Guidelines for NIBIB P30 Biomedical Technology Core Centers

Summary. NIBIB-supported Biomedical Technology Core Centers (P30 Centers) are intended to provide biomedical core resources to a group of independently-funded NIH investigators requiring access to specialized technology and expertise that are not generally available. They serve to establish, support, and maintain infrastructure and resources needed by the biomedical sciences community and operate to help that community gain access to these resources. Infrastructure and resources could range from open bioinformatics systems to shared instrumentation. Consistent with their function to help the community gain access to these resources, P30 Centers should engage in dissemination activities, and may engage in training activities.

P30 Centers must serve investigators from multiple institutions outside the applicant institution and are expected to be regional or national in scope. Cores may be based solely at the applicant institution or located at multiple institutions, and funded through subcontracts. If subcontracts are to be utilized, the applicant must clearly demonstrate how a cohesive and integrated operation will be ensured, and describe the advantages of this approach to the performance of Core functions.

Each P30 Center will be expected to develop its own program in accordance with local talents, interests, and resources, and must also be responsive to regional or national needs.

Potential P30 applicants are encouraged to contact Dr. Alan McLaughlin (see contact information below) at least three months in advance of the proposed receipt date to discuss their application.

P30 Awards are for a five year period, are capped at $500K per annum (direct costs), and can be renewed.

P30 Centers generally consist of one Administrative Core and one, or more, Technology Service Cores.

I. ADMINISTRATIVE CORE

A Director who will be responsible for the scientific and administrative leadership of the P30 Center must be identified. The Director should be an experienced and respected scientist with a proven track record for obtaining NIH and/or other relevant funding, and demonstrated administrative capabilities. He/she must be able to coordinate, integrate, and provide guidance in the establishment and maintenance of Technology Service Cores. The Director must devote a minimum of 25% effort to the P30. At least 10% of this effort must be on the Administrative Core. Additional scientific staff who will be involved in the administrative, scientific, training (where applicable), and dissemination efforts of the Center should be named. Appropriate administrative support may also be proposed.

The Director of the Administrative Core also must be the director of at least one of the Technology Service Cores.

It is expected that the organization of the Administrative Core should encompass a supportive structure sufficient to ensure accomplishment of the following: coordinating and integrating the Center components and activities; overseeing the user programs; monitoring the utilization and quality of Technology Service Cores; organizing appropriate dissemination activities; reviewing training activities (where applicable); interacting with the scientific community in order to develop relevant goals for the Center; developing and maintaining an effective External Advisory Committee to provide periodic review of Center activities.

The final administrative structure of the Center should be determined by the applicant institution, and should reflect the complexity and interdependence of the different Technology Service Cores. However, effective development of the Center programs requires close interaction between the Center Director, the investigators using the Cores, and appropriate institutional administrative personnel. The application should include formation of an External Advisory Committee. This committee should have a majority of membership from outside the applicant institution and may include investigators using the Technology Service Cores and other experts in the relevant fields supported by the Center. New P30 grant applications should not constitute their External Advisory Committee prior to or during the review of their application because individuals either invited or named to this group would not be able to serve as peer reviewers of the application.

For existing Centers, the members should be specifically identified and the frequency and outcome of External Advisory Committee meetings documented. The Administrative Core of the Center grant should also include funds for program outreach, including workshops and presentations at appropriate scientific meetings, as well as costs of other dissemination activities including, newsletters, mailings, flyers or websites.

A general description of overall facilities and any information regarding institutional commitment to the P30 Center (e.g., laboratory or office space, facilities, research funds, etc.) should also be included here.

II. TECHNOLOGY SERVICE CORES

Definition: A Technology Service Core is a shared facility that provides a needed service to investigators, enabling them to conduct their funded individual research projects more effectively. Cores may be proposed in a range of technology areas.

Limited developmental research is also an appropriate function of a Technology Service Core. Such activities, however, must be directly related to enhancing the function or utility of the Core.

Multiple Technology Service Cores are typical for a P30 Center.
Justification for proposing a Core: The establishment and continued support of Technology Service Cores within a P30 Center is justified on the basis of use by independently-funded investigators. The minimum requirement for establishing a Core is significant usage by five or more investigators with independently-funded, peer-reviewed projects.

Investigators may be trained to operate the instruments or systems, or may submit samples or data that will be processed by Center personnel. Appropriate data analysis activities and resources may be an important part of Cores.

Investigators should not receive funding directly from the Core, but should utilize the Core resources in support of their independently-funded research.

Personnel: A director must be named for each Technology Service Core. Core directors may be acknowledged experts with independently-funded research programs that use the Core services. The minimum effort for a Core director is 10%. Where appropriate, an established expert in the Core activities could also be included as a consultant to the Core. Technicians, engineers, etc., are allowable in accordance with the volume and type of work in the Core. These staff should have appropriate scientific or engineering skills to operate or maintain the instruments or to develop data base structures and software. Effort directed to user training and other user support activities should be identified.

Facilities, space, and special arrangements: For initial applications, the physical arrangements and instrumentation for the Technology Service Cores should be fully described. For renewal applications, any changes should be carefully documented.

Management of the Core: The organization and proposed mode of operation of each Technology Service Core should be presented. A plan for prioritizing investigator use of the Core, as well as a definition of qualified users, should be included. If part of the activity of the Core is to train investigators in special techniques, the mechanism for this training should be included.

Renewal applications: Information relative to Technology Service Cores in renewal applications should generally cover all of the same points as initial applications. In addition, past performance and accomplishments should be described.

Special Considerations: The P30 Center application should describe in detail the Technology Service Core infrastructure to be established or maintained. The specific technology areas and regions served should be identified. Specific equipment or other resources should be described and Core budgets should identify the costs of operating and maintaining instruments or data bases including professional, scientific, engineering, or other staff associated with resource maintenance and improvement. The Cores should implement and maintain appropriate commercial instruments or instruments developed by Core staff. Whenever possible, open-source software should be utilized.

III. RESEARCH BASE

Investigators using the Technology Service Cores are expected to have highly-regarded existing programs of biomedical research funded by a range of NIH Institutes or Centers, or other peer-reviewed research projects, such as those supported by other Federal Agencies or other nationally or internationally-recognized funding sources.

Specific scientific details of the core-utilizing research projects are not required. However, brief descriptions of each project, outlining the need for and previous use (where appropriate) of Technology Service Core facilities should be provided. If more than twenty research projects will use the Technology Service Cores, descriptions of only twenty selected projects should be provided, and all proposed projects should be identified in tables listing project title, investigator name, institution and relevant peer-reviewed funding. Separate tables should be used for each Core.

The process by which additional projects will be selected to utilize the Core resources should be delineated.

Investigators are required to acknowledge the use of the NIBIB P30 Center resources in their publications.

IV. PREPARATION OF APPLICATION

Description
Applications must be submitted in hard copy using PHS Form 398 (11/07 Revision, see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-028.html). Standard receipt dates for P30 applications are January 25, May 25 or September 25, (http://grants.nih.gov/grants/funding/submissionschedule.htm).

Submit the signed original application, including the Checklist, plus three signed photocopies, in one package to:

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

At time of submission, two additional copies of the application must be sent to:

David T. George, Ph.D.
Director, Office of Scientific Review
National Institute of Biomedical Imaging and Bioengineering
6707 Democracy Boulevard, Suite 920, Room 956, MSC 5469
Bethesda, MD 20892-5469 (20817 for FedEx, UPS, and other courier services)
Voice: (301) 496-8633
Fax: (301) 480-0675
Email: GeorgeD@nih.gov

Appendix material should NOT be included as part of the grant application. The scientific review officer (SRO) will contact the PI after receipt of the application for instructions on submitting appendix material.

The arrangement of materials should follow both the instructions in the PHS Form 398 application kit and the more specific guidance detailed below. Applications not in accordance with Center guidelines will be returned to the applicant and will not undergo scientific peer review.

Applicants should keep in mind that the written application is the primary basis for the merit review. Particular attention should be given to the format of the application. Basic information useful for preparing the application follows. Applicants may also consult with NIBIB staff concerning the technical aspects of preparing the application.

Other Submission Requirements:

Potential P30 Center applicants should contact Dr. Alan McLaughlin at least three months before submitting the application, i.e., as you are developing plans for the study.

Dr. Alan McLaughlin
Director, Division of Applied Science and Technology, NIBIB
(301) 496-9321
mclaugal@mail.nih.gov

P30 proposals are funded through the "Center" budget track, and awards are thus subject to the availability of funds.

Content Order for Applications

SECTION 1: INTRODUCTION

- Face Page
- Description and Key Personnel
- Table of Contents
- Budgets
  1. Detailed Budget for Initial Budget Period
  2. Budget for Entire Proposed Project Period
  3. Budget Justification
- Biographical Sketches for all Center participants beginning with Center Director and followed by Core Directors and other participants in alphabetical order. Include current and pending support for Key personnel.
- General description of the proposed or established Center; explanation of Cores proposed, regional or national niche of Cores, and description of user needs (limit: 10 pages). For Renewals: changes from the original Center design should be highlighted
- For Resubmission applications include a response to previous reviewers' comments (up to one page per Core).

