

National Institute on Deafness and Other Communication Disorders
(NIDCD)

<http://www.nidcd.nih.gov>

GUIDELINES FOR NIDCD RESEARCH CORE CENTERS (P30)

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I. INTRODUCTION

This document provides administrative guidelines on the eligibility criteria and application process for NIDCD Research Core Centers (P30). Applications for Core Centers are sought through a NIH Guide Notice with three receipt dates per year <http://grants2.nih.gov/grants/guide/notice-files/NOT-DC-04-001.html>.

The Research Core Center Grant (P30) is an institutional award, made in the name of a principal investigator, intended to support one or more research cores providing centralized resources and facilities shared by investigators with existing research projects. The P30 may serve as an “intellectual hub” to stimulate and support cooperative and interactive research, to increase the effectiveness, capabilities or productivity of current research endeavors and/or to promote new research directions. Research cores may provide for the sharing of technical expertise or the centralization of labor-intensive tasks common across several principal investigators, for the staffing, maintenance and training of shared equipment or resources, and/or for problem-solving through innovative technical solutions using state-of-the-art methodologies/technologies. Although no funds are provided for direct support of research projects, a P30 helps to integrate and promote research in existing projects. Additionally, P30s may provide benefits to other core centers or the larger community through data or technology sharing.

The P30 is awarded for up to 5 years and is subject to budgetary caps. The P30 does not provide funds for the conduct of research pilot and feasibility studies outside that associated with user projects.

II. REQUISITE RESEARCH BASE AND BUDGETARY CAPS

A strong research base, as evidenced by a critical mass of funded grants, is a fundamental requirement for, and a major factor in, establishment of a P30. Any institution or consortium applying for a P30 must have an active, established program in basic, clinical, and/or epidemiological biomedical or behavioral research in one or more mission areas of the NIDCD. Institutions applying for a Core Center grant must hold, on the date of grant application submission, a minimum of six NIH research project R01 grants, each with at least one year of support remaining. Grants in a no-cost extension do not qualify. The six grants must focus on NIDCD mission areas and four of the six must be supported by the NIDCD.

A Core Center must be an identifiable organizational unit either within a single grantee institution or representing a consortium of cooperating institutions (e.g., geographic or web-based). Joint applications may be submitted by investigators at neighboring, independent, or multi-campus institutions. Only one P30 award is allowed per institution. Exceptions may be made for different user groups working in different NIDCD mission areas within the same institution.

Institutions holding six or more R01s focused on NIDCD mission areas, four of which must be NIDCD funded, may request direct costs not to exceed a total of \$1.5 million over a five year period; those holding twelve or more R01s, eight of which must be NIDCD funded, may request direct costs not to exceed a total of \$2.0 million over a five year period; those holding eighteen or more R01s, twelve of which must be NIDCD funded, may request direct costs not to exceed a total of \$2.5 million over a five year period. Re-competing applications may not exceed the stated caps.

Competitive supplemental applications requesting an additional research core to existing P30s are allowed, but may not exceed the term of award or budgetary cap of the parent P30.

III. RESEARCH CORES

The P30 supports research cores, shared resources that enhance productivity or in other ways benefit a group of investigators working in areas related to the stated goals of the Core Center. A research core provides a service or resource that enables P30 investigators to conduct their independently funded individual research projects more efficiently or more effectively, and may through interaction with others, lead to new research paradigms and projects. A research core may also attract new investigators to an area of research by offering specialized services not easily duplicated in an individual laboratory. Research cores may provide for the sharing of technical expertise or the centralization of labor-intensive tasks common across several principal investigators, for the staffing, maintenance and training of shared equipment or resources, or for problem-solving through innovative technical solutions using state-of-the-art methodologies/technologies. Research cores should enhance the research in progress, consolidate resources, and/or contribute to cost effectiveness by providing a service at less cost or of higher quality than if each investigator were to attempt the same process(es) individually. The design and purpose of each research core may vary in how it serves its users. Cores may also vary in the provision of standard versus innovative services.

In addition to an administrative core, one or more research core(s) must be proposed. Each research core must have extensive use by a minimum of three R01s in NIDCD mission areas. Training grants (e.g., T32/F32), career development awards (e.g., K08/K23), small grants (R03), AREA grants (R15) and developmental/exploratory awards (R21) as well as non-NIH peer reviewed projects do not count as part of the requisite research base, but may be users of the P30. Established and junior investigators with expertise outside the NIDCD mission areas and desiring to transition into NIDCD mission areas are also encouraged to use P30 services, although they do not count toward the requisite three users.

