeasible.

Reviewers should characterize the uniqueness of the BT Resource Center's technological goals and the synergy between core and collaborative projects in advancing the focal technology. Reviewers should identify what makes this resource "unique" in the technological goals it is pursuing as well as in the cluster of collaborative projects to which the advanced technology is being applied. In competing continuation requests, reviewers should look for evidence of new meritorious efforts and significant progress during the past grant period.

b. Collaborative Research:

The application reviewers should determine whether the Resource Staff is continuously developing new, significant applications of the resource technology in the biomedical sciences through high-quality collaborative research projects. The projects served by the new technology should be broad in scope and involve a variety of biomedical research fields.

The resource is expected to be highly responsive to a regional or national user community whose members are primarily grantees and contractors of other NIH programs. It is the applicant's responsibility to identify user communities that both need and will use the research capabilities to be provided by the resource.

Collaborative projects that have already been peer-reviewed should be evaluated on the basis of how they clearly advance and motivate further technological R&D and for the appropriate use and impact of the new technology on the collaborative project itself. Those that have not been peer-reviewed should include more detail and will be evaluated on the scientific merit of the research proposed.

In competing continuing requests, reviewers should evaluate the balance that has developed between collaboration and technology R&D, and between collaboration and service. Reviewers should assess whether collaborative projects are driving core research and whether collaborative projects are making good use of the new technological advances. Long-term collaborations should roll over into service projects and new collaborators in important biomedical fields should be actively sought to invigorate the Resource. In addition, reviewers should determine that the resource has been properly acknowledged by collaborators and service users in publications resulting from use of the resource.

c. Service:

Reviewers should determine if the Resource is available to outside users. The equipment and technology utilized for service should be state-of-the-art and should meet significant biomedical research needs. The nature of the service projects should be multicategorical and have a regional or national geographical distribution. For Resources that do a substantial amount of service, reviewers should evaluate the plan for how costs are shared by the users if this is a component of the application.

d. Training:

Reviewers should evaluate, in new applications, the adequacy of plans for providing opportunities for training; and, in competing continuation applications, if there have been reasonable results accruing from these efforts to date. Examples of appropriate training activities include the individual, special training given to collaborators and service users; the experiences of graduate students and postdoctoral personnel engaged in core research; training and education on the technology/methodology through hands-on laboratory experience, seminars and lectures on a regular basis; and short courses, symposia and workshops on the use of the Resource's technology in biomedical research.

Training courses offered by the Resource may not constitute a requirement for receipt of an academic degree.

e. Dissemination:

The reviewers should evaluate in new applications, the adequacy and appropriateness of the proposed plans; and in competing continuation applications, if there has been reasonable and timely progress in this area. Appropriate dissemination activities involve informing the scientific community about the Resource's technology or accomplishments by publishing articles, books, patents, newsletters, annual reports, special issues of technical journals, World Wide Web pages, and press releases; presenting research results at meetings; conducting conferences; distributing software products; and transferring technologies to industry where they will be distributed widely. In Resources that are developing software, reviewers should determine if the software is portable when appropriate, well documented, user-friendly, and readily available to the user community.

f. Scoring:

For resource grant applications, each core project in the technological R&D should be scored separately. Also, each of the other Resource components - collaboration, service, training, and dissemination - should be scored separately. Finally an overall score for the resource grant application should be assigned as shown below.

- Project Scoring
- Technological Research and Development
- Each Core Project Receives a Score
- Collaboration
- Service
- Training
- Dissemination

OVERALL SCORE FOR THE RESOURCE

The overall score for the resource should not be the average of the individual scores but rather should take into account the synergy of the individual components and reflect the individual scores weighted in a balance that is appropriate for the goals of the resource and the stage of development of the resource technology.

