#### GUIDELINES FOR THE BIOMEDICAL TECHNOLOGY RESEARCH RESOURCE PROGRAM National Center for Research Resources National Institutes of Health

#### **Overview**

The National Center for Research Resources (NCRR) supports "Biomedical Technology Research Resources" (BTRRs) in a variety of areas of biomedical science, using the P41 funding mechanism. BTRRs create critical, often unique technology and methods at the forefront of their respective fields, and apply them to a broad range of basic, translational, and clinical research. They also promote the broadest possible use of those technologies through training and dissemination activities.

BTRRs serve a unique purpose in the broad context of NIH-funded research. This specialized role requires a distinct set of qualities that can be defined largely in terms of their resulting impact on the biomedical sciences. It is the breadth and depth of this impact that are the measure of these Resources. It is important that applicants be mindful of both this overarching mission and the unique qualities that support it.

BTRRs may be developed in a specific, narrow technological area, or they may represent an integrated approach to the development of tools and methods across a broader line of inquiry. In either case, they represent a critical mass of both technological and intellectual resources assembled with the intent of exploiting advances in instrumentation and methodology for biomedical research. These Resources create critical, often unique technology and methods at the forefront of their respective fields that are applicable to a wide variety of problems in the biological sciences. This is accomplished through a synergistic interaction of technical and biological expertise, both within the Resources and through intensive collaborations with other leading laboratories. At their best, these Resources should be in an optimal position to identify unexpected opportunities for technological advances to open new lines of biological inquiry and appreciate which problems they may be in a position to solve by creation of new tools. This intense synergy between technology development and biological problem-solving gives the resources a fundamentally different character from that of labs engaged in investigator-initiated research or other center-related projects with more narrowly defined goals.

A properly constituted BTRR constantly strives to provide service and training to outside investigators and to disseminate the technology and methods it has developed. These efforts require the commitment of far greater financial and personnel resources to non-science activities than might be expected in any other setting. Providing other investigators with ready access to resource tools and personnel has a substantial impact on administration and daily operation of the laboratory. Efforts to train the broader scientific community and disseminate technology require a fundamentally outward-looking philosophy that may, on the surface, appear at odds with the competitive nature of modern science. The goal of these efforts is to, so far as is possible, export the technology and expertise of the resource into the broader community, achieving a broader impact on biomedical research than would be possible through the projects in which the resource can participate directly. Ultimately, this process should drive toward the widespread and routine application of the technologies being actively disseminated.

#### Criteria for Consideration of Proposed Biomedical Technology Research Resources

Five activities—Technology R&D, Driving Biomedical Projects, Collaboration and Service, Training, and Dissemination—must be present in a Biomedical Technology Research Resource. The technological capabilities of the Resource must be state-of-the-art and not broadly available by other means. The projects served by the new technologies must be broad in scope and involve a variety of biomedical research areas. The Resource is expected to serve investigators across the nation.

#### **Coordination with NIH Program Staff to Develop Applications**

For both new BTRR grant applications and competing continuations, prospective grantees are required to discuss the proposed application and the proposed budget with NCRR Division of Biomedical Technology 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 DBT BTRR 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 <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html</a>.

#### **Contact information for DBT program staff:**

Division of Biomedical Technology National Center for Research Resources National Institutes of Health 6701 Democracy Blvd, MSC 4874 Bethesda, MD 20892-4874 Tel: (301) 435-0755 Fax: (301) 480-3659 E-mail: <u>BTADir@NCRR.NIH.GOV</u> Web: <u>http://www.ncrr.nih.gov/biomedical\_technology/</u>

#### Contact Information for business and fiscal issues:

Office of Grants Management National Center for Research Resources 6701 Democracy Blvd, MSC 4874 Bethesda, MD 20892-4874 Tel: (301) 435-0844 Fax: (301) 480-3777 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.