Examples of research cores include the sharing of technical expertise (e.g., histology, automated brainstem response); the centralization of labor-intensive tasks (e.g., genotyping, human subject recruitment and database management); the staffing, maintenance and training of shared equipment or complex resources (e.g., confocal microscopy, electron microscopy, virtual reality

lab, sound field laboratory); and problem-solving through innovative technical solutions using state-of-the-art methodologies/technologies (e.g., engineering, imaging).

The administration of services and prioritization of user requests within each research core must be addressed and each research core must have a plan for quality control, when appropriate.

Limited developmental research (not including pilot studies) may also be an appropriate function of a research core if it is directly related to enhancing the functioning, utility or methodology of the core or if it is directly related to a user project and is not an undertaking that could be supported through other funding mechanisms.

IV. ADMINISTRATION

Organizational Description and Requirements

A Core Center should constitute an identifiable organizational unit within a single grantee institution or a consortium of cooperating institutions. The Core Center Director will be responsible for the organization and operation of the overall P30. The Director should provide scientific and administrative leadership for the total program, and have demonstrated ability to coordinate, integrate, and provide guidance in establishment of new research programs. The organization of the P30 Administrative Core should include a structure sufficient to coordinate and integrate the P30 activities, determine the distribution and utilization of funds, and provide advice to the Core Center Director about the activities of the P30.

While the final administrative structure of the P30 will, for the most part, be left to the discretion of the applicant, the effective development of a P30 requires close interaction among the Core Center Director, research core directors, the principal investigators of the funded grants utilizing the core, appropriate institutional administrative personnel, and other members of the institution in which the P30 is located. Therefore, each Core Center applicant should establish and describe an administrative structure that will permit the development of such interaction. This structure will be evaluated as part of the review process (see section VIII.C.).

Institutional Facilities

While facilities available for each research core will be described in the application, a more general description of overall facilities and a statement regarding institutional commitment to the Core Center should be included in the overall description.

Applications from institutions that have a General Clinical Research Center (GCRC) funded by the National Center for Research Resources (NCRR) at NIH may wish to identify the GCRC as a resource for conducting the proposed research. In such a case, a letter of agreement from

the Program Director of the GCRC should be included with application material in the Administrative Core. Collaborations among other NIH supported P30s are encouraged.

V. HUMAN SUBJECTS/VERTEBRATE ANIMALS and INCLUSION OF WOMEN, MINORITIES AND CHILDREN IN STUDY POPULATIONS

HUMAN SUBJECTS

All research cores involving human subjects at any time during the proposed project period must comply with the regulations for Protection of Human Subjects, 45 CFR 46. See PHS Form 398 for variations allowed by applicant organizations. For each core that involves human subjects and is not exempt from the regulations, address the six points listed in the Instructions for PHS 398.

In many instances, the research cores encompass research supported by research project grants for which the IRB review of human subjects is already complete or an exception is already designated. This review or exemption designation is sufficient, provided the IRB determines that the research is not substantially modified by the Core. The appropriate grants must be identified along with their IRB review dates or exemption designation (in Section 1: Budgets and Other Supporting Forms).

VERTEBRATE ANIMALS

If vertebrate animals are to be used in the project, the five items described under Section f of the PHS 398 research grant application instructions will be assessed. Evidence must be provided that each research core that involves vertebrate animals has been reviewed and approved by the Institutional Animal Care and Use Committee. For each research core that involves vertebrate animals, address the five points listed in the Instructions for PHS 398.

In many instances, the research cores encompass research supported by research project grants for which IACUC review is already complete. This review is sufficient, providing the research is not substantially modified by the core. The appropriate grants must be identified together with their IACUC review date (in Section 1: Budgets and Other Supporting Forms).

INCLUSION OF WOMEN, MINORITIES and CHILDREN IN STUDY POPULATIONS

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. 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 biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.

It is the policy of NIH that children (i.e. individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt data after October 1, 1998.

These policies may be accessed at the following sites:

Women and Minorities:

http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm

Children:

<http://www.nih.gov/grants/guide/notice-files/not98-024.html>

VI. PRE-APPLICATION PROCESS

Individuals from institutions with interest in applying for a P30 are strongly encouraged to discuss the potential application with the NIDCD staff members identified below. Potential applicants are encouraged to make this contact as early as possible in the application preparation process. A Letter of Intent listing the key participants, and providing a description of the currently funded research base as well as the proposed research cores, is requested at least one month prior to the submission date.

