Summary Statements
For Research Resource Applications

http://grants.nih.gov/grants/guide/pa-files/PAR-08-259.html

A Summary Statement capturing the essence of the review will be prepared after the meeting. This document enables both the applicant and program personnel at the National Center for Research Resources (NCRR) to understand the reasons for the criticisms and priority score. The entire Summary Statement is usually about 20-30 pages long. Reviewers should prepare preliminary written critiques prior to the study section meeting; it is best if panel members bring both a hard copy and an electronic version.

A ***Resume*** (of the panel's deliberations) is prepared by the Scientific Review Officer. The applicant's abstract is included verbatim as the overall ***Description*** of the project.

An ***Overall Critique*** is drafted by the Chair of the study section. This may be modified immediatelyafter the review to incorporate comments from other panelists. It should summarize the general strengths and weaknesses of the proposal (based on the unique aspects of the NCRR researchresource program), and include the panel's rationale for arriving at its final level of enthusiasm.

Technological Research and Development. Two or more reviewers are assigned to each of the projects in this section. The applicant should provide an abstract for each project, which is used *verbatim*. The scientific critique should evaluate strengths and weaknesses of the proposed research, and the qualifications and contributions of the key investigators. For a revised application, it is desirable to discuss changes in the amended version. For a renewal proposal, it is appropriate to consider progress during the previous funding period. It is helpful if a concluding paragraph summmarizes the deciding factors for the critique.

Immediately after the study section meets the primary reviewer for a project will combine all reviews for that project and incorporate salient points made in discussion. The draft, "blended" critique is ultimately read back to the panel for additional comments.

Infrastructure. This section is not always included in a Biomedical Technology Research Resource (BTRR) application. If it is, briefly describe the project(s) presented. Critiques should address whether the technological infrastructure requested in this section is necessary and appropriate for the research proposed in the BTRR.

Driving Biomedical Projects. This section covers all of the Driving Biomedical Projects (DBPs) included in the application.

The written comments should reflect the philosophy underlying the DBPs; namely, all DBPs should either advance or test the technology being developed by the proposed resource. If there are a large number of projects, reviewers may be assigned to groups. Each assigned reviewer should identify the collaborators' sources of support, describe the DBP in one or a few sentences, and write a short critique. Reviewers are not expected to review extensively the science of the DBPs which are usually already funded. The essence of the critique should be the relevance of the DBP to the technology of the resource - that is, how the DBP drives, and is driven, by the resource core projects. Draft "blended" critiques are read back to the panel for additional comments.

Collaboration and Service. The applicant should provide a summary description of collaboration and service projects, which will be used verbatim. The critique of the collaboration and service activities should assess ease and fairness of access and whether the project is an example of a good use of the technology under development. For new applications, the plans for collaboration and service should be evaluated. The combined draft critique is read back to the panel for additional comments.

Training. Describe (briefly) and critique educational programs of the resource; a new application should have, at a minimum, suitable plans for training. Assess the national significance of these activities. Note that "training" here refers to specific training in the technology, not a generalized experience for graduate students or postdocs. A blended critique is read back to the panel for comment.

Dissemination. Critique mechanisms (or, for a new project, plans) for technology transfer to both expert and non-expert communities via publications, meetings, commercialization, and the Internet. The draft review is read back to the panel for additional input.

Administrative. Assess the arrangements to promote planning and interaction. Evaluate whether plans exist for succession of the investigators and whether the advisory committee is suitable. Evaluate the institutional setting and support, and any other significant factors. The draft critique is read back to the panel for comments.

Budget. The budget is to be addressed after the scientific review is complete. It is important to consider whether each project is appropriately budgeted. The idea is not to nickel and dime the proposed budget, but the bottom line should make sense. Consider especially carefully personnel and big ticket items like equipment. Recommended budgets are decided by consensus, with assigned reviewers usually leading the discussion for their components.

Vertebrate Animals and Protection of Human Subjects from Research Risk. Any comments or concerns are incorporated into theSummary Statement and are specifically brought to the attention of program personnel. For thoseapplications involving human subjects, ***every critique*** should address human subject issues.

Additional Comments. As indicated above, a successful resource must be engaged in five activities: technological research and development, driving biomedical projects, collaboration and service, training, and dissemination, usually in that order of importance. The infrastructure section is not always present. It is possible for the resource investigators to collaborate with themselves; e.g., if they are using the resource to enrich their own R01 research (and presumably test the new P41 technique), it may be either a DBP or a collaborative project. The technological research and development must be research on developing the technique (not just using it).

The projects served by the resource must involve a variety of NIH research areas. If narrow in scope, e.g., all cancer research, support should be sought from a specific institute, such as NCI.

A proposed resource is expected to be a national resource. It is entirely appropriate for the panel toindicate whether the users are predominantly local.

12/05/2008

P41 Summary Statement Template:

Grant number PI name here

Resume and Summary of Discussion: "written by SRO"

DESCRIPTION (provided by the applicant):

CRITIQUE: OVERALL "written by chair"

Progress over the past funded cycle:

TECHNOLOGY RESEARCH AND DEVELOPMENT

TRD Core 1: "Title Here"
Priority score:

DESCRIPTION (provided by the applicant):

CRITIQUE:

Interaction with Driving Biomedical Projects:

Overall Evaluation:

"All other TRD Cores follow here and are formatted in the same manner as TRD Core 1"

INFRASTRUCTURE

Overall Evaluation:

DRIVING BIOMEDICAL PROJECTS
Priority score:

Overall Evaluation: "for the DBPs as a whole"

"List each project number, title of the project
Collaborator(s) name, institution, funding source"

"Evaluative paragraph"

COLLABORATION AND SERVICE
Priority score:

DESCRIPTION (provided by the applicant):

Overall Evaluation:

TRAINING
Priority score:

DISSEMINATION

Priority score:

ADMINISTRATION

12/05/2008

Part I Overview Information

Department of Health and Human Services

Participating Organizations

National Institutes of Health (NIH) (http://www.nih.gov)

Components of Participating Organizations

National Center for Research Resources (NCRR) (http://www.ncrr.nih.gov)

National Institute on Alcohol Abuse and Alcoholism (NIAAA), (http://www.niaaa.nih.gov)

Title: Biomedical Technology Research Resource (P41)

Announcement Type

New

Looking ahead: As part of the Department of Health and Human Services' implementation of e-Government the NIH will gradually transition each research grant mechanism to electronic submission through Grants.gov and the use of the SF 424 Research and Related (R&R) forms. For more information and an initial timeline, seehttp://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-035.html. NIH will announce each grant mechanism change in the NIH Guide to Grants and Contracts (http://grants.nih.gov/grants/guide/index.html).