# **Technologies Currently Supported**

A directory of current Biomedical Technology Research Resources is available on the NCRR web site to assist scientists in learning about the types of BTRRs supported by the program (<u>http://www.ncrr.nih.gov/biomedical\_technology/</u>). 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 a broad range of technologies that fall into five main areas:

Imaging Technology Informatics Resources Optical and Laser Technology Technology for Structural Biology Technology for Systems Biology

# THE SIX COMPONENTS OF A BIOMEDICAL TECHNOLOGY RESEARCH RESOURCE

# **Technology Research and Development**

The central activity of a Biomedical Technology Research Resource is the Technology Research and Development (TR&D) that serves as the foundation for all other Resource activities. The mission of a BTRR may range from the narrowly focused, fundamental advancement of a single technology area (e.g. accelerator mass spectrometry, flow cytometry) to the development of an integrated approach to a general class of problems (e.g. proteomics, data visualization). The BTRR technology must be dynamically evolving and an important area for R&D in its own right. TR&D should be at the cutting edge of the technological field, with a goal of increasing its usefulness in biomedical research.

Regardless of the scope of the TR&D activities undertaken, a BTRR is an inherently multidisciplinary enterprise, requiring a range of specialized expertise to integrate multiple approaches to complex technical and biomedical challenges. For example, these projects may involve development of new or significant modification of existing instruments and associated control and data analysis systems, development of new computer algorithms and related

software, new physical or chemical 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. In order to encourage synergistic interaction, Driving Biomedical Projects (DBPs) serving as test-beds for TR&D must be included in the application (see below). The relationship between TR&D projects and DBPs should be delineated explicitly in each case.

Modest biomedical test-bed projects designed to generate data for use in technology development may be included in TR&D projects if necessary. However, these projects should not be interpreted as a substitute for DBPs. Further, data collection for specific biomedical research projects is not the purpose of this program.

The TR&D projects to be conducted must be presented in detail. Each project should include descriptions of the Background, Objectives, Rationale, Methods, Significance, and Facilities available to conduct the project. The investigator(s) who will be primarily responsible for each project should be listed. All related DBP should be listed for each project. Generally, three or more TR&D projects constitute this section of the grant application, although there is not a minimum requirement. The application should describe the relationship between these projects, and their support of the overall goals of the BTRR.

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 national basis.

There is no page limit on this section of the application, 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 project to permit its evaluation.

#### Infrastructure

In some circumstances, TR&D activities may require substantial investment in the design and development of technological infrastructure which cannot be purchased but does not constitute a research challenge in its own right (e.g. a test platform for new instrument components or a LIMS). If necessary, such a project may be included in the application under the Infrastructure heading, with prior approval of program staff.

Activities such as software development or instrument design and fabrication that are inherent in TR&D projects should be included within those projects. Only clearly separate activities that provide infrastructure support for TR&D should be placed in this section of the application. In most cases it is anticipated that an Infrastructure section will not be necessary. This section of the application is limited to ten pages.

# **Driving Biomedical Projects**

Development of new biomedical research tools is most effective when pursued in the context of challenging problems that drive the technology forward. These Driving Biomedical Projects (DBPs) should be collaborative in nature, with experts in the technology, usually resource personnel, working jointly with investigators outside the Resource who have expertise in a particular biomedical discipline. Projects should be selected on the basis of both their potential for significant biomedical impact and their appropriateness as test-beds for new technology. Projects should present substantial technical challenges that would make the problem difficult to solve with current approaches. Optimally, there should be an iterative push-pull between Technology R&D and the DBPs, advancing both the technology and the biomedical projects. Such efforts should lead to joint publications, and in some cases, patents.

The description of each DBP should begin with the following header information: collaborating investigator's name, institution and funding status of the project including principal investigator, grant number, project period dates, and source of funds. Each DBP should include the following sections: (1) Rationale for the proposed approach to the problem, (2) Methods and procedures to be used; (3) Significance of the proposed work; and (4) Impact of the expertise of the Resource investigators and technology on the project. The driving relationship between specific TR&D and DBP projects should be delineated explicitly in this section of the project description. Provide literature citations.

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 BTRR'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. However, the number of DBPs included in an application should generally not exceed twenty.

No support may be requested in the application for DBP activities conducted outside of the BTRR in the collaborating laboratories. Support for Resource staff conducting DBP-related work should be requested.