The program staff who should be contacted are:

Balance/Vestibular Program:

Christopher Platt, Ph.D.
Division of Scientific Programs, NIDCD
6120 Executive Boulevard, EPS 400C
MSC 7180
Bethesda, MD 20892-7180
Tel: (301) 496-1804
Fax: (301) 402-6251
Email: plattc@nidcd.nih.gov

Hearing Program:

Amy Donahue, Ph.D.
Division of Scientific Programs, NIDCD
6120 Executive Boulevard, EPS 400C
MSC 7180
Bethesda, MD 20892-7180
Telephone: (301) 402-3458
Fax: (301) 402-6251
Email: donahuea@nidcd.nih.gov

Smell/Taste Program:

Barry Davis, Ph.D.
Division of Scientific Programs, NIDCD
6120 Executive Boulevard, EPS 400C
MSC 7180
Bethesda, MD 20892-7180
Phone: 301-402-3464
Fax: 301-402-6251
Email: davisb@nidcd.nih.gov

Speech and Voice Program:

Lana Shekim, Ph.D.
Scientific Programs Branch
Division of Scientific Programs, NIDCD
6120 Executive Boulevard, EPS 400C
MSC 7180
Bethesda, MD 20892-7180
Phone: 301-496-5061
Fax: 301-402-6251
Email: shekiml@nidcd.nih.gov

Language Program:

Judith Cooper, Ph.D.
Division of Scientific Programs, NIDCD
6120 Executive Boulevard, EPS 400C
MSC 7180
Bethesda, MD 20892-7180
Phone: 301-496-5061
Fax: 301-402-6251
Email: cooperj@nidcd.nih.gov

For fiscal and administrative matters, contact:

Ms. Sara Stone
Grants Management Branch, NIDCD
6120 Executive Boulevard, EPS 400C
MSC 7180
Bethesda, MD 20892-7180
Telephone: (301) 402-0909
Fax: (301) 402-1758
Email: stones@nidcd.nih.gov

VII. APPLICATION FORMAT AND CONTENT

VII.A. General Information

The P30 application should include a description of the requisite research base and research cores. The application should provide descriptive information on how the cores will provide services to the individual R01s beyond what is currently available and/or how the cores will encourage and facilitate collaborative work. The application should also describe how each core will be administratively managed and how access and utilization of services will be prioritized.

The P30 application should be arranged in the format specified below.

The most current version of Form PHS 398 must be used. Individual cores should be prepared and written separately on Form PHS 398. The arrangement of materials should follow both the instructions in Form PHS 398 application kit and the more specific instructions detailed below. Applications not in accordance with P30 guidelines will be returned to the applicant without further review.

Submit a signed, typewritten original of the application, including the checklist, and five signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

In addition to mailing the application to the Center for Scientific Review, send two (2) copies of the application, plus five (5) sets of any appendices, to:

Chief, Scientific Review Branch
National Institute on Deafness and Other Communication Disorders
6120 Executive Boulevard, EPS 400C
MSC 7180
Bethesda, MD 20892-7180
Rockville, MD 20852 (for express/courier service)
Telephone: (301) 496- 8683

Applications requesting \$500,000 or more in direct costs for any year must include a cover letter identifying the NIDCD staff member who has agreed to accept assignment of the

application. This policy applies to all investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended or revised version of these grant application types. Additional information on this policy is available in the NIH Guide for Grants and Contracts, October 19, 2001 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html>.

VII.B. Content Order for Applications

Applications should be written in the style and within the page limitation described in the PHS 398 instruction kit and the applications guidelines below. Applicants may also consult with NIDCD staff concerning the technical aspects of preparing the application.

Face Page of Form PHS 398. Complete all items on the face page as directed. In the title block, item 1, put “Core Center.” Add “NIDCD Research Core Center P30” for the title.

Page 2: Describe the proposed Core Center indicating the goals and objectives of the research cores. Do not exceed the space allowed. Key personnel are the Core Center Director, Associate or Co-Center Director (optional), research core directors, participating investigators who will use any research core to a moderate or extensive degree, and consultants.

Table of Contents: Discard this page from Form PHS 398 and prepare a Table of Contents appropriate for the Core Center application. The Table of Contents should list 4 sections: *Section 1, Budget and Other Supporting Forms*, should include all budgets, biographical sketches, other support, human and animal assurances table; *Section 2, Biomedical Research Base*, should include the general overview of the P30, and presentation of the research base; *Section 3, Administration*, should include the administrative structure, facilities and equipment, floor plans and/or campus maps, and letters of institutional commitment and support; and *Section 4, Research Cores*, should include a brief overview of the research cores, followed by separate sections using PHS 398 for each research core. Each core should be listed by the title. Specifically list the location of the checklist, which is the last page of the application. If appendices are to be included, these should be listed in *Section 5, Appendices*.

VII.B.1. Budgets and Other Supporting Forms

(The following budget information applies to *Section 1: Budgets and Other Supporting Forms* as well as *Section 4, Research Cores*, since there will be budget information in both.)

Budget: Use Form Pages 4 and 5 in PHS Form 398 for all budgets. Justify and document all costs for current and future years throughout. Details and justifications for all budget items below must be part of the individual budgets. See the Instructions for PHS 398 on how to prepare budget pages and justifications. A modular budget format is not allowed.

The overall Core Center budget, “Summary Center Budget,” is to be presented first using PHS 398 Form Page 4 entitled “Detailed Budget for Initial Budget Period” (see sample document 1). Presentation of a consolidated budget for the first 12 months should then follow in a tabular form, providing information on budgetary categories for the administrative and each of the research cores (see sample document 2). Form Page 5 of PHS 398, “Budget for Entire Proposed Period of Support”, should follow next, summarizing all individual budgets and administrative costs (see sample document 3). For the purpose of establishing future year budget requests, the applicant should not exceed cost escalations specified by the NIH. Future years may not exceed the cap.

Separate budget pages and justifications for the overall Core Center administration and for each individual research core initial year and 5 year composite, should be included later in the application with each individual core for which funding is sought and should not be repeated elsewhere in the application. The potential for budgetary overlap between the user research projects and the P30 cores, specifically overlap of personnel effort, as well as all other expenditures, must be discussed. In some instances, overlap will be minimal. In others, budgetary overlap could be considerable. Specifically address the strategies for deciding what expenses will be charged to the P30 versus the participating research grants. A statement should be provided indicating how budgetary expenses for the user R01s or any other funding mechanisms with potential overlap, will/will not be modified upon receipt of the P30 award. If appropriate, a strategy for reimbursement of core services should be delineated. NIDCD program and grants management staff will negotiate with both the P30 Director and the Principal Investigator of ongoing research project grants utilizing P30 facilities regarding potential budgetary overlap.

Personnel: The P30 Director will have responsibility for overall direction of the entire P30. Additionally, a director should be named for each research core. A research core director must have the scientific expertise and leadership skills necessary to be the primary decision-maker for the management and conduct of the core, both technical and administrative. The percent effort for a research core director is expected to be relatively low (5 to 10%). In the unusual circumstance that a core director requests greater than 10% effort, it should be justified through activities beyond typical administrative functions. Additional levels of commitment beyond 10%, supported by the university and not requested from the NIDCD, should be noted in the application as institutional commitment (section VII.B.3. Administration).

Limited support for administrative staff may be requested to the extent that it relates directly to the management of P30 activities. Justification for administrative support should fully describe the duties to be performed. This justification will be closely scrutinized, as efficient administration is expected.

Support for technical personnel or positions to be filled in research cores may be included. The time and salary of all technical and support personnel must be related to their effort on the

research core. Technical support personnel may receive up to 100% salary support from the P30.

Equipment: Although this grant mechanism is not intended for the acquisition of equipment which should be funded through other sources or through other funding mechanisms (e.g., NCRR Shared Instrumentation Grant), equipment requests are allowed. When expensive items of equipment are needed, the application should document available equipment within the institution and provide clear justification for requested equipment in terms of core service to be provided. In addition, the potential for cost sharing must be explored prior to the application submission and the results of such exploration (i.e., institutional commitment demonstrated through cost sharing) must be clearly stated in the application.

Supplies: Consumable supplies directly related to the operation of the cores (photographic supplies, electronics parts, machine shop stock, tissue culture media, glassware, chemicals, animals, etc.) are allowed.

Travel: Appropriate travel requests include travel of scientific, technical, or administrative staff for training that would enhance the quality, conduct or utilization of a research core or travel required to maintain the operation of a core. However, this training must take place in a focused, active intensive training session or a specific course or workshop, as opposed to a session at a national meeting or the equivalent. This grant mechanism is not intended for the travel for scientific speakers for departmental seminars unless it is directly and explicitly related to the enrichment of core services.

Consultant Costs: Consultant costs may be requested.

Other Expenses: Equipment maintenance, maintenance contracts, and computer time are examples of the many types of allowable costs.

Consortium/Contractual Costs: Funds may be requested. Indirect costs on subcontracts are included as portion of the direct costs of the application and are subject to the cap. Subcontracts to foreign organizations are not allowed.

Items not allowed: Funds for alteration and renovation, rental space, staff retreats, direct support of individual research projects, direct support for pilot studies, salary and support for central institutional administrative personnel or secretarial support that is usually paid from institutional overhead charges, travel of investigators, or page and publication charges for staff investigators are not allowed.

Biographical Sketches: Biographical sketches are required for key professional personnel, which includes the Core Center director, and research core directors (including consultants) in the Core Center application. Biographical sketches are also required for the principal

investigator of each grant listed in the research base. Forms from the most recent version of PHS 398 should be used. Place individual sketches in alphabetical order. These pages should not be duplicated in the individual research cores.

Other Support and Research Base Summary: Other support should be listed for all individuals listed in the Key Personnel section, with the exception of consultants. These pages should not be duplicated in the individual component projects and cores.

Assurance Documentation: A master table listing the status of human subject and animal usage approval dates should be included.

VII.B. 2. Biomedical Research Base of the Core Center

This section is presented on continuation pages in narrative fashion.

General Overview of the Core Center: The goals and objectives of the Core Center should be explicitly stated. This section should not exceed two single-spaced pages, should state concisely any areas of special interest, and should identify any research ideas, disease entities, and target populations to be studied. Applicants will include an overview of current research conducted at their institution in sufficient detail to allow reviewers to judge its extent and the interrelationships of ongoing research. Interrelationships among Center members, quality and productivity of the research programs, demonstrated or potential interdisciplinary coordination, and how establishment of a Core Center will further extend, stimulate and provide added dimensions to the current research activities are all important considerations for review and subsequent funding.

Presentation of the Research Base: Begin with an abstract, no longer than half a page, summarizing the research base. This should be followed by a section, not to exceed 5 pages, addressing the scientific focus and demonstrated or potential collaborations/interrelations of research conducted by Core Center investigators. Research projects included in the research base should be grouped into aggregates of projects with similar overall goals and objectives since an assessment of the research base is important as a primary criterion in the evaluation of applications. Since most, if not all, of the research base will have undergone separate peer review, the quality of the individual funded projects is already established. The more important aspects will be: (1) interactions and interrelationships of the research efforts; (2) uses and benefits of core services; and (3) plans to continue/develop productive collaboration among Core Center investigators. Documentation of a collaborative environment may be included here (listing of co-authored publications from P30 user PIs).

Size of the Research Base. To document the research base of the proposed Core Center, a table listing the funding mechanism and grant number, funding source, PI name and grant title, percent effort of the investigator, award duration, and annual support (direct cost) is required. A

total current year direct cost dollar amount for research grants in the research base of the P30 must be provided.

VII.B.3. Administration

Administrative activities of the overall P30 that are not contained in the separate research cores (e.g., Core Center Director percent effort) should be presented as a separate Administrative Core. Presentation of the administrative structure (See Section IV) should follow the presentation of the research base and should include a discussion of the Director and if designated, Associate Director, as well as the relationship and lines of authority and sanction by appropriate institutional officials. Administrative costs for the P30 are intended to be minimal. Thus strong justifications for administrative costs must be provided.

Provide a general overall description of facilities and institutional commitment including letter(s) of institutional commitment and, if applicable, of the General Clinical Research Center (GCRC) Director. The description of the physical arrangements and instrumentation for the cores should be included. Campus maps and floor plans of space for the P30 cores may be helpful in some instances.

Institutional commitment to provide space or to share in the cost of purchasing equipment needs to be documented. Core Centers are encouraged to enter into cooperative arrangements with established P30 cores in other centers or resource grants offering a similar type of service at the applicant institution.

VII.B.4. Research Cores

Overview: Introduce this section with a narrative overview of all of the proposed research cores and their impact on ongoing research. The purpose of each research core may vary, such as providing increased efficiency for routine ongoing services, promoting or enhancing new or ongoing collaborations, and/or providing new and innovative resources or services currently unavailable. The justification will likely vary based on the purpose.

Research Cores: (See Section III) Present each core separately using Form PHS 398 with an abstract and research plan that includes all the items in PHS 398. Instructions specific to the P30 follow below. The presentation for each research core (sections 4 – 8 below) is limited to 25 pages. It may not be necessary to use all 25 pages.

(1) Summary page: Use PHS Form 398 Form Page 2.

(2) Budget: Provide comprehensive justifications for the budget and discuss issues of overlap and accounting strategies for future expenses, as well as mechanisms for reimbursing core services, if appropriate.