2. Administrative, Management, and Fiscal Aspects:

The reviewers should evaluate the administrative and managerial aspects presented in the written proposal. In addition, if a site visit takes place, reviewers should examine the discrete space set aside for the resource and the laboratory facilities, including those available to visiting scientists. In the case of a competing continuing application, the logbooks recording the hours of usage of the instruments and their idle and down time should be examined. Reviewers should take note of which instruments are in place and operational and which staff members are currently on site.

a. Institutional Commitment:

Reviewers should evaluate the institution's commitment to the Resource: for example, allocated space, costs associated with alterations and renovations and purchase of instrumentation and computers, and salary support for some Resource Staff.

b. Staff Credentials:

The reviewers should evaluate the scientific and managerial credentials of the principal investigator and the credentials of other key professional and technical staff.

c. Resource Advisory Committee:

Reviewers should evaluate the role of the advisory committee, or (in proposed resources) plans for the committee (and associated committees such as local executive and medical committees), and whether the members have or will have sufficient breadth and ability to take an effective role in the review and guidance of the resource operations.

d. Budget:

Details of the budget including the length of the grant period should be discussed after the resource application has been finally scored. Percentage of effort for personnel should be evaluated in the context of their specific contribution to the research of the Resource. Graduate student and postdoctoral personnel support can be requested only if they are active participants in a core research project. Requests for individual instruments or for aggregates of instruments should be consistent with the technological goals of the resource and with the projected timetable for technology development as presented in the application.

Activities for which funds may be requested are technological R&D, training, dissemination, advisory committee meetings, and the Resource's share of efforts associated with collaborative and service projects. In collaborative and service projects, the outside investigators must derive their primary support from sources outside the resource grant. Individuals, not included in the resource budget, who participate in the training experiences may not be paid a stipend.

Specific justifications should be given for equipment requests and for any proposed subcontractual or consortium arrangements. In applications where total annual direct costs excluding equipment exceed the BT Resource Center Program's budget ceiling of \$700,000, scientific reasons for exceeding the ceiling must be provided in the application. Major equipment requests should include a plan for obtaining funding from other sources should the BT Resource Center Program be unable to support the full request for equipment. All budget requests that exceed the \$700,000 per year ceiling for direct costs, excluding equipment, and/or \$500,000 for equipment for the full

duration of the grant application must receive a written waiver from the NCRR BT Director. The direct recurring costs (excluding equipment) requested for the first year of a competitive renewal application cannot exceed the last year's direct recurring costs budget by more than 20 percent.

3. Animals and Human Subjects:

All required IRB and IACUC, and other assurances for all research projects should have been submitted with the grant application. Any additional data reviewers request for clarification should be obtained and distributed before the review.

Investigators should be aware that NIH urges applicants to give added attention, where feasible and appropriate, to the inclusion of minorities, women and children in study populations. If minorities and/or women are not included in a given study involving human subjects, a clear rationale for their exclusion must be provided.

II. RESEARCH PROJECT GRANTS (R01, R21)

For additional information on research project grant mechanisms, the applicant is encouraged to visit the NIH/NCRR Web site http://www.ncrr.nih.gov/) and view the relevant Program Announcements (PA) and Requests for Applications (RFA).

A. RESEARCH PROJECT GRANT(R01):

The mission of the Biomedical Technology area of the NCRR is to support research to discover, create, and develop innovative technologies and to provide access to these advanced technologies to the biomedical research community. The BT Program is especially interested in **technology-driven** research on new or improved instruments, devices, and related methodologies that may have broad application to biomedical research.

The research supported may involve conceptualization, design, fabrication, and/or testing of the technology with the overall objective leading to a more powerful and more precise technology for biomedical research. Areas of emphasis are biomedical engineering, biomedical computing, and technologies for the study of the structure and function of biological systems at all levels of complexity.

This mechanism supports R&D in new instruments or technologies with broad biomedical research application. Proposals to develop instruments/technologies that apply only to a specific disease or category of research should be addressed to the appropriate categorical institute of NIH. An R0l grant application should have a well-defined research agenda with measurable goals or benchmarks that addresses a specific instrument/technology.