It is important to draw distinctions between Driving Biomedical Projects and two other types of collaborative research. Purely technical collaborations focused on advancing some aspect of TR&D should be included in that section of the proposal, within the relevant TR&D project(s). Collaborations with biomedical researchers that make use of the technology and expertise of the

BTRR but are not intended to serve as primary test-beds for technology development should be included in the Collaboration and Service section. These are not considered DBPs. Please see below. There is no page limit on this section of the application.

#### **Collaboration and Service**

The concentration of instrumentation, software, methods, and expertise developed in a BTRR represents an important resource for biomedical and clinical researchers. Active engagement with this community to seek out opportunities for collaboration and provide broad access to Resource capabilities is an important aspect of the program. Application of Resource technologies and expertise may take many forms, including consultation and advice, routine analyses, and more challenging collaborative biomedical projects.

Long-term research projects may require significant creativity and intellectual involvement on the part of both Resource staff and the collaborating biomedical or clinical researchers. These projects are characterized by extensive use of resource technologies and expertise, but are distinguished from Driving Biomedical Projects because they do not serve as primary test-beds for the newest technologies still in the early stages of development. Rather, they exploit the more robust, mature capabilities of the resource.

Collaboration and Service may also include access to expertise in the resource for consultation and data interpretation, access to software and associated technical support, and access to instrumentation for routine work by outside users. It also includes assistance provided to other laboratories or institutions as they work to build their own independent capabilities.

It is expected that BTRR support will be acknowledged in papers resulting from all Collaboration and Service research projects, regardless of whether BTRR staff are listed as authors. While service is one of the key elements of the Resource, the P41 mechanism is not intended to support centers that are predominantly focused on routine service. The primary purpose of this component of a BTRR is to provide access to the advanced technologies created in the Resource, which are, presumably, not available elsewhere.

A representative sample of no more than 20 Collaboration and Service projects should be presented. Each project should be described in sufficient detail to allow the evaluation of the need for the Resource technologies 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. The BTRR should strive to conduct the major portion of its Collaboration and Service projects with researchers outside their institution. There is no page limit on this section of the application.

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-tablesearch.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.

# Training

The technologies, methods, and software developed in BTRRs are often sophisticated, conceptually novel, and unique. Some level of training is generally necessary for the scientists who will use them. This training should be planned for and provided by the BTRR. A hallmark of the BTRR program is that these centers represent a critical mass not only of technological capability but also of expertise. As a center matures to the point that it has technologies mature enough for broad application, it must also allocate sufficient resources to the task of training both specialists and non-specialists to make the best possible use of these new tools.

Formal pedagogy and direct responsibility for training of students and post-doctoral fellows are important components of any academic research enterprise, and it is expected that students and post-docs within the BTRR will play a major role in the technology R&D component of the center. However, the Training component of the program must go far beyond that, to build technical competence in the broader community of researchers not formally affiliated with the center. The overall goal should be twofold: to improve the general understanding of the center technologies in the appropriate population, and to create a cadre of biomedical researchers fluent in the technology and able to apply it effectively in their research.

Plans for training should be presented in the application, but no specific methods or activities are prescribed. The choice of approaches should be informed by the special constraints and opportunities presented by the circumstances of the center in question. A required feature of Training activities is direct interaction between center personnel and the trainee (e.g. web-based self-service tutorials would fall under Dissemination).

Examples of successful approaches have included: hands-on laboratory experience including residencies in the BTRR laboratories for researchers from other laboratories or reciprocal visits by BTRR personnel; seminars and lectures; courses offered for academic credit; short courses or symposia offered independently or in conjunction with society meetings attended by the user community; workshops on appropriate topics that bring together researchers in multidisciplinary areas from academic institutions, hospitals and industry for discussions on the use of the BTRR'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.

This section of the application may not exceed ten pages. A progress report should be included in competing renewal applications. The boundary between Training and Dissemination activities may not always be rigid. Approaches that incorporate elements of both components should be presented only within one section of the application, whichever is deemed more appropriate by the applicant.

# Dissemination

The fundamental motivation for the BTRR program is to bring cutting edge technology to bear on biomedical research problems. The final critical step for a center toward meeting this objective is to maximize the impact of their technical innovations by sharing them as broadly as possible, reducing them to practice and quickly bringing them into routine use. Each component of a BTRR builds toward this overall goal, from the early biomedical collaborations, through routine access and training of the user community, and culminating in an effort to push the technology out the door.