Program Announcement (PA) Number: PAR-08-259

Catalog of Federal Domestic Assistance Number(s)

93.389, 93.273

Key Dates

Release Date: August 28, 2008

Letters of Intent Receipt Date(s): Not Applicable

Application Submission Dates(s): Standard dates apply;please see http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward

Peer Review Date(s): Standard dates apply; please see http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward

Council Review Date(s): Standard dates apply; please see http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward

Earliest Anticipated Start Date: Standard dates apply; please see http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward

Additional Information To Be Available Date (Url Activation Date): Not Applicable

Expiration Date: May 8, 2011

Due Dates for E.O. 12372

Not Applicable

Additional Overview Content

Executive Summary

- **Purpose.** This FOA issued by the National Center for Research Resources (NCRR), National Institutes of Health (NIH), solicits grant applications for national Biomedical Technology Research Resources. These Resources conduct research and development on new technology and new/improved instruments driven by the needs of basic,

translational, and clinical researchers. The Resources are charged to make their technologies available, to train members of the research community in the use of the technologies, and to disseminate these technologies and the Resource's experimental results broadly. Only those with current P41 awards from NCRR or those who have been approved through the X02 pre-application process can submit an application under this FOA.

- **Mechanism of Support.** This FOA will utilize the P41 grant mechanism and runs in parallel with a FOA of identical scientific scope, PAR-08-260, that allows pre-applications under the X02 mechanism.
- **Funds Available and Anticipated Number of Awards.** Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will depend upon the mechanism, numbers, quality, duration, and costs of the applications received.
- **Budget and Project Period.** Typical direct costs are expected to be between $500,000 and $1,200,000 per year. Support may be requested for up to five years.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1.A. are eligible to apply.

- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.
- **Number of PDs/PIs.** Only one PD/PI may be designated on the application.
- **Number of Applications.** Applicants may submit more than one application, provided that each application is scientifically distinct.
- **Resubmissions.** Resubmission applications will be accepted. Such application must include an Introduction addressing the previous peer review critique (Summary Statement).

- **Renewals.** Applicants may submit a renewal application.
- See Section IV.1 for application materials.
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY 301-451-0088

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2. Peer Review Contact(s)

3. Financial/ Grants Management Contact(s)

Section VIII. Other Information - Required Federal Citations

Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

The National Center for Research Resources (NCRR) uses the P41 mechanism to support Biomedical Technology Research Resources (BTRRs) in a variety of areas of biomedical science. BTRRs create critical, often unique, technologies 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. Details concerning current BTRRs can be found at http://www.ncrr.nih.gov/biomedical_technology/biomedical_technology_research_resources/ .

The National Institute of Biomedical Imaging and Bioengineering (http://www.nibib.nih.gov, NIBIB) has a similar program that supports Biomedical Technology Resource Centers. Details about that program can be found at http://www.nibib.nih.gov/Research/ResourceCenters . Applicants who are interested in submitting an application to the NIBIB program need to use their application procedures rather than those in this announcement.

BTRRs may be developed in a specific, narrow technological area, or they may utilize an integrated approach to the

development of tools and methods across a broader line of inquiry. ("BTRRs" and "Resources" are used as synonyms throughout this text.) In either case, a BTRR contains 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 technology and methods at the forefront of their respective fields that are applicable to a wide variety of problems in the biomedical sciences. This is accomplished through a synergistic interaction of technical and biomedical expertise, both within the Resources and through intensive collaborations with other leading laboratories. Ideally, these Resources identify unexpected opportunities for technological advances that open new lines of biomedical inquiry and appreciate which problems the Resource can solve by the creation of new tools. This intense synergy between technology development and biomedical problem-solving defines the Resources as fundamentally different in character from laboratories engaged in investigator-initiated research or other center-related projects that may have more narrowly defined goals.

A BTRR also must provide service and training to outside investigators and must 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 is expected for other types of research efforts. Providing other investigators with ready access to Resource tools and expertise 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. Industrial partnerships are not required, but they are welcome when appropriate. Ultimately, this process should aim for the widespread and routine application of the technologies being actively disseminated.

See Section VIII, Other Information - Required Federal Citations, for policies related to this announcement.

Section II. Award Information

1. Mechanism of Support

This funding opportunity announcement (FOA) will use the P41 award mechanism. The applicant will be solely responsible for planning, directing, and executing the proposed project.

This FOA uses “Just-in-Time” information concepts. It also uses non-modular budget formats described in the PHS 398 application instructions (see http://grants.nih.gov/grants/funding/phs398/phs398.html).

2. Funds Available

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the IC(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds.

Facilities and administrative costs requested by consortium participants are not included in the direct cost limitation, see NOT-OD-05-004.

NIH grants policies as described in the NIH Grants Policy Statement will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

The following organizations/institutions are eligible to apply:

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education
- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Other:
    - Eligible Agencies of the Federal Government

1.B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with his/her institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

2. Cost Sharing or Matching

This program does not require cost sharing as defined in the current *NIH Grants Policy Statement*.

3. Other-Special Eligibility Criteria

Applicants may submit a resubmission application, but such application must include an Introduction addressing the previous peer review critique (Summary Statement).

Applicants may submit a renewal application.

Applicants may not submit a new application unless they have submitted an X02 pre-application under PAR-08-260, or its successor announcements, and have been approved to submit a full application. The full application may not be significantly different from what was proposed in the X02 application. Significant differences between the full application and the X02 may result in the full application being returned without peer review.