(3) Resources and Environment: Special attention should be given to describing the space and resources available for the core service(s) proposed. The location of the core services performance sites and the physical relationship of the core resources to the core users should be included.

(4) Specific Aims: Describe the broad, long-term objectives and goals of the core and delineate the services to be provided.

(5) Background and Significance: State the reasons why a core is needed. This justification should include (a.) how the core will provide increased or innovative/new capabilities, (b). how the core will facilitate increased productivity or effectiveness through the sharing of expertise or the centralization of labor-intensive tasks, and/or (c.) how the core will facilitate collaborative or new research directions. These must be justified beyond what is currently available through R01 support. For all user R01s, articulate how the core services will likely benefit the research accomplishments within each R01, and if appropriate, how the core services may enhance collaborative research efforts for that R01 or attract new investigators into the area. The ability to articulate user benefit is a critical factor in review. Both major and minor users of the core should be included.

A minimum of three funded-investigator users does not in itself provide sufficient justification. A larger number of NIDCD-funded investigators using each core to a moderate or extensive degree would generally strengthen the justification. In the event that a proposed research core is not in use 100% of the time, the application must justify this circumstance.

A table should be provided to describe the projected use (both period of core use and degree of use: minimal, moderate, extensive) of the proposed core by funded investigators.

(6) Prelim Studies/Progress Report. (This section should primarily be used for competing renewals or competitive supplements). For new applications, this section will likely be shorter than in an R01 application and may include examples of previous/ongoing services/techniques that have provided increased productivity within the research environment. Competing continuation applications should document the impact the Core Center has had (see section VII.B.8). Accomplishments, shared resources, new collaborations, and other outcomes of the core should be documented. Information on core usage and information on core benefit to the scientific research enterprise should be discussed. Specific problems in core administration and management should also be noted.

(7) Research Design and Methods: Each proposed technique or service should be described in enough detail to allow a comprehensive evaluation. Are personnel and equipment in place to provide the services? Existing methodologies already in use at the institution may be very briefly described. Methodologies new to the institution should be described in greater detail and strategies for successful implementation should be delineated. Include any developmental

methods research or training, if proposed. If applicable, include sections on quality control. Separate sections on gender, minority and children inclusion should be included as appropriate, in addition to Human Subjects/Vertebrate Animals (see PHS 398 Instructions). If not applicable, mark them N/A.

(8) Administration and Organization: The administration, organization and proposed management of the core should be included and is a critical issue in review of the application. A plan to implement core services and prioritize investigator use should be presented. If the core is used to train investigators in special techniques, the nature and extent of this training should be described and the qualifications of core personnel to provide and oversee this training should be described.

(9) Literature Cited and (10) Consortium/Contractual Arrangements: If not applicable, mark them N/A.

VII.B.5. Appendices

Appendices may be submitted with P30 applications to the NIDCD. If such materials are submitted, they should be mailed separately from the application and sent directly to the NIDCD Scientific Review Branch at the address listed in Section VII.A. Include key reprints and other supporting material. See PHS 398 Instructions. Different sections of the P30 application may be reviewed by different reviewers, thus each piece of appendix material should be labeled with the name of the Center Director and the title of the research core to which it belongs.

All appended material must be packaged and clearly identified with the appropriate research core. No more than ten reprints or manuscripts accepted for publication may be submitted for any research core. Five complete and collated sets of Appendix material must be received by the NIDCD Scientific Review Branch within three weeks of the submission of the P30 application.

VII.B.6. Revised Applications

All revised applications must have an introduction which addresses the criticisms from the previous review and notes changes made in the application. Do not exceed two pages of introduction for the overall P30 and three pages of introduction per core. All changes in the research plan must be clearly marked, per PHS 398 instructions.

VII.B.7. Supplemental Applications

A competitive supplemental application requesting the addition of a research core(s) to an existing P30 is allowed, but may not exceed the term of award or budgetary cap of the parent

P30. These applications are due on the standard NIH receipt dates (February 1, June 1, and October 1), and must be in accordance with all previously outlined P30 criteria. NIDCD program staff should be contacted as early as possible to determine eligibility.

Supplemental applications should include a brief overview of the administrative structure and research base of the parent P30 (this could be sections from the original application), as well as a brief overview of the currently funded cores. Reviewers will evaluate the supplemental core in the context of the overall P30 and the appropriateness of administrative oversight. This should precede the information for the individual research core(s) requested.

VII.B.8. Competing Continuation Applications

In a competing continuation application, the application should document the impact the Core Center has had. This includes the qualifications, experience, and commitment of the Core Center investigators and their proven ability to interact with each other and attract additional investigators to the mission areas of the NIDCD. Include a general progress report that highlights achievements under the Core Center since the last competitive review.