1. Application Form:

A cover letter may be included with the application if the principal investigator (PI) is making a request for assignment to a particular awarding component or initial review group. The PI may also suggest special expertise required to review the application or alert the NIH Center for Scientific Review (CSR) to potential conflict of interest with individuals or organizations. These suggestions will be taken into consideration at the time of assignment, although the final determination will be made by the CSR. A list of initial review groups, their rosters, and meeting dates can be found at http://www.csr.nih.gov. We strongly encourage applicants who submit an application that matches the mission of the Biomedical Technology area to identify NCRR as the potential primary or secondary funding source.

An investigator-initiated research grant application should be prepared in accordance with the PHS Form 398. Application kits should be available within each institution's sponsored research office. If necessary, an application kit may be requested from the Office of Extramural Outreach and Information Resource, National Institutes of Health, 6701 Rockledge Drive, Suite 6095, Bethesda, Maryland 20892. Tel: (301) 435-0714; e-mail: grantsinfo@nih.gov). Forms also may be obtained at the NIH Web site: http://www.nih.gov/grants/funding/phs398/phs398.html. Required information, in addition to that requested in the Form PHS 398 instructions, is listed below by section.

Section 9, Research Plan, Item a, Specific Aims: This instructs the applicant to state "the hypotheses to be tested". Since the goal of BT is technology development, hypothesis testing per se may not be applicable. Instead, in this section identify concisely the technology or methodology to be developed and its potential impact on biomedical research

Section 9, Research Plan, Item b, Background and Significance: Here clarify the innovative nature of the proposed research. Elaborate on how the technology development proposed in this project is a significant improvement over presently available capabilities. Explain the potential of the proposed technology for having a broad impact on biomedical research or on improved human health.

2. Review Criteria:

In addition to applying the normal review criteria for a research project grant as stated in PHS

Form 398, the following criteria should be used.

Significance: Does the study focus on the development of an important technology? If the technological aims of the project are achieved, will it have a significant impact in advancing biomedical research?

Approach: Are the experimental and engineering approaches adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation: Does the project propose new technological approaches or explore new research paradigms in engineering, instrumentation, physical sciences, mathematics or computer science as applied to biomedical research or challenge existing paradigms in these fields?

Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

Environment: Does the scientific and technological environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

Investigators should be aware that NIH urges applicants to give added attention, where feasible and appropriate, to the inclusion of minorities and women in study populations. If minorities and/or women are not included in a given study involving human subjects, a clear rationale for their exclusion must be provided.

Deadlines for submission of all <u>new</u> R01 grants are: **February 1, June 1, and October 1** and for competing continuation R01 grants are: **March 1, July 1, and November 1.**

B. INNOVATIVE APPROACHES TO DEVELOPING NEW TECHNOLOGIES GRANT (R21):

The Exploratory/Developmental grant (R21) supports innovative approaches to the development of technologies for applying new research paradigms in engineering, instrumentation, physical sciences, mathematics or computer science to biomedical science. These **technology-driven research** projects explore the feasibility of new approaches and may contain an element of high risk and, unlike applications for the R01 mechanism described above, investigators are not expected to include preliminary data in their applications. This NCRR BT mechanism provides a

unique opportunity to support pilot efforts to develop new technologies, methods, devices, and materials that would not normally be supported under the R01 mechanism.

The technologies/instruments/methodologies to be developed under this mechanism must be applicable to a spectrum of biomedical research areas. Those that apply only to one categorical NIH institute or a specific disease, generally do not meet the guidelines for this program. Such applications will be considered only if the applicant clearly demonstrates the long-term potential of the technology for having a broad impact on biomedical research. Applications that represent incremental changes in already established research programs will not be considered. These may be more appropriate for the R01 mechanism described above.

Support for the Exploratory/Developmental grants is limited to up to two years with direct costs limited to \$75,000 per year. Indirect costs will be provided. These funds may not be used to supplement or supplant projects currently supported by Federal or non-Federal funds, or to provide interim support for projects under review. Although these R21 grants are not renewable, they should provide the opportunity to collect sufficient preliminary data so that the principal investigator can apply for support from either the NCRR or other NIH Institutes through other NIH grant mechanisms.