Applicants may submit more than one application, provided that each application is scientifically distinct.

Section IV. Application and Submission Information

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1. Address to Request Application Information

The PHS 398 application instructions are available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. Applicants must use the currently approved version of the PHS 398. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY 301-451-0088.

2. Content and Form of Application Submission

Applications must be prepared using the most current PHS 398 research grant application instructions and forms. Applications must have a D&B Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The D&B number can be obtained by calling (866) 705-5711 or through the

web site at http://www.dnb.com/us/. The D&B number should be entered on line 11 of the face page of the PHS 398 form.

The title and number of this funding opportunity must be typed in item (box) 2 only of the face page of the application form and the YES box must be checked.

Additional information is available in the PHS 398 grant application instructions.

3. Submission Dates and Times

See Section IV.3.A. for details.

3.A. Submission, Review and Anticipated Start Dates

Application Receipt Date(s): Standard dates apply, please see http://grants.nih.gov/grants/funding/submissionschedule.htm

AIDS Application Submission Date(s): Standard dates apply, please see http://grants.nih.gov/grants/funding/submissionschedule.htm

Peer Review Date(s): Standard dates apply, please see http://grants.nih.gov/grants/funding/submissionschedule.htm

Council Review Date(s): Standard dates apply, please see http://grants.nih.gov/grants/funding/submissionschedule.htm

Earliest Anticipated Start Date(s): Standard dates apply, please see http://grants.nih.gov/grants/funding/submissionschedule.htm

3.B. Sending an Application to the NIH

Applications must be prepared using the research grant application forms found in the PHS 398 instructions for preparing a research grant application. Submit a signed, typewritten original of the application, including the checklist, and five signed photocopies in one package to:

Center for Scientific Review

National Institutes of Health

6701 Rockledge Drive, Room 1040, MSC 7710

Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)

Bethesda, MD 20817 (for express/courier service; non-USPS service)

Personal deliveries of applications are no longer permitted (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-040.html).

3.C. Application Processing

Applications must be **submitted** on or before the application receipt/submission dates described above (Section IV.3.A.) and at http://grants.nih.gov/grants/dates.htm.

Upon receipt applications will be evaluated for completeness by CSR. Incomplete applications will not be reviewed.

The NIH will not accept any application in response to this funding opportunity that is essentially the same as one currently pending initial merit review unless the applicant withdraws the pending application. The NIH will not accept any application that is essentially the same as one already reviewed. However, the NIH will accept a resubmission application, but such application must include an Introduction addressing the critique from the previous review.

Information on the status of an application should be checked by the Principal Investigator in the eRA Commons at: https://commons.era.nih.gov/commons/.

4. Intergovernmental Review

This initiative is not subject to intergovernmental review.

5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement*.

Pre-award costs are allowable. A grantee may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or competing renewal award if such costs: 1) are necessary to conduct the project, and 2) would be allowable under the grant, if awarded, without NIH prior approval. If specific expenditures would otherwise require prior approval, the grantee must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing renewal award.

The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. NIH expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project (see NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part6.htm.)

6. Other Submission Requirements and Information

Technology Research and Development (TR&D)

The central activity of a Biomedical Technology Research Resource is the Technology Research and Development (TR&D) projects that serve 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 research and development in its own right. The proposed technology research and development should be at the cutting edge of the technological field, with a goal of increasing its utility 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 analysis, or development of innovative applications through the integration of existing technologies.

Technological development projects are most effective when they respond to the emerging needs of the biomedical research community. 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 must be delineated explicitly in each case.

A TR&D project should not focus on data collection. However, in some cases, modest components designed to generate data for use in technology development or testing may be included as a part of a TR&D project. Such projects should be included only in cases for which data to test tools, devices, or software are not available elsewhere. These small data collection components cannot substitute for DBPs.

The TR&D projects 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(s) should be listed for each TR&D project. A BTRR is

expected to have at least three TR&D projects. The application should describe the relationship between these projects, and their support of the overall goals of the BTRR. It is expected that the TR&D projects will be related to each other and that the description of these projects will show synergy among them. An element of high risk (and potentially high payoff) may be present in one or more of the TR&D 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.

For renewal applications, new activities should be specifically identified. The continued development of innovative technology and the steady infusion of new areas of technological R&D are important considerations in reviewing renewal applications. Long-term support of a Resource depends strongly on a demonstrable commitment to the introduction and application of new technology and to serving biomedical investigators on a national basis.

The description of each TR&D project is limited to a total of 25 pages or less.

Infrastructure

In some circumstances, TR&D activities may require substantial investment in the design and development or implementation of technological infrastructure that does not constitute a research challenge in its own right (e.g., a test platform for new instrument components or a laboratory information management system). If necessary, such activities may be included in the application under the Infrastructure heading.

Only activities that provide infrastructure support for TR&D should be placed in this section of the application. Activities such as software development or instrument design and fabrication that are inherent in a TR&D project should be included within that project. In many applications, an Infrastructure section will not be necessary.

This section of the application is limited to a total of ten pages or less.

Driving Biomedical Projects (DBP)

Development of new biomedical research tools is most effective when pursued in the context of challenging problems that drive the technology forward. A Driving Biomedical Project (DBP) should be collaborative in nature, with Resource personnel working jointly with investigators outside the Resource who have expertise in a particular biomedical discipline. DBPs 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 make the problem difficult to solve with current approaches. There should be an iterative push-pull relationship between Technology R&D and the DBPs, advancing both the technology and the biomedical projects. Such efforts are expected to lead to joint publications, and in some cases, patents.

The DBPs served by the new technology should be broad in scope and involve a variety of biomedical research areas. The Resource is expected to be highly responsive to a 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.

The description of each DBP should begin with the following header information:

(1) collaborating investigator’s name

(2) the institution of the collaborating investigator

(3) the funding status of the project including

- the grant number

- project period dates

- source of funds

- the principal investigator's name if it is different from the collaborating investigator.