Include the following information:

(1) A summary of major accomplishments that can be attributed to the Core Center program and a brief explanation of how these accomplishments have contributed to the achievement of the stated objectives of the grant. Such achievements may include significance of the contribution of products and services from these individual cores to the research base; evidence that the Core Center shared resources effectively and efficiently; the extent of core utilization by individual principal investigators associated with the research base; effectiveness of the Core Center in facilitating collaborations or helping to attract investigators to communication disorders research; and the ability of the individual cores, and overall Core Center, to provide a significant advantage beyond what could practically or efficiently be supported on individual research grants.

(2) A list of all publications, including those in press, that have resulted from the Core Center grant. Do not include manuscripts in preparation or under review.

(3) Any data sharing activities undertaken as part of the P30.

(4) Any other information that is considered attributable to the use and conduct of the P30.

VIII. REVIEW PROCEDURE AND CRITERIA

VIII.A. Review Process

Applications for P30 grants will undergo an initial examination for completeness by the Center for Scientific Review and for responsiveness by NIDCD staff. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration. Applications that are complete and responsive will be evaluated for scientific and technical merit in accordance with the standard NIH procedures by an initial review group (IRG) convened by the NIDCD. As part of the initial review, all applications will be discussed and receive a written critique and will receive a second level of review by the NIDCD Advisory Council.

As part of the initial scientific review, reviewers will rate each individual research core as well as the overall P30; the scores will appear in the summary statement. Since the NIDCD is interested in funding only the best research cores, individual cores of lesser quality (for example, those falling below the score of fundable P30 applications) may not be funded, even if recommended, under the “umbrella” of the P30 grant application.

Each individual core must fit in and contribute to the overall P30 and each application should be complete at the time of submission. Site visits are not anticipated as part of the review process.

VIII.B. Review Criteria for Individual Research Core

Individual research cores are evaluated on the facilities/services provided, their utility, and their ability to fulfill the goals of the Core Center program. Important factors include:

- Significance of the core support to the research base. How the core will support and enhance ongoing research projects beyond currently available resources.
- The potential of the core to promote collaborative research and/or attract new investigators to research in communication disorders.
- The potential of the core to provide enhanced or increased efficiency of services.
- The potential of the core to offer services that are new, unique or otherwise unavailable on individual R01s.
- The administrative management of the core, including implementation, allocation, user prioritization, quality control and utilization of services.
- Training and appropriateness of the core director and personnel, the commitment of the investigators, and the ability to devote the required time and effort to the core.
- Adequacy of the facilities, equipment and institutional commitment to the core.

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

- The adequacy of plans to include children, both genders, minorities, and their subgroups, as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.
- The reasonableness of the proposed budget and duration in relation to the proposed research.
- The adequacy of the proposed protection for humans, animals or the environment, to the extent they may be adversely affected by the project proposed in the application.

VIII.C. Overall Core Center Evaluation

An overall priority score will be assigned to the application. The score will reflect not only the quality of the individual cores, but also plans for leadership and administration, and how the proposed Core Center will enhance the research base.

The following elements will be evaluated:

Leadership and Administration:

- The plans for coordination of ongoing research between the separately funded projects and the Core Center including mechanisms for internal monitoring.
- The plan for the establishment and maintenance of internal communication and cooperation among the Core Center investigators.
- Appropriate scientific and administrative leadership, and the time commitment of the Core Center Director for the effective management of the Core Center program.
- The management proposed for fiscal administration, procurement, property and personnel management, planning, budgeting, etc.
- The overall environment for a Core Center. This includes the institutional commitment to the program, lines of accountability regarding management, and the institution's partnership with the Core Center. This also includes the academic environment and resources in which the activities will be conducted, such as the availability of space, equipment, facilities, and the potential for interaction with scientists from other departments and schools.

Research Base and Enhancement by the Core Center

- The relevance and interrelation of these separately funded research projects to the central themes of the Core Center.
- The likelihood for new or enhanced collaborations among Core Center investigators. This includes demonstrated interactions and interrelationships of the research efforts as well as

plans to further develop productive interdisciplinary collaborations among Core Center investigators.

- Ability of the Core Center to significantly enhance (further extend, stimulate and provide added dimension to) the established research base of the host institution.

VIII.D. Supplemental Application Evaluation

For supplemental applications, reviewers will rate each individual research core and the score will appear in the summary statement. The appropriateness of administrative oversight will also be evaluated and scored as an integral part of each supplemental core.