Application Form:

An Exploratory/Developmental Grant Application should be prepared in accordance with the PHS Form 398. Instructions specific to the submission of R21 applications can be found on the Web site http://www.ncrr.nih.gov/biotech.htm. All investigators should check the box to indicate that this is in response to a Program Announcement (PA) and include the title and number of the most recent PA. Application kits should be available within each institution's sponsored research office. If necessary, an application kit may be requested from the Office of Extramural Outreach and Information Resource, National Institutes of Health, 6701 Rockledge Drive, Suite 6095, Bethesda, Maryland 20892, Tel (301)435-0714; e-mail: grantsinfo@nih.gov. Deadlines for submission for NCRR's Exploratory/Developmental Grants are: **June 1 and October 1.**

Instructions specific to the submission of R21 applications:

1. Face Page of the application:

Item 2. Check the box marked "YES" and type the number and title of this program announcement.

Item 7a, DIRECT COSTS REQUESTED FOR INITIAL BUDGET PERIOD:

Direct costs are limited to a maximum of \$75,000 per year for a maximum of two years. The award may not be used to supplement an ongoing project. R21 awards are not renewable.

Item 8a, DIRECT COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT:

Direct costs requested for the proposed period may not exceed \$150,000.

2. Description:

As part of the description, identify concisely what new engineering, scientific, or physical principle is to be employed and the technology or methodology to be developed; its innovative nature; its relationship to presently available capabilities; and its expected impact on biomedical research.

9. Research Plan:

Item a., Specific Aims: The instructions for this section suggest that the applicant state "the hypotheses to be tested." Since the goal of this program announcement is to develop innovative technologies, hypothesis testing per se may not be the driving force in developing such a proposal and, therefore, may not be applicable. Furthermore, preliminary data are not required, but when available, should be included. Importantly, however, research that develops new technologies requires the application of principles from fields such as engineering, materials science, physics, mathematics or computer science. A clear statement of these underlying principles and the nature of the innovation are essential.

Item b., Background Significance: Elaborate on the innovative nature of the proposed research. Clarify how this project is a significant departure from ongoing work. Explain the potential of the proposed technology for having a broad impact on biomedical research or on improved human health. Clearly identify how the project, if successful, would result in new capabilities for research, and how these capabilities would differ from those existing today.

Items a-d:

Do not exceed a total of ten pages for items a-d in the Research Plan. Tables and figures are included in the ten-page limitation. Applications that exceed the page limitation or NIH requirements for type size and margins (refer to PHS 398 application for details) will be returned to the applicant without further consideration.

The ten-page limitation does not include items e-i (Human Subjects, Vertebrate Animals, Literature Cited, Consortia, Consultants/Collaborators).

10. Appendix:

Color illustrations or original photographs may be included in an Appendix. These are allowed only if they are copies of black and white figures appearing in the body of the application. No other appendix material is permitted.

Review Criteria

In addition to the NIH review criteria for a research project grant application (see http://grants.nih.gov/grants/guide/notice-files/not97-010.html), other aspects of the proposed project that will be addressed by the initial review group include:

The potential for developing ground-breaking technology or methodology that may lead to significant expansion of biomedical research horizons, precipitate a paradigm shift in research, or lead to substantial improvements in human health.

<u>The degree of innovation</u>: Does the project challenge existing paradigms or develop new methodologies or technologies?

<u>Impact:</u> Does the project have the potential for broad impact on biomedical research?

<u>Organization</u>: Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Although preliminary data and biological hypotheses are not required for R21 applications, have the investigators made a plausible scientific case for the project?

Ability of investigator(s) to carry out the proposed project: Is the investigator appropriately trained and well-suited to carry out this work? Are the available and requested resources adequate to conduct the proposed work?

Investigators should be aware that NIH urges applicants to give added attention, where feasible and appropriate, to the inclusion of minorities and women in study populations. If minorities and/or women are not included in a given study involving human subjects, a clear rationale for their exclusion must be provided.