The driving relationship between specific TR&D and DBP projects must be delineated explicitly in this section of the project description. The description of each DBP should include the following sections:

(1) Significance of the proposed work

(2) Rationale for the proposed approach to the problem

(3) Methods and procedures to be used, emphasizing the relationship between the DBP and BTRR personnel and technologies

(4) Impact of the expertise of the Resource investigators and technology on the project.

New applications should have at least one driving biomedical project for each TR&D project. It is possible that one DBP could drive more than one TR&D project. Generally, the DBPs should be with investigators outside the BTRR's host institution. In competing renewals, the number of DBPs is expected to increase significantly, with the majority being from outside the host research institution.

DBPs that have already been peer-reviewed will be evaluated on how they advance and stimulate BTRR technological development. Those projects that have not been peer-reviewed should include more detail and will be evaluated for scientific merit of the research proposed as well as on their impact on a T&D project. It is expected that most of the DBPs will have

been peer reviewed.

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. Purely technical collaborations focused on advancing some aspect of TR&D should be included within the relevant TR&D project. Collaborations with biomedical researchers that make use of the technology and expertise of the BTRR but are not intended to serve as a primary driver for technology development should be included in the Collaboration and Service section (see below).

No more than ten driving biomedical projects can be presented in detail. For DBPs that have been peer reviewed, this description is restricted to 7 pages divided into the four sections listed above for each DBP. For DBPs that have not been peer reviewed, the description of each DBP is restricted to 12 pages.

At the end of the DBP section, a table of every DBP should be attached. For renewal applications, all of the DBPs from the previous funding period, including those that are not part of the renewal application, should be identified and listed following the new and continuing DBPs. Each entry in the table should include:

(1) the PI for the DBP

(2) the institution of the PI

(3) the title of the project

(4) the name(s) of Resource personnel involved with the project

(5) the TR&D project(s) with which the DBP interacts

(6) start and finish dates for the DBP

(7) the external funding status of the project

(8) for renewal applications only: publications that have resulted from the DBP.

Collaboration and 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. The concentration of instrumentation, software, methods, and expertise developed in a BTRR represents an important resource for biomedical and clinical researchers. A BTRR is expected to actively engage this research community both to collaborate and to provide broad access to Resource capabilities. Application of Resource technologies and expertise may take many forms, including consultation and advice, routine analyses, and engagement in challenging collaborative biomedical projects. Collaboration and Service are key elements of the Resource, but the P41 mechanism is not intended for support of a Resource that is predominately focused on routine service. The BTRR should strive to conduct the major portion of its Collaboration and Service projects with researchers who are outside the applicant institution.

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. That acknowledgement should use the NCRR grant number.

Collaboration and Service activities differ from those in a DBP in that these activities do not drive the development of new technologies or devices. Nonetheless, Collaboration and Service projects may involve long-term projects and may require

significant creativity and intellectual involvement on the part of both Resource staff and the collaborating biomedical or clinical researchers. These projects may make extensive use of Resource technologies and expertise, but are distinguished from Driving Biomedical Projects when they do not serve as primary drivers for the newest technologies still in the early stages of development. Collaboration and Service projects generally exploit the more mature capabilities of the Resource.

A representative sampling of no more than 10 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 description of each Collaboration and Service project should begin with the following header information:

(1) collaborating investigator's name

(2) the institution of the collaborating investigator

(3) the funding status of the project including

- the grant number
- project period dates
- source of funds
- the principal investigator's name if it is different from the collaborating investigator.

The BTRR should strive to conduct the major portion of its Collaboration and Service projects with researchers outside their institution.

This section of the application is limited to a total of 25 pages or less.

Following the description of the service and collaboration section, a complete table of service and collaboration activities should be attached to the end of this section of the application. Each entry in the table should include:

(1) the PI for the Collaboration/Service project

(2) the institution of the PI

(3) the title of the project

(4) the name(s) of Resource personnel involved with the project

(5) start and finish dates for the project

(6) the external funding status of the project

(7) publications that have resulted from the project

(8) for renewal applications, service and collaboration activities from the previous funding period should be included in the table following the listing of current service and collaboration activities. The start of the service and collaboration activities from the previous funding period should be clearly labeled.

As an administrative issue, 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 BTRR must be included

on the “Checklist Page” of all renewal and non-competing 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). Costs 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 likely are sophisticated and conceptually novel. Training generally is necessary to facilitate use by scientists outside the BTRR. This training of the research community should be planned for and provided by the BTRR. A BTRR must allocate sufficient resources for training both specialists and non-specialists to make the best possible use of the new tools.

Formal pedagogy and direct responsibility for training of students and post-doctoral fellows are important components of the academic research enterprise, and it is expected that students and post-doctoral fellows within the BTRR will play major roles in the technology R&D component of the Resource. However, the Training component of the program must go far beyond these groups to build technical competence in the broader community of researchers who may or may not be formally affiliated with the Resource. The overall goal of the training component of a BTRR is expected to be twofold: to improve the general understanding of the Resource’s technologies in the appropriate population and to create a cadre of biomedical researchers trained in the technology so that they can effectively apply it in their own research. Training courses offered by the Resource are not allowed to constitute a requirement for receipt of an academic degree.

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 BTRR in question. A defining feature of Training activities is the direct interaction between Resource personnel and the trainee. Note that activities such as web-based self-service tutorials would fall under Dissemination since there is no direct interaction

between Resource personnel and the researcher.

Examples of successful approaches may include hands-on laboratory experience such as 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. Because of the increasing importance of translational and clinical research, plans for training researchers involved in those efforts are strongly encouraged.

Funds to support courses given for academic or other types of credit may not be requested. Individuals benefiting from the training experiences may not be paid a stipend nor may the training experience be a requirement for receipt of an academic degree.

The boundary between Training and Dissemination activities may not be well defined. 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.

For renewal applications, a progress report on training activities should be included in this section for renewal applications.

This section of the application should be at least five but no more than ten pages long.