Appropriateness of Administrative Oversight

The overall Core Center administration will have been previously reviewed, and approved by NIDCD staff. The following elements will be evaluated:

- Plans for coordination of ongoing research between separately funded projects and the supplemental core.
- Plans for the establishment and maintenance of internal communication and cooperation with the existing Core Center investigators (demonstrated interaction as well as plans to further develop productive interdisciplinary collaborations).

Review Criteria for Individual Research Core

The review criteria for individual research cores in supplement applications are the same as for the individual cores of the parent P30 (See section VIII.B.).

VIII.E. Competing Continuation Applications

A competing continuation application should document the impact the Core Center has had. This includes the qualifications, experience, and commitment of the Core Center investigators and their proven ability to interact with each other and attract additional investigators to the mission areas of the NIDCD. In addition to the previously stated criteria, reviewers will consider the following:

- Significance of the contribution of products and services from these individual cores to the research base.
- Evidence that the Core Center shared resources effectively and efficiently. The extent of core utilization by individual principal investigators associated with the research base.
- Effectiveness of the Core Center in facilitating collaborations or helping to attract investigators to communication disorders research.
- Ability of the individual cores, and overall Core Center, to provide a significant advantage beyond what could practically or efficiently be supported on individual research grants.

IX. SHARING RESEARCH DATA

NIH reaffirms its support for the concept of data sharing (http://grants.nih.gov/grants/policy/data_sharing) and believes that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. The NIH endorses the sharing of final research data to serve these and other important scientific goals. The NIH expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers. Applicants are encouraged to include data sharing plans as part of the P30 application.

Reviewers will not factor the proposed data-sharing plan into the determination of scientific merit or priority score. Program staff will be responsible for overseeing the data sharing policy and for assessing the appropriateness and adequacy of the proposed data-sharing plan.

X. REPORTING REQUIREMENTS AND ANNUAL EVALUATION

Annual progress reports, submitted as part of the annual noncompeting continuation application are due two months before the anniversary date of the award. These reports are used by the NIDCD and advisory committees to review the Core Center and its progress. A progress report containing the following information is to be submitted with the annual continuation application (PHS Form 2590).

The report should include a detailed summary of each research core, including a listing of the Core Center Director and key personnel with percent effort, budgets, and a description of each core's progress and activities. It is especially important that the significance and utility of each research core be discussed in the summary description.

The following are required:

1. A budget of the requested funds for each research core. In conjunction with the programmatic description, this report will describe allocations in the usual budget categories (e.g., personnel, supplies) as well as the total expenditures. Separate budget pages should be used for each research core in addition to a composite budget for the entire Core Center. With the exception of the administrative core, it is allowable to request a redistribution of funds for individual cores different than in the original application. Such reallocations across cores should be clearly stated and justified in the budget section;
2. An updated table (same format as original application) showing all support associated with the Core Center. The table should list the funding mechanism and grant number, funding source, PI name and grant title, percent effort of the investigator, award duration, and annual support (direct cost) is required. A total current year direct cost dollar amount for research grants in the research base of the P30 must be provided. This table should include all individual research

grants, center grants, training grants, National Research Service Awards, career development awards, etc. that are currently users of the core.

3. An overall discussion of the effectiveness of the P30 in furthering the goals as proposed. This should include a summary of the general accomplishments that can be attributed to the P30. This should also include a discussion of any problems that impeded the accomplishment of the stated goals of the P30. The section should address the administration and conduct of the P30 and address organizational issues within the institution that have impact on the P30, both positive and negative.

5. A summary (equivalent to no more than 4 single-spaced pages) of the goals and significant activities of each individual research core. List specific accomplishments or gains seen from use of the core. List what has been accomplished and what would not have been done without it; e.g., new research findings, new investigators brought to the field, efficiency of services, tables of usage, etc.

6. A list of all collaborative efforts that the Core Center has established and is conducting with other institutions/Core Centers. This list should include a description of each activity, identification of the other Core Center(s) involved, and any results obtained so far;

7. Other information that, from year-to-year, may be requested by NIDCD staff.

The expanded progress report is in addition to, and does not replace, other management reports required by PHS policy. In addition to the annual progress report, NIDCD program staff may conduct site visits to gain added insight into the various aspects of the P30 operations.

XI. SAMPLE DOCUMENTS

Sample I. Detailed Budget for Initial Budget Period (Form page 4)

Sample II. Consolidated Budget for First Year (Table Form)

Sample III. Budget for Entire Proposed Period of Support (Form page 5)