SECTION 2: ADMINISTRATIVE CORE

- Director, summary of qualifications

- Presentation of the administrative structure
- Relationship and lines of authority
- Advisory Committee structure
- General overall description of facilities
- Dissemination and Outreach activities.
- Other Considerations.
  (Limit: 10 pages)

SECTION 3: TECHNOLOGY SERVICE CORES

- Technology Service Cores (present each Core separately; 10 pages maximum for each separate Core)
  - o Objectives of the Core
  - o Core functions
  - o Proposed developmental research (if applicable)
  - o Training Activities (if applicable)
  - o For Renewal: Core use during the last grant period should be summarized.
- Research Base (see Section III); overview and expected impact of the P30 Center on the Research Base. Project descriptions (excluding tables) should be limited to 20 pages total.
- For Renewals: Progress Report including description of significant findings and new users. One page summary highlights of major findings are an appropriate means of illustrating progress. Publications citing support from the P30 Center should be listed here. The Progress Report is not included in page limitations.
- Checklist

V. BUDGET CONSIDERATIONS

Unless otherwise indicated in the Notice of Grant Award, allowable costs and policies governing the research grant program of the NIH will prevail. The anticipated award will be for five years. Budgets are capped at $500K (direct costs).

Budget Categories

Professional Personnel: This category may include support for salaries of Key personnel who contribute to allowable activities of the Center. The salaries derived from the Center grant will depend on the effort provided and institutional salary as well as existing NIH policies. The Center director is expected to devote at least 25% of his/her efforts to the Center. A minimum of 10% of this effort must be devoted to the Administrative Core. The Center application should include salaries for individual Technology Service Core directors only to the extent that they provide an essential Center function. No overlap of time or effort between the Center and separately-funded projects is permitted.

Technical and Support Personnel: This may include salaries for identified positions to be filled in the Center. No overlap of time or effort between the Center and separately- funded projects is permitted.

Equipment: Requests for large equipment costs must include descriptions of equipment available elsewhere in the region or the nation and provide a clear justification in terms of Core need and service to Center investigators. General purpose equipment needs should be included only when necessary to support the functions of visiting investigators.

Supplies: Consumable supplies related to the operation of the Center are allowed and include office materials, as well as scientific supplies.

Other Expenses: Service contracts for major equipment items are allowed and should be outlined in this category.

Travel: Domestic and foreign travel of project personnel directly related to the activities of the Center is allowable.

Consultants: Consultants (including Advisory Committee members) and any associated costs (consultant fees, per diem, travel) may be included when their services are required within the Center.

VI. REVIEW PROCESS AND CRITERIA

Upon receipt, applications will be evaluated by the Center for Scientific Review (CSR) for completeness and by the NIBIB for responsiveness. Incomplete and/or non-responsive applications will not be reviewed.

Complete and responsive applications will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIBIB in accordance with the criteria stated below. Following this review, applications will receive a programmatic review by the NIBIB Advisory Council. Besides scientific priority, program relevance and availability of funds will be significant factors in funding decisions.

Review Criteria

The goals of the NIBIB Biomedical Technology Core Centers are to promote use of advanced and complex technologies by NIH-funded and other federally-funded investigators to advance biomedical research.

In the written comments reviewers will be asked to evaluate the following aspects of the application in order to judge the likelihood that the proposed Technology Cores will advance the above mission. In assigning an overall score, each of the criteria will be weighted appropriately for each application.

Specific review criteria are:

- Potential of the Technology Service Cores for contribution to ongoing funded research base, including the impact and uniqueness of Core facilities. Renewal applications must document the use and impact of each Core, and demonstrate

progress of any developmental research in the Cores. Progress will be judged in part by the publications supported by the Cores.

- The breadth and depth of the proposed or actual user community, and the scientific excellence of the research base.
- Scientific and administrative abilities of the Center Director and Scientific staff and their commitment and ability to devote adequate time to the effective management of the P30 Center.
- The Administrative organization proposed, including: coordination of ongoing Technological Service Cores, mechanisms for prioritizing usage of shared resources, functioning of the Advisory Committee.
- Effectiveness of dissemination and outreach to the community.
- Effectiveness of user training activities (if applicable).
- The adequacy of proposed plans for human or animal research.

In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following:

- The adequacy of the proposed plan to share data.
- The reasonableness of the proposed budget and duration of the proposed research.

Funding decisions will be based on the quality of the proposed Center as determined by peer review, overall balance in the NIBIB Centers program, and the availability of funds.

VII. EVALUATION AND REPORTING REQUIREMENTS

The annual Application for Continuation Grant (Progress Report), which is due two months before the anniversary date of the award, should be submitted as described in the PHS Form 2590 application kit which is sent automatically to NIH grantees. The following order for presentation of information in the Continuation Grant Progress Report is suggested:

1. Cumulative Budget
2. Budget for each Core
3. List of new Key personnel followed by biosketches
4. Other support for all Key personnel
5. Administrative Core: Highlight significant accomplishments
6. Biomedical Service Cores: Highlight significant changes from previous report, describe services provided and number of users, provide one-page summary highlights of key results, and list publications citing support from the Center.

VIII. SPECIAL CONSIDERATIONS

Each Center will be expected to develop its own program in accordance with local talents, interests, and resources, and must also be responsive to regional or national needs to develop new approaches for providing advanced Technology Cores.

Within the context of these guidelines, potential applicants for Center grants are encouraged to exercise the flexibility necessary to utilize the strengths of their particular institutions and personnel in preparing a plan that will eventually cover the spectrum of required activities.