Dissemination activities should have two overall objectives: informing the scientific community about the BTRR's technical capabilities and accomplishments, as well as promoting and enabling the broader use of technologies. This may be accomplished by a variety of approaches, including: publishing articles, books, patents, newsletters, annual reports, or special issues of technical journals; issuing press releases; presenting research results at meetings; conducting conferences; distributing software products; transferring technologies to other laboratories directly; licensing technologies to industry where they will be distributed widely; and web-based training modules and tutorials.

A robust web presence is required for every BTRR. The site should provide basic information about the Resource's research focus and capabilities, contact information. Links should be provided to online tutorials, information on availability of software, reagents, and other resources if applicable. Links should also be provided to other related BTRRs and the NCRR BTRR program web page.

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. NCRR encourages sharing of source code, consistent with the NIH data-sharing policy. Software is not required to be open source. However if it will not be, written justification is required.

All dissemination activities must acknowledge NCRR grant support.

This section of the application may not exceed ten pages. A progress report should be included in competing renewal applications. The boundary between Training and Dissemination activities may not always be rigid. Approaches that incorporate elements of both components should be presented only within one section of the application, whichever id deemed more appropriate by the applicant.

# ADMINISTRATIVE, MANAGEMENT, AND FISCAL ASPECTS

#### **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: Technology R&D, Driving Biomedical Projects, Collaboration and Service, Training, Dissemination, and general resource administration. Describe the scientific and technical expertise of the staff that will operate, maintain, and develop the Resource capabilities, and their distribution of effort across their areas of responsibility.

# **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 criteria and methods for selecting DBPs as well as Collaboration and Service projects. Include samples of any forms to be filled out by collaborators and users, and the instructions on how they are to acknowledge support provided by the Resource in any resulting publications.

# Support of Driving Biomedical Projects, Collaboration, and Service

Direct support from resource funds for collaborative or user activities conducted outside of the Resource in the collaborating laboratory is not allowed. Support may be requested for costs associated with the portion of collaborative work conducted by Resource staff within the BTRR.

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.

# **Annual Progress Report**

A Non-Competing Grant Progress Report (PHS form 2590) is required annually as part of the non-competing continuation award process, as described in the NIH Grants Policy Statement, <a href="http://grants1.nih.gov/grants/policy/nihgps\_2003/index.htm">http://grants1.nih.gov/grants/policy/nihgps\_2003/index.htm</a>. Instructions for the PHS form 2590 can be found at: <a href="http://grants.nih.gov/grants/funding/2590/2590.htm">http://grants1.nih.gov/grants/policy/nihgps\_2003/index.htm</a>. Instructions for the PHS form 2590 can be found at: <a href="http://grants.nih.gov/grants/funding/2590/2590.htm">http://grants.nih.gov/grants/funding/2590/2590.htm</a>. For NCRR-supported Center and Resource grants, the PHS form 2590 incorporates an Annual Progress Report (APR), which provides information in greater detail than the standard PHS form 2590. The NCRR uses

the information contained in the APR to facilitate programmatic stewardship of the grant and to respond to inquiries from other governmental agencies and the public. Specific instructions for completing the APR and including it in submission of the PHS form 2590 can be found at <a href="http://aprsis.ncrr.nih.gov">http://aprsis.ncrr.nih.gov</a>. Special instructions applicable to the BTRR program can be found at <a href="http://aprsis.ncrr.nih.gov/xml/BTRR">http://aprsis.ncrr.nih.gov/xml/BTRR</a> Instructions.pdf</a>).

# **External Advisory Committee**

The External Advisory Committee (EAC) 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 and the chair should be from outside the host institution. NCRR encourages the inclusion of scientists not affiliated with the Resource, though inclusion of collaborators is not prohibited. Membership should be rotated periodically. The EAC should meet at least annually at the BTRR and prepare a written report of its recommendations, addressed to the PI. This report must be supplied as part of the Resource's Annual Progress Report.

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.

The role of the EAC should be described in the application. 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. It is not required that committee members be appointed prior to submission.

Funds should be requested in the Consultant Costs category of the budget for support of EAC member travel expenses for the annual meeting. The funds will be restricted for this purpose, and may not be rebudgeted without prior approval by program staff.

# SPECIAL APPLICATION INSTRUCTIONS AND SUBMISSION DATES

# **Special Application Instructions**

The current version of Form PHS 398, should be used for BTRR grant applications. Forms are available on the NIH Web site: <u>http://grants1.nih.gov/grants/forms.htm</u>. 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 BTRR 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 Technology R&D, Infrastructure (with prior approval), Training, Dissemination, External Advisory Committee meetings (under Consultant Costs) and the Resource's expenses associated with Driving Biomedical Projects, Collaboration and Service. Graduate student and postdoctoral support can be requested only if they are active participants in a TR&D 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 BTRR.

An overall budget should be included, as well as individual budgets (Form pages 4 and 5) for each TR&D project, and for each of the other BTRR components listed above.

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 should be specified for a) each of the TR&D projects, b) infrastructure, c) DBPs, and d) Collaboration and 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 BTRR 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, in order to exceed these ceilings, applicants must obtain a written waiver from the Director of the NCRR Division of Biomedical Technology and include it in their application. The waiver must be requested well in advance of submission of 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.

Major equipment purchases (more than \$500,000 over the course of the project period) often require support from other sources when the BTRR Program is unable to fund the entire request. Plans for such shared funding should be detailed in the application.

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 noncompeting 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 Director of the NCRR Division of Biomedical Technology well in advance of the application receipt date. The waiver to the ceiling must be approved in writing by the DBT Director before the BTRR's competing renewal application is submitted and accepted. Applicants should contact program staff well in advance to discuss these requests.

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. There are no page limits on the TR&D, DBP, Collaboration and Service, or Administration and Management sections. However, the Infrastructure, Training, and Dissemination, sections should are limited to ten pages each. The length of the application should be consistent with the scope of the proposed research and the number of DBPs and Collaboration and Service projects. It is important to be concise, but there should be sufficient information about each project to permit its evaluation. It is not appropriate to submit an incomplete application in the expectation that ambiguities will be resolved at a site visit. The application should stand on its own.

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 BTRR 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 BTRR's progress should be included. Include copies of the Resource's most recent annual progress report and the most recent External Advisory Committee report in the Appendix.

Section 9, Research Plan D: Research Design and Methods should include a discussion of the proposed research in each of the five major resource activities: Technology R&D, Driving Biomedical Projects, Collaboration and Service, Training, and Dissemination, as well as Infrastructure if this section is necessary. Indicate the relative emphasis to be given to these activities and explain the proposed division of effort.

#### **Submission Dates**

Deadlines for submission of all new, revised, and competing continuation BTRR grants are: January 25, May 25, and September 25.

# **Review of BTRR Applications**

BTRR applications are reviewed individually by a Special Emphasis Panel organized by the NIH Center for Scientific Review. Scientific Review Administrators with relevant expertise recruit reviewers appropriate for a particular application. Specific review criteria for BTRR applications are used by the reviewers in evaluating the application (see http://cms.csr.nih.gov/ResourcesforApplicants/PolicyProcedureReview+Guidelines/ <u>Guidelines+for+Review+of+Specific+Applications/</u> <u>Guidelines+for+Review+of+Specific+Grant+Applications/P41/</u> <u>NCRRP41ReviewGuidelinesPDFFormat.htm</u>).

These review criteria assist members of study sections in their review of BTRR grant applications, as well as to provide guidance to potential applicants. In addition, NCRR DBT Program Staff attend the review to present and interpret program guidelines.

The six components -- TR&D, Infrastructure, DBPs, Collaboration and Service, Training, and Dissemination, -- should be clearly described. 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 TR&D and DBP research projects at the time of application and to detail their plans for expanding these and adding the Collaboration and 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.

# Scoring

For BTRR grant applications, each TR&D project is scored separately. Also, each of the other Resource components – Infrastructure, Driving Biomedical Projects, Collaboration and Service, Training, and Dissemination - should be scored separately. Finally an overall score for the resource grant application should be assigned. 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 and community engagement.