The initial review group will also examine the adequacy of the proposed means for protecting against or minimizing potential adverse effects upon humans, animals or the environment.

In addition to review of the merit of the application, the review committee will also examine the appropriateness of the requested budget.

III. RESOURCE-RELATED RESEARCH PROJECT GRANT (R24)

The R24 grant normally is used only for applications in response to a specific Program Announcement (PA) or Request for Application (RFA). Information on application development, review criteria, and budget issues for a PA or RFA that specifies the R24 mechanism are included in that announcement.

IV. CONFERENCE GRANTS (R13, U13)

Scientific meetings may be funded by assistance mechanisms (R13 grants and U13 cooperative agreements). All applications for such funding will be evaluated for programmatic relevance by BT Program staff and reviewed for merit by NCRR's Office of Review. Applications of interest to more than one NIH component may be co-funded. A prospective applicant should inquire in advance concerning the BT Program's interest in a proposed conference by contacting the program. When NCRR determines that there is sufficient need to have substantial involvement in the planning and conduct of a scientific meeting, NCRR may determine that a cooperative agreement (U13) be awarded. Specific terms and conditions of the award may be obtained from BT Program staff.

The application should contain the following information on the proposed conference: title, location, anticipated number of registrants, dates, composition and role of planning committee, registration fee, physical facilities, publicity, transportation and per diem costs, agenda and justification for the conference. Applicants should pay special attention to including appropriate women, minority and scientists with disabilities as presenters and participants. The application must be prepared using the PHS-398 form utilizing "supplemental instructions for application form PHS 398 for conference awards" described in "Guidelines for Support of Scientific Meetings by NIH," *NIH Guide for Grants and Contracts*, October 30, 1998 and "Guidelines on Inclusion of Women, Minorities, and Persons with Disabilities in NIH-Sponsored and/or Supported Intramural and Extramural Scientific Meetings and Conferences," *NIH Guide for Grants and Contracts*, April 28, 1995.

Applications must be submitted not less than six months prior to the scheduled conference.

VI. SHARED INSTRUMENTATION GRANTS (S10)

Shared Instrumentation Grants (SIG) provide funding to groups of NIH-supported researchers for the purchase of expensive (over \$100,000), commercially available instruments too costly to be obtained through individual research grants. A Memorandum of Understanding exists with the National Science Foundation (NSF) for joint NIH/NSF review and funding of requests for a single instrument costing in excess of the current SIG funding ceiling of \$500,000. There is one receipt date annually for SIG applications, usually in March. Eligibility criteria, guidelines and application procedures are described in a separate program announcement available through the NCRR Web site http://www.ncrr.nih.gov/biotech/btshrgr.htm. Applicants should note that the SIG Program does not fund research to advance the design of or develop new instruments.

Direct inquiries and hard copies of the program announcement can be obtained from: Shared Instrumentation Grant Program
Biomedical Technology Area
National Center for Research Resources
6701 Bemocracy Boulevard, Room 962
Bethesda, MD 20892-7965
Tel: (301) 435-0772

Fax (301) 480-3659 e-mail: SIG@mail.nih.gov

VII. SMALL BUSINESS GRANTS (R41, R42, R43, R44)

The BT area actively participates in Federal set-aside programs designed to support innovative research conducted by small business that has commercial potential. The great majority of the funds awarded are for grants, but occasionally the BT area does solicit contracts. These are

detailed in the solicitations below that are published each year and can be obtained in hard copy from:

PHS SBIR/STTR Solicitation Office 13685 Baltimore Avenue Laurel, MD 20707-5096 Tel: (301) 206-9385 Fax: (301) 206-9722 e-mail: a2y@cu.nih.gov

or in electronic form at the NIH Web site: http://www.nih.gov/grants/funding/sbir.htm

Innovation and the potential for commercialization are important factors stressed in the review criteria included in these solicitations. The BT Program is especially interested in **technology-driven** research on new or improved instruments, devices, and related methodologies that may have broad application to biomedical research. These include, but are not limited to: biomedical engineering approaches for basic/clinical research with potential for preventing or treating disease and/or significantly reducing health care costs (e.g., biomaterials, microsensors, monitoring devices, noninvasive diagnostics approaches, alternatives to radioactive-based methods, robotics, and drug delivery systems); bioimaging (laser applications including flow cytometry, magnetic resonance imaging and spectroscopy, electron and optical microscopy); applications of informatics or computer science/technology to biomedical or behavioral research problems (e.g., computer visualization, image processing, computer modeling/simulation including neural networks, structure-based drug design); and applications of mass spectrometry, x-ray absorption/diffraction, and integrated technologies such as glycobiology and the human genome.

The Fast-Track initiative, described at: http://grants.nih.gov/grants/funding/sbirsttr1/index.pdf, is designed to expedite the decision and award of SBIR Phase II funding for scientifically meritorious applications for projects that have a high potential for commercialization. Only the National Institutes of Health (NIH) engages in Fast-Track grant applications. Before submitting small business applications under the Fast-Track initiative applicants are strongly encouraged to consult with the NIH small business program staff representative for NCRR:

Dr. Amy Swain National Center for Research Resources 6705 Rockledge Drive Bethesda, MD 20892-7965 Tel: (301) 435-0752

Fax: (301) 480-3659

e-mail: SwainA@mail.nih.gov

A cover letter may be included with the application if the principal investigator is making a request for assignment to a particular awarding component or initial review group. The principal investigator may also suggest special expertise required to review the application or alert the Center for Scientific Review (CSR) to potential conflict of interest with individuals or organizations. These suggestions will be taken into consideration at the time of assignment, although the final determination will be made by the CSR. A list of initial review groups, their

rosters, and meeting dates can be found at www.csr.nih.gov. We strongly encourage applicants who submit an application that matches the mission of the Biomedical Technology area to identify NCRR as the potential primary or secondary funding source.

A. SMALL BUSINESS INNOVATION RESEARCH (SBIR) GRANT (R43, R44)

The SBIR Program is intended to support small business innovative research in the United States that results in commercial products or services that benefit the public. Normally the award period for Phase I is for six months for an amount up to \$100,000. Normally, Phase II is for two years and for up to \$750,000. This total includes direct costs, indirect costs, and fixed fees. Applicants may propose longer periods of time and greater amounts of funds if justified.

The small business grant is awarded to the small business concern. Academic investigators may be named as consultants or facilities at research institutions may be included under subcontracts but these are not required. Eligibility requirements are addressed in the SBIR solicitation at http://www.nih.gov/grants/funding/sbir.htm.

Receipt deadlines for SBIR applications are: April 1, August 1, and December 1.

B. SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) GRANT (R41, R42)

The STTR Program is intended to support small business innovative research in the United States that results in commercial products or services that benefit the public. However, in the STTR Program the research is conducted cooperatively by a small business concern and **a research institution**.

Normally, the award period for Phase I is for one year for an amount up to \$100,000. Normally, Phase II is for two years and for up to \$500,000. This total includes direct costs, indirect costs, and fixed fees. Applicants may propose longer periods of time and greater amounts of funds, if justified.

Eligibility requirements are addressed in the SBIR solicitation at http://www.nih.gov/grants/funding/sbir.htm.

Receipt deadlines for STTR applications are: April 1, August 1, and December 1

VIII. CONTRACTS

A contract is normally used to acquire a product or service to help NCRR achieve a specific objective. Using this mechanism, the NCRR formally specifies the activity through a "statement of

work". Contracts are awarded based on Requests for Proposals (RFPs) published in the <u>NIH</u> <u>Guide</u> and at the NCRR Web site. This mechanism is also available to support SBIR activity through a solicitation published annually. These mechanisms are not frequently used by NCRR.

IX. COOPERATIVE AGREEMENTS

A cooperative agreement is used to complement grant supported activities. It is an assistance mechanism in which substantial programmatic involvement on the part of NCRR is necessary for the conduct of the activity. The BT area solicits cooperative agreement proposals to support projects with highly specific aims.

X. SUPPLEMENTS

The following three types of administrative supplements are available for R01 and P41 parent grants. Applicants are advised to carefully read the eligibility criteria and provisions and to consult with BT Program Staff before applying. These applications are submitted to Program Staff rather than to the Center for Scientific Review.

A. RESEARCH SUPPLEMENTS FOR INDIVIDUALS WITH DISABILITIES

NIH Guide Publication Date: 5/14/1999, PA Number: PA-99-105 http://grants.nih.gov/grants/guide/pa-files/PA-99-105.html

Under the initiative cited above, individuals with disabilities are encouraged to pursue biomedical research careers in areas within the missions of all the awarding components of the NIH through supplemental awards to certain ongoing research grants. The NIH initiative is designed to extend opportunities to individuals who have qualifying disabilities and are capable of entering or resuming research careers.

The plan provides funding at several different stages in a research career: high school students, undergraduate students, graduate research assistants, individuals in postdoctoral training, investigators developing independent research careers, and established investigators who become disabled.

Research Supplement programs for individuals with disabilities have been designed to attract individuals who have disabilities to research careers and are not intended to provide an alternative means of supporting disabled individuals who already receive support from a research grant or a research training grant or any other Department of Health and Human Services (DHHS) funding mechanism. Applications should be submitted through the Program Staff person assigned to the parent grant.

B. RESEARCH SUPPLEMENTS FOR UNDERREPRESENTED MINORITIES

NIH Guide Publication Date: 5/14/1999, PA Number: PA-99-104 http://grants.nih.gov/grants/guide/pa-files/PA-99-104.html

Although the NIH currently provides opportunities for minorities through the traditional research grant programs and through special initiatives supported by various components of the NIH, these administrative supplements, in addition, are available to increase the number of underrepresented minority scientists participating in biomedical and behavioral research.

The mechanisms described in this announcement are designed to attract underrepresented minorities into biomedical and behavioral research and provide support for research experiences at grantee institutions for minorities throughout the continuum from high school to the faculty level. The supplements are not intended to provide an alternative means of supporting individuals who already receive support from a research grant or a research training grant or any other DHHS funding mechanism. Applications should be submitted through the Program Staff person assigned to the parent grant.

C. SUPPLEMENTS TO PROMOTE REENTRY INTO BIOMEDICAL AND BEHAVIORAL RESEARCH CAREERS, NIH Guide Publication Date: 05/14/1999, PA NUMBER: PA-99-106

http://grants.nih.gov/grants/guide/pa-files/PA-99-106.html

This initiative is designed to support individuals (women or men) with high potential to reenter an active research career after taking time off to care for children or parents or to attend to other family responsibilities. The aim of these administrative supplements is to encourage fully trained individuals to reenter research careers within the missions of all the program areas of NIH. This initiative will provide administrative supplements to existing NIH research grants for the purpose of supporting full-time or part-time research by these individuals in a program geared to bring their existing research skills and knowledge up to date. It is anticipated that at the completion of the supplement, the reentry scientist will be in a position to apply for a career development (K) award or for a research project or resource grant award.

The following guidelines will generally be applied with discretion by the individual ICs: In general, the duration of the career interruption should be for at least two years and no more than eight years. Examples of qualifying interruptions would include child rearing; an incapacitating illness or injury of the candidate, spouse, partner, or a member of the immediate family; relocation to accommodate a spouse, partner, or other close family member; pursuit of non- research endeavors that would permit earlier retirement of debt incurred in obtaining a doctoral degree; and military service.

The program is not intended to support graduate or postdoctoral training and is not intended to support career changes from non research to research careers for individuals without prior research training. Generally, at the time of application, a candidate should not be engaged in

full-time paid research activities. Because ICs may have varying degrees of flexibility in interpreting and implementing the reentry program, potential applicants should consult with Dr. Abraham Levy (telephone: (301) 435-0777 or e-mail: LevyAbra@mail.nih.gov) at the earliest possible stage to discuss his or her unique situation.