Dissemination

A fundamental motivation for the BTRR program is to bring cutting edge technology to bear on biomedical research problems. A critical step to meeting this objective is to share new technologies and methods as broadly as possible in order

to bring them into routine use. The DBPs, Collaboration and Service, and Training components of a BTRR all build toward this overall goal of broad dissemination.

Dissemination activities should have two overall objectives: informing the scientific community about the technical capabilities and accomplishments of a BTRR, as well as promoting and enabling the broader use of technologies. A variety of approaches can be proposed to meet these goals. These approaches can include but are not limited to: publishing articles, books, patents, newsletters, annual reports, or special issues of technical journals; issuing press releases; presenting research results at meetings; conducting workshops and conferences; distributing software products; transferring technologies to other laboratories directly; licensing technologies to industry; and web-based training modules and tutorials. All BTRR dissemination activities must acknowledge NCRR grant support. That acknowledgement should use the NCRR grant number.

A robust web presence is required for every BTRR. Support from NCRR should be acknowledged on that web site. The web site should provide information about:

(1) the Resource's research focus and capabilities

(2) how to establish driving biomedical projects or other collaborations

(3) contact information

(4) a section on current newsworthy items directed to the general public

(5) links to online tutorials

(6) the availability of software, reagents, and other resources as applicable.

(7) links to other related NIH funded resources including other 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. Although software is not required to be open source, if a restrictive license will be used to distribute the software, written justification is required in the application.

The boundary between Training and Dissemination activities may not be well defined. 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.

A progress report should be included in renewal applications.

This section of the application should be at least five but no more than ten pages long.

Administration

Following the research plan, the administrative structure of the BTRR should be described. This section should be broken down into: organizational structure and staff responsibilities, Resource operating procedures, and the external advisory committee.

Organizational Structure and Staff Responsibilities

Describe the organizational structure of the Resource. Indicate the relationship of the Resource to the administrative structure of the grantee institution. Describe how the principal investigator and the proposed Resource staff will be organized with respect to the Resource components: 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 specifying 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 requests for the use of the equipment and facilities in the Resource and to schedule that use once it has been approved. Describe criteria and methods for prioritizing and selecting DBPs as well as Collaboration and Service projects. Include samples of the forms to be filled out by collaborators and users. Include instructions on how users are to acknowledge support provided by the Resource in any resulting publications.

External Advisory Committee

The External Advisory Committee (EAC) is appointed by the principal investigator (PI) and advises the PI on future directions for the Resource particularly in planning additional grant applications and in setting priorities for allocation of Resource facilities. Each Resource must have an EAC. 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.

EAC members and the chair should be from outside the host institution. NCRR encourages the inclusion of scientists who are not affiliated with the Resource; however, inclusion of collaborators on the EAC is not prohibited. Membership should be rotated periodically. The EAC should meet at least annually and prepare a written report of its recommendations, addressed to the PI. This report must be supplied as part of the BTRR’s Annual Progress Report.

In this section of the application, the role of the EAC should be described. The committee's role in advising on instrument purchases, reviewing collaborative and service projects for merit and appropriateness, allocating instrument time, and on the research plans for the BTRR should be presented. Names of current committee members and a brief description of their qualifications should be included. Potential EAC members should not be contacted or appointed prior to submission of the application; however, the scientific disciplines of anticipated committee members should be described.

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 re-budgeted without prior approval by program staff.

A local executive committee or other local committee to deal with specialized topics may be proposed as an adjunct to the EAC. The function and meeting schedule for these committees should be described in this section.

SPECIAL APPLICATION INSTRUCTIONS

The current version of Form PHS 398 should be used for BTRR grant applications. 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 must be complete and able to stand on its own.

Form Pages 4-5: The detailed 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, Training, Dissemination, External Advisory Committee meetings (under Consultant Costs) and the Resource's expenses associated with Driving Biomedical Projects, Collaboration and Service. Support for the development and maintenance of a web site should be included. Support for graduate students and postdoctoral fellows can be requested only if they are active

participants in a TR&D research project. The outside investigators of collaborative and service projects must derive support for their projects from sources outside the BTRR.

There is an annual meeting of BTRR PIs, usually in the Washington, DC area. It is expected that the PI and one other senior member of the BTRR attend this meeting. Funds to support travel to this meeting should be requested in the budget.

The budget justification beginning on PHS Form Page 5 should include a detailed justification for key personnel. The percent effort for each member of the BTRR staff should be broken down by component (each of the TR&D projects, infrastructure, driving biomedical projects, collaboration and service, training, and dissemination).

A justification should be supplied for the equipment requested for the Resource. Price quotes should be included for major items of equipment costing more than $25,000. The budget justification section should include an evaluation of alternative instruments or manufacturers along with a discussion of the proposed procurement plan.

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 (http://grants.nih.gov/grants/guide/notice-files/not99-052.html). Waivers to these ceilings may be requested. Applicants should direct such requests to program staff. Waivers require written approval by the Director of the NCRR Division of Biomedical Technology. Applicants must include this approval letter in their application following the budget justification. In applications where the budget request exceeds the ceilings, scientific reasons for exceeding the ceiling must be provided in the application. A waiver must be requested at least six weeks 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 Director of the NCRR Division of Biomedical Technology 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.

Research Plan Page Limitations

The page limitation specified in the PHS 398 for the Research Plan does not apply, and the format in the PHS 398 should be replaced by the format specified above. Page limitations for each section are specified above and are summarized here.

Technology Research and Development – A minimum of three TR&D projects are required. Each project is limited to 25 pages or less.

Infrastructure – This section, if included, is limited to 10 pages or less. This section may not be present in every BTRR application.

Driving Biomedical Projects – A maximum of 10 driving biomedical projects may be presented. Each peer reviewed DBP is restricted to 7 pages; DBPs that have not been previously peer reviewed are permitted 12 pages. Following the description of the DBPs, a comprehensive table containing information about all DBPs must be presented. This table does not count toward the page limits in this section.

Collaboration and Service - A maximum of 10 collaboration/service projects may be presented. This section is limited to 25 pages. Following the description of these projects, a comprehensive table containing information about all collaboration and service projects must be presented. This table does not count toward the page limits in this section.

Training – This section is limited to 10 pages, but is expected to be at least five pages long.

Dissemination – This section is limited to 10 pages, but is expected to be at least five pages long.

Administration – There are no formal page limits on this section, but applicants are expected to be concise.

References

References can be collected either into a single section as described in the PHS 398 instructions (item 7a), or they can be presented at the end of each of the sections described above. The instructions for the format of these citations in the PHS 398 must be followed. References are not included in the page limitations.

For renewal applications, the title and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the BTRR since it was last reviewed competitively must be included in item 7 of the PHS 398 instructions. Publications that explicitly acknowledge support from this BTRR award should be distinguished from those that do not.

Animals and Human Subjects

The instructions in the PHS 398 must be followed when describing experiments involving animal and human subjects. The institution applying for the Resource is responsible for obtaining their own institutional IRB and IACUC approvals, regardless of whether DBPs or Collaboration and Service projects have separate approvals.

Specific Instructions for Applications Requesting $500,000 (direct costs) or More per Year

Applicants requesting $500,000 or more in direct costs for any year (excluding consortium F&A costs) must carry out the following steps:

1) Contact the IC program staff at least 6 weeks before submitting the application, i.e., as plans are being developed for the study;

2) Obtain agreement from the IC staff that the IC will accept the application for consideration for award; and,

3) Include a cover letter with the application that identifies the staff member and IC who agreed to accept assignment of the application.

This policy applies to all new, renewal, revision, or resubmission applications. See NOT-OD-02-004, October 16, 2001.

Appendix Materials

All paper PHS 398 applications submitted **must** provide appendix material on CDs only. Include five identical CDs in the same package with the application. .(See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-031.html.)

Do not use the Appendix to circumvent the page limitations of the Research Plan component. An application that does not observe the required page limitations may be delayed in the review process.

For renewal applications, include copies of the Resource's most recent annual progress report and the most recent External Advisory Committee report in the Appendix.

Resource Sharing Plan(s)

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value of, and advance, research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. If the final data/resources are not amenable to sharing, this must be explained in Resource Sharing section of the application. See http://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm.

(a) *Data Sharing Plan*: Regardless of the amount requested, investigators are expected to include description of how final research data will be shared, or explain why data-sharing is not possible. This plan should detail the nature of the database, the vocabulary used to describe an experiment as well as the results of experiments, the data sharing infrastructure that will be used to distribute data, and any required approval processes for data requests. Applicants are encouraged to discuss data-sharing plans with their NIH program contact. See Data-Sharing Policy or http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html.

(b) *Sharing Model Organisms*: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms and related resources, or state appropriate reasons why such sharing is restricted or not possible. See Sharing Model Organisms Policy, and NIH Guide NOT-OD-04-042.

(c) Genome-Wide Association Studies (GWAS): Regardless of the amount requested, applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. A genome-wide association study is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight) or the presence or absence of a disease or condition. For further information see Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, NIH Guide NOT-OD-07-088, and http://grants.nih.gov/grants/gwas/.

Section V. Application Review Information

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1. Criteria (**Update:** Enhanced review criteria have been issued for the evaluation of research applications received for

potential FY2010 funding and thereafter - see NOT-OD-09-025).

Only the review criteria described below will be considered in the review process.

2. Review and Selection Process

Applications submitted for this funding opportunity will be assigned on the basis of established PHS referral guidelines to the ICs for funding consideration.

Applications that are complete will be evaluated for scientific and technical merit by an appropriate peer review group convened by the Center for Scientific Review (CSR) in accordance with NIH peer review procedures (http://grants1.nih.gov/grants/peer/) using the review criteria stated below.

As part of the scientific peer review, all applications will:

- Receive a written critique.
- Receive a second level of review by the appropriate national advisory council or board.

Applications submitted in response to this funding opportunity will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Compliance with resource sharing policies.

The goals of NIH supported research are to advance our understanding of biological systems, to improve the control of

disease, and to enhance health. In their written critiques, reviewers will be asked to comment on each of the following criteria in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, and weighted as appropriate for each application. Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a meritorious priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Approach: Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

Investigators: Are the investigators 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? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition to the above review criteria, the following criteria will be addressed and considered in the determination of scientific merit and the rating.

Component scoring:

Each TR&D project receives a separate score.

Components that are scored as a whole regardless of the number of activities subsumed within the component:

-Driving Biomedical Projects

-Collaboration and Service

-Training

-Dissemination

-The Infrastructure and Administrative and Management sections do not receive separate scores, but are factored into the determination of the overall, priority score.

Priority Score (the final score, which is recorded by all reviewers who are present for the discussion of the BTRR and who are not in conflict):

A single, overall priority score for the Resource grant application will be assigned at the end of the discussion of the components. 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. The priority score may be more or less than the average of the

component scores. In determining this final score, the goals of the Resource and the stage of development of the Resource technology and community engagement should be taken into account.

A) Technological Research and Development Review Criteria

Is the Resource technology dynamically evolving, state-of-the-art, an important area for research and development in its own right, and likely to advance the frontiers of biomedical research? Are alternative approaches to solving technological problems presented? What is the potential impact of the BTRR's technological goals? Is there synergy between a TR&D project and the DBP(s) in advancing the focal technology? How is this Resource unique and useful to the community in the technological goals it is pursuing as well as in the cluster of driving biomedical projects to which the advanced technology is being applied? Is the Resource technology already broadly available? Are the TR&D projects synergistic?

In renewal applications, is evidence provided of new meritorious efforts and significant progress during the past grant period?

B) Infrastructure

Is the technological infrastructure requested in this section necessary for the BTRR? Has the applicant chosen the most cost effective and appropriate infrastructure?

C) Driving Biomedical Projects

Is the Resource staff continuously developing new, significant applications of the Resource technology in the biomedical sciences through high quality Driving Biomedical Projects?

For DBPs that have already been peer-reviewed, does the DBP advance and motivate further technological research and development in the Resource? Is the technology appropriate and will it have high impact on the science being explored in

the DBP? In addition, for DBPs that have not been peer-reviewed, what is the level of scientific merit of the research proposed?

For renewal applications, does the BTRR have an appropriate balance between time and effort spent on DBPs and on Collaboration and Service projects? Are DBPs driving TR&D research and are Collaboration and Service projects making good use of the new technological advances? For this Resource, is the balance right between continuing DBPs, DBPs that have finished, and DBPs that have turned into Collaboration and Service projects? Are new DBPs in important biomedical fields being actively sought to invigorate the Resource?

D) Collaboration and Service

Is the Resource available to outside users? Are the equipment and technology utilized for Collaboration and Service state-of-the-art? Do the equipment and technology meet significant biomedical research needs? Do the Collaboration and Service projects have a national geographical distribution? For Resources that do a substantial amount of service, are the plans for sharing costs by the users, including fee for service systems, appropriate?

E) Training

Are plans for providing opportunities for training appropriate?

In renewal applications, have there been reasonable results accruing from these efforts to date?

F) Dissemination

Are the proposed dissemination plans adequate and appropriate? In Resources that are developing software, is the software portable when appropriate, well-documented, user-friendly, and readily available to the user community? Have there been

efforts to make both non-expert and expert communities aware of the new technology?

In renewal applications, is the web site easy to find? Does the material on the web site provide useful information to the biomedical research community? Has there been reasonable and timely progress in this area?

G) Administrative and Management

Are the administrative and managerial aspects presented in the written proposal appropriate and adequate? In addition, if a site visit takes place, is the discrete space set aside for the Resource and the laboratory facilities, including those available to visiting scientists, appropriate and adequate? In the case of a renewal application, is the usage of the instruments developed and supported by the Resource, appropriate and adequate? Are instruments in place and operational, and are staff members currently on site?

Is the institution's commitment to the Resource appropriate and adequate? For example, are the allocated space, costs associated with alterations and renovations and purchase of instrumentation and computers, and salary support for some Resource staff adequate?

Are the scientific and managerial credentials of the Principal Investigator and the credentials of other key professional and technical staff appropriate?

In renewals, is the role of the external advisory committee or in new applications plans for the committee and types of committee members appropriate? Do the members of this committee have sufficient breadth and ability to take an effective role in the review and guidance of the Resource operations? In renewal applications, is there evidence that the EAC is active? Are there plans for rotation of the members of this committee?

If other committees such as a local executive committee are proposed, are the composition and organizational plans for

these committees adequately described? How they will benefit the Resource?

NIH considers the following in evaluating Center grant applications:

- · The scientific and technical merit of the proposed program;
- · The qualifications and experience of the center director and other key personnel;
- · The statutory and program purposes to be accomplished;
- · The extent to which the various components of the proposed program would be coordinated into one multi-disciplinary effort within the center;
- · The extent to which the center's activities would be coordinated with similar efforts by other organizations;
- · The administrative and managerial capability of the applicant; and
- · Other factors which the awarding IC considers appropriate in light of its particular statutory mission

2.A. Additional Review Criteria:

In addition to the above criteria, the following items will continue to be considered in the determination of scientific merit and the rating:

Resubmission Applications (formerly “revised/amended” applications): Are the responses to comments from the previous scientific review group adequate? Are the improvements in the resubmission application appropriate? Remove if not applicable

Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed (see the Research Plan section on Human Subjects in the PHS 398 instructions).

Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders,

all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated (see the Research Plan section on Human Subjects in the PHS 398 instructions).

Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the five points described in the Vertebrate Animals section of the Research Plan will be assessed.

Biohazards: If materials or procedures are proposed that are potentially hazardous to research personnel and/or the environment, determine if the proposed protection is adequate.

2.B. Additional Review Considerations

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The priority score should not be affected by the evaluation of the budget.

2.C. Resource Sharing Plan(s)

When relevant, reviewers will be instructed to comment on the reasonableness of the following Resource Sharing Plans, or the rationale for not sharing the following types of resources. However, reviewers will not factor the proposed resource sharing plan(s) into the determination of scientific merit or priority score, unless noted otherwise in the FOA. Program staff within the IC will be responsible for monitoring the resource sharing.

- Data Sharing Plan. [http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm]
- Sharing Model Organisms. [http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html]
- Genome Wide Association Studies (GWAS). [http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html]

3. Anticipated Announcement and Award Dates

Not Applicable

Section VI. Award Administration Information

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1. Award Notices

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant. For details, applicants may refer to the *NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General*.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See Also Section IV.5. Funding Restrictions.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization. The NoA signed by the grants management officer is the authorizing document. Once all administrative and programmatic issues have been resolved, the NoA will be generated via email notification from the awarding component to the grantee business official (designated in item 12 on the Application Face Page). If a grantee is not email enabled, a hard copy of the NoA will be mailed to the business official.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the NoA. For these

terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm) and Part II Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part9.htm).

3. Reporting

When multiple years are involved, awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually and financial statements as required in the *NIH Grants Policy Statement.*

A BTRR is a complex, multidisciplinary enterprise with a significant, wide-ranging impact on biomedical research. The value of a BTRR is expressed in its creation of meaningful improvements in technology, and the breadth and depth of the impact of those technologies. However, because it is so broad, this impact can be difficult to track and assess. Each year, the scientists in a BTRR pursue dozens of projects with scores of collaborating colleagues, and influence many more through training and dissemination efforts. In order to understand the nature and extent of a Resource's impact, it is important to gather data in a number of areas on an annual basis, beyond what is required in the standard non-competing renewal application.

NCRR requires that every BTRR submit an Annual Progress Report (APR) addressing details of research progress, the status of individual TR&D, DBP, and Collaborative and Service projects, as well as Training and Dissemination activities. The APR also reports all publications and presentations, and statistical data for every project, particularly those involving external collaborators, including information on their grant support, institutions, and geographic breakdown. The APR is submitted online, either through a web-based manual entry option or a standard XML format for system-to-system transfer. Both formats utilize the NCRR APR website for submission (http://aprsis.ncrr.nih.gov). Instructions for submission of the APR can be found at (http://aprsis.ncrr.nih.gov/xml/BTRR_Instructions.pdf). After filling in the required information in the

progress report, the final document will be attached to the PHS 2590.

A final progress report, invention statement, and Financial Status Report are required when an award is relinquished when a recipient changes institutions or when an award is terminated.

Section VII. Agency Contacts

We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

1. Scientific/Research Contacts:

General questions concerning the BTRR program in NCRR should be addressed to

Dr. Michael Marron

Director, Division of Biomedical Technology

National Center for Research Resources

One Democracy Plaza, Room 962

6701 Democracy Boulevard

Bethesda, MD 20892

Telephone: (301) 435-0755

FAX: (301) 480-3659

Email: marron@nih.gov

Questions concerning BTRR applications in NCRR in particular scientific areas should be addressed to the appropriate

program staff member. Details are available at http://www.ncrr.nih.gov/biomedical_technology/contacts.asp.

Questions concerning the BTRR program in NIAAA should be addressed to:

Dr. John Matochik

Division of Neuroscience and Behavior

National Institute on Alcohol Abuse and Alcoholism

5635 Fishers Lane, Room 2048

Bethesda, MD 20892-9304

Telephone: (301) 451-7319

FAX: (301) 443-1650

Email: jmatochi@mail.nih.gov

2. Peer Review Contacts:

N/A

3. Financial or Grants Management Contacts:

Judy Musgrave

Division of Grants Management

National Center for Research Resources

One Democracy Plaza, Room 1048

6701 Democracy Boulevard

Bethesda, MD 20892

Telephone: (301) 435-0841

FAX: (301) 480-3777

Email: musgravj@mail.nih.gov

Judy Fox

Chief, Grants Management Branch

National Institute on Alcohol Abuse and Alcoholism

5635 Fishers Lane, Room 3023

Bethesda, MD 20892-9304

Telephone: (301) 443-4704

FAX: (301) 443-3891

Email: jfox@mail.nih.gov

Section VIII. Other Information

Required Federal Citations

Use of Animals in Research:

Recipients of PHS support for activities involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf) as mandated by the Health Research Extension Act of 1985 (http://grants.nih.gov/grants/olaw/references/hrea1985.htm), and the USDA Animal Welfare Regulations (http://www.nal.usda.gov/awic/legislat/usdaleg1.htm) as applicable.

Human Subjects Protection:

Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with

reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).

Data and Safety Monitoring Plan:

Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

Sharing Research Data:

Investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing).

Investigators should seek guidance from their institutions, on issues related to institutional policies and local IRB rules, as well as local, State and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

Policy for Genome-Wide Association Studies (GWAS):

NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease through a centralized GWAS data repository. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition. All applications, regardless of the amount requested, proposing a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why

submission to the repository is not possible. Data repository management (submission and access) is governed by the Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, NIH Guide NOT-OD-07-088. For additional information, see http://grants.nih.gov/grants/gwas/

Sharing of Model Organisms:

NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see http://grants.nih.gov/grants/policy/model_organism/index.htm). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh Dole Act (see the NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm). All investigators submitting an NIH application or contract proposal, beginning with the October 1, 2004 receipt date, are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

Access to Research Data through the Freedom of Information Act:

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Applicants may wish to place data collected under this funding opportunity in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application

should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

Inclusion of Women And Minorities in Clinical Research:

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

Inclusion of Children as Participants in Clinical Research:

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as

participants in research involving human subjects (http://grants.nih.gov/grants/funding/children/children.htm).

Required Education on the Protection of Human Subject Participants:

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. The policy is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

Human Embryonic Stem Cells (hESC):

Criteria for federal funding of research on hESCs can be found at http://stemcells.nih.gov/index.asp and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (http://escr.nih.gov/). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

NIH Public Access Policy Requirement:

In accordance with the NIH Public Access Policy (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html), investigators must submit or have submitted for them their final, peer-reviewed manuscripts that arise from NIH funds and are accepted for publication as of April 7, 2008 to PubMed Central (http://www.pubmedcentral.nih.gov/), to be made publicly available no later than 12 months after publication. As of May 27, 2008, investigators must include the PubMed Central reference number when citing an article in NIH applications, proposals, and progress reports that fall under the policy, and was authored or co-authored by the investigator or arose from the investigator's NIH award. For more information, see the Public Access webpage at http://publicaccess.nih.gov/.

Standards for Privacy of Individually Identifiable Health Information:

The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule", on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

URLs in NIH Grant Applications or Appendices:

All applications and proposals for NIH funding must be self-contained within specified page limitations. For publications listed in the appendix and/or Progress report, internet addresses (URLs) **must** be used for **publicly** accessible on-line journal articles. Unless otherwise specified in **this** solicitation, Internet addresses (URLs) should **not** be used to provide any **other** information necessary for the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

Healthy People 2010:

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

Authority and Regulations:

This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372. Awards are made under the authorization of Sections 301

and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at http://grants.nih.gov/grants/policy/policy.htm.

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

Loan Repayment Programs:

NIH encourages applications for educational loan repayment from qualified health professionals who have made a commitment to pursue a research career involving clinical, pediatric, contraception, infertility, and health disparities related areas. The LRP is an important component of NIH's efforts to recruit and retain the next generation of researchers by providing the means for developing a research career unfettered by the burden of student loan debt. Note that an NIH grant is not required for eligibility and concurrent career award and LRP applications are encouraged. The periods of career award and LRP award may overlap providing the LRP recipient with the required commitment of time and effort, as LRP awardees must commit at least 50% of their time (at least 20 hours per week based on a 40 hour week) for two years to the research. For further information, please see: http://www.lrp.nih.gov/.

Weekly TOC for this Announcement

NIH Funding Opportunities and Notices

Office of Extramural Research (OER)

National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892

Department of Health and Human Services (HHS)

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