



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

Division of Research Infrastructure

Institutional Development Award (IDeA) Program

Program Guidelines

**IDeA Centers of Biomedical Research
Excellence (COBRE)**

**IDeA Networks of Biomedical Research
Excellence (INBRE)**

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INSTITUTIONAL DEVELOPMENT AWARD (IDEA) PROGRAM
PROGRAM GUIDELINES

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INSTITUTIONAL DEVELOPMENT AWARD (IDeA) PROGRAM

PURPOSE

For many years, NIH has used the Institutional Development Award (IDeA) Program to make a special effort to stimulate research at educational institutions that traditionally have not received significant levels of competitive research funding from NIH. In FY 1998, investigators from the 23 eligible IDeA states and Puerto Rico accounted for only eight percent of the total number of NIH research grant applications, most likely because there are too few investigators trained to conduct biomedical research in those states.

The IDeA Program broadens the geographic distribution of NIH funding for biomedical and behavioral research, fosters health-related research, and enhances the competitiveness of investigators at institutions located in states in which the aggregate success rate for applications to NIH has historically been low, by increasing the competitiveness of investigators through support for faculty development and enhancement of the research infrastructure at institutions located in the currently eligible 23 states and Puerto Rico.

ELIGIBILITY

Fiscal Year 2007 eligibility is limited to those states that attained a success rate of less than 20 percent in obtaining NIH grant awards or received less than an average of \$120 million in NIH grant funds over the five-year period, 2001-2005. Based on these two criteria, the following 23 states and Puerto Rico are currently eligible:

Alaska	Kansas	Montana	North Dakota	South Dakota
Arkansas	Kentucky	Nebraska	Oklahoma	Vermont
Delaware	Louisiana	Nevada	Puerto Rico	West Virginia
Hawaii	Maine	New Hampshire	Rhode Island	Wyoming
Idaho	Mississippi	New Mexico	South Carolina	

OVERVIEW

The two main components of the IDeA Program are: Centers of Biomedical Research Excellence (COBRE) which augment and strengthen institutional biomedical research capabilities by expanding and developing biomedical faculty research capability through support of a multidisciplinary center, led by a peer-reviewed, NIH-funded investigator with expertise central to the theme of the grant proposal; and IDeA Networks of Biomedical Research Excellence (INBRE) which enhance biomedical research capacity, expand and strengthen the research

capabilities of biomedical faculty, and provide access to biomedical resources for promising undergraduate students throughout the eligible states.

CENTERS OF BIOMEDICAL RESEARCH EXCELLENCE (COBRE)

NCCR's Centers of Biomedical Research Excellence (COBRE) support thematic multidisciplinary centers that augment and strengthen institutional biomedical research capacity by expanding and developing biomedical faculty research capability and enhancing research infrastructure, including the establishment of core facilities needed to carry out the objectives of a multidisciplinary, collaborative program.

COBREs are expected to grow through the promotion of collaborative interactive efforts among researchers with complementary backgrounds, skills, and expertise; and to compete independently for external peer-reviewed center or program project grant support. In some instances, COBRE support will facilitate the development of new disease-specific research centers or augment the capability of existing centers.

Each COBRE includes:

- a principal investigator who is an established biomedical or behavioral research scientist with expertise central to the research theme of the center, has an active research laboratory, relevant peer-reviewed funding, and has demonstrated administrative leadership and mentoring experience;
- three to five individual research projects – each supervised by a single junior investigator – that stand alone but share a common thematic scientific focus; and
- at least one mentor for each junior investigator, and a development and mentoring plan addressing how the junior investigators will transition to competitive grant support from NIH Institutes and Centers or other Federal or non-Federal agencies or organizations.

IDeA NETWORKS OF BIOMEDICAL RESEARCH EXCELLENCE (INBRE)

NCCR's IDeA Networks of Biomedical Research Excellence (INBRE) promote the development, coordination, and sharing of research resources and expertise that will expand the research opportunities and increase the number of competitive investigators in the IDeA-eligible states.

INBREs are intended to enhance the caliber of scientific faculty at research institutions and undergraduate schools, thereby attracting more promising students to these organizations. INBRE is the second phase of the Biomedical Research Infrastructure Networks (BRIN) Program, which began by providing planning grants in 2001.

Each INBRE grantee establishes a multidisciplinary research network with a scientific focus that will:

- build and strengthen the lead and partner institutions' biomedical research expertise and infrastructure;
- build and increase the research base and capacity by providing research support to faculty, postdoctoral fellows, and graduate students at the participating institutions;
- provide research opportunities for undergraduate students and serve as a "pipeline" for undergraduate students to continue in health research careers within IDeA states;
- provide outreach activities to students at undergraduate institutions, community colleges, and tribal colleges participating in the state's network; and
- enhance science and technology knowledge of the state's workforce.

CENTERS OF BIOMEDICAL RESEARCH EXCELLENCE (COBRE)

PURPOSE

The Centers of Biomedical Research Excellence (COBRE) program is one of the approaches taken by the National Center for Research Resources (NCR) to implement the Institutional Development Award (IDeA) Program. COBRE awards are made to support investigators at independent biomedical research institutions, or biomedical research institutions that award doctoral degrees in the health sciences or sciences related to health, within IDeA-eligible states. Collaboration with other non-doctoral degree-granting and research-performing institutes or institutions is encouraged.

RESEARCH OBJECTIVES

The COBRE program seeks to promote the initiation and implementation or expansion of unique, innovative, state-of-the-art biomedical and behavioral research at institutions in IDeA-eligible states. The research focus of this program cuts across the full spectrum of the basic, translational, and clinical sciences (e.g., cellular and molecular biology, biophysics and biotechnology, genetics and developmental biology, pharmacology, *et cetera*). NIH recognizes that the contributions that the institutions in IDeA-eligible states can make are important and essential in fulfilling the promise of the NIH research agenda.

The objectives of the COBRE program are to strengthen an institution's biomedical research infrastructure through the establishment of a thematic multi-disciplinary center, and to enhance the ability of investigators to compete independently for complementary NIH individual research grants or other external peer-reviewed support. Since a significant part of the COBRE program is to build and develop thematic multi-disciplinary research centers, it is expected that progress will be made toward establishing centers that can compete independently for external peer-reviewed center or program project grant support. In some instances, Centers may be more effectively maintained by the Centers' investigators collectively competing for individual investigator-initiated research support.

ELIGIBILITY REQUIREMENTS

An eligible institution must be within an IDeA state, and be either a domestic, public or private, or non-profit research institution that awards doctoral degrees in health sciences or sciences related to health, or an independent biomedical research institute.

Applications are accepted from eligible institutions that hold two or less active COBRE awards. Eligible institutions that do not hold a current COBRE award are encouraged to apply. Please note that applications will NOT be accepted from institutions that hold three or more active COBRE awards; these institutions cannot submit applications.

Applications are encouraged from veterinary and dental schools in IDeA states. Veterinary and dental school components of institutions are treated as separate eligible entities and are allowed to submit applications in addition to the parent institution.

No eligible institution, including veterinary and dental schools, can submit more than one application per fiscal year. Multiple applications received from these institutions or applications received from ineligible institutions (those that hold three or more active COBRE awards) are not reviewed. If an institution is planning more than one application, it is the responsibility of that institution to appoint a steering or selection committee to decide which single application to submit.

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their 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.

MECHANISM OF SUPPORT

The administrative and funding instrument for COBRE is the P20 exploratory grant award mechanism.

Responsibility for planning, directing, and executing a proposed project is solely that of the applicant. All current policies and requirements that govern the research grant programs of NIH will apply to grants awarded for COBRE.

An applicant may request a project period of five or fewer years and a budget for direct costs of up to \$1.5 million/year, excluding F&A costs on consortium arrangements.

FUNDS AVAILABLE

An applicant may request a project period of five years and may request a budget for direct costs of up to and no more than \$1.5 million per year, excluding facilities and administrative (F&A) costs on consortium arrangements. The applicant may also request additional direct costs – in year one only – of up to \$500,000 as a one-time expenditure for Alteration and Renovation of laboratory or animal facilities. If Alteration and Renovation costs are requested, then the total budget request for year one must not exceed \$2 million in direct costs, excluding F&A costs on consortium arrangements. Regardless whether Alteration and Renovation costs are requested, budget requests for years two through five cannot exceed \$1.5 million per year, excluding F&A costs on consortium arrangements.

Funds may be used to develop Offices of Sponsored Programs or to recruit additional faculty who complement the scope of the proposed program. Recruitment funds are limited to \$200,000 per year for each position. These funds may be used for salary, supplies, and/or equipment costs.

The Principal Investigator (PI) must communicate plans for the expenditure of funds for recruitment purposes to the NCCR for Programmatic Review.

FUNDING RESTRICTIONS

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 continuation award if such costs are necessary to conduct the project, and 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 continuation 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 (NIH Grants Policy Statement; http://grants.nih.gov/grants/policy/nihgps_2003/nihgps_part6.htm).

COST SHARING OR MATCHING

This program does not require cost sharing as defined in the current NIH Grants Policy Statement. The most current Grants Policy Statement can be found at: http://grants.nih.gov/grants/policy/nihgps_2003/index.htm/

PROGRAM CHARACTERISTICS

Each COBRE has to have a thematic science focus in one research area – such as neuroscience, cancer, structural biology, immunology, or bioengineering – and may use basic, translational, and/or clinical research approaches to attain its goals. The scientific leadership provided by one or more established biomedical research faculty is critical to the success of this initiative, especially for the mentoring of promising junior investigators. The Center is intended to support investigators from several different disciplines, thereby developing a critical mass of investigators who will enhance competitiveness in a research area, and increase success in competing for other complementary NIH research grant support. It is also anticipated that, in some instances, the support through this initiative will facilitate the development of new disease-specific research centers, or augment the capability of existing centers.

Essential elements for the COBRE include a Principal Investigator/Magnet Investigator, core laboratory (ies), new faculty recruits, and an external advisory committee.

The prime objectives of this program are accomplished by supporting a magnet investigator to serve as mentor to the junior investigators, and by supporting three to five research projects with a thematic science focus. The Principal Investigator enhances the ability of the institution(s) to compete for complementary NIH individual research grant support, and serves as a mentor for more junior faculty at the institution(s). This initiative is not intended to replace the support for ongoing, investigator-initiated research programs of established investigators, and the investigator of a pilot project must submit one or more investigator-initiated external peer-reviewed grant applications at the end of three years in order to receive continued support for the fourth and fifth years.

Collaboration with other non-doctoral degree-granting and research-performing institutes or institutions is encouraged. However, funds for research activities cannot be used at collaborative institutions in non-IDeA states.

Each COBRE must include an External Advisory Committee (EAC) comprising scientists with national scientific reputations in their fields and expertise directly relevant to the scientific theme of the respective COBRE.

The EAC critiques the scientific progress of the COBRE and also offers advice on scientific matters to the COBRE PI. The EAC activities include developing and planning concepts and programs, encouraging and assisting faculty development and mentoring, identifying resources, evaluating the development of the Center, evaluating the progress of the individual research projects, and evaluating the junior investigators' progress toward acquiring independent status. The PI shares the advice and critiques provided by the EAC with other COBRE investigators at the Center. The EAC also reviews and recommends candidate investigators for replacement/substitute projects, as required, before such requests are forwarded to the NCRR for Programmatic Review. The EAC must meet at least twice per year. Video-, teleconferencing or other means may be used in situations where it would be difficult to hold an in person meeting. A summary of the issues discussed at each EAC meeting, recommendations made, and actions taken must be included in the yearly progress reports submitted to the NCRR.

PRINCIPAL INVESTIGATOR (PI)

COBREs are expected to engage in future growth through the promotion of collaborative interactive efforts among researchers with complementary backgrounds, skills and expertise, and to compete independently for external peer-reviewed center or program project grant support. This goal is accomplished through the direction provided by a PI who provides leadership to junior investigators, and has the primary responsibility for administering the program and for overseeing the development of the Center and its associated core facilities. The PI must be an established biomedical or behavioral research scientist who has demonstrated the administrative abilities to effectively carry out the objectives of the COBRE program and meet its goals; has an active research laboratory and relevant peer-reviewed funding (either NIH, NSF or other Federal or non-Federal investigator-initiated support); and has the administrative leadership and mentoring experience needed to effectively carry out the objectives of the COBRE program and

to meet its goals. A minimum time commitment of 25 percent is required for the PI. However, up to 50 percent effort will be supported for mentoring and administrative oversight of the COBRE. If the PI is not in place at the institution at the time of review or award, a plan to recruit such an individual must be included in the application that will result in having that individual on the full-time faculty within one year of the peer-review of the institution's application. An award will not be made until the institution has appointed a permanent COBRE PI.

ALLOWABLE COSTS

FACULTY

Funds may be used for faculty expansion (i.e. recruitment of additional faculty who complement the scope of the proposed program) up to \$200,000 per year for each position. These funds may be used for salary, supplies, and equipment costs.

MEETINGS

The COBRE project should budget for an annual two-day meeting in Bethesda, Maryland with NCRR staff.

CONSORTIA

Facilities and Administration (F&A) costs for consortium organization(s) are excluded from the limit on the amount of direct costs that can be requested for the entire application. Applicants are encouraged to review the *NIH Grants Policy Statement* for policy and procedures applicable to consortium agreements.

RENOVATIONS

Alteration and Renovation (A&R) costs to improve existing research laboratories or animal facilities are allowed.

UP-TO-DATE INFORMATION

All potential applicants and grantees must ensure they have the latest information about the IDeA and COBRE programs by visiting the IDeA and COBRE Web pages (http://www.ncrr.nih.gov/research_infrastructure/ and http://www.ncrr.nih.gov/research_infrastructure/institutional_development_award/centers_of_biomedical_research_excellence/).

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps_2003/index.htm).

APPLICATION PROCEDURES

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Number and title of the announcement to which the applicant is responding

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review. The letter of intent is to be sent by the date, and to the person, listed in the relevant announcement.

GENERAL INFORMATION

Applications must be prepared using the most current approved version of the PHS 398 research grant application instructions and forms, following standard instructions except where modified according to the COBRE announcement in response to which the application is being submitted. The PHS 398 application instructions are available in an interactive format at: <http://grants.nih.gov/grants/funding/phs398/phs398.html>.

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 should be entered on line 11 of the face page of the PHS 398 form. The D&B number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dnb.com/us/>.

The title and number of the funding opportunity must be typed on line 2 of the face page of the application form and the YES box must be checked.

For further assistance, contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov. Telecommunications for the hearing impaired: TTY 301-451-0088.

SUBMISSION REQUIREMENTS

An application for a COBRE award must include the following:

- A clear and full explanation of the necessary administrative, fiscal, and scientific aspects of the proposed COBRE.

- A research plan for five years that describes the organization and component functions of the COBRE. The plan should demonstrate the applicant's knowledge, ingenuity, practicality, and commitment to developing and maintaining a significant and productive research program.
- A description of and justification for the proposed individual research projects and core service facilities that collectively will contribute to the Center. Applicants should ideally propose at least three and up to five meritorious individual research projects and must describe the nature and scope of any scientific research collaborations
- A description of the research and research training or career development goals and capabilities of the proposed COBRE.
- A description of the infrastructure for conducting studies aimed at developing a nationally competitive biomedical research program.

ORDER OF CONTENT

Applicants should follow the order of content described in the PHS 398 document instructions and indicated on the Table of Contents page. With respect to specific sections:

- The Budget section should begin with the summary or composite budget for the Center, followed by the individual budgets for all projects, cores, consortia and contractual arrangements. Do not separate the individual project budgets into each project section.
- All Biographical Sketches should be grouped together with the PI's biographical sketch presented first followed by all other sketches in alphabetical order. Do not separate the biographical sketches into each project section.
- The Research Plan for the Center should be followed with letters indicating institutional commitment and any letters of support for the proposed center (if applicable). Do not place these letters in the Appendix.
- The Research Plan for the Center (including letters) should be followed by the core descriptions and individual investigator Research Plans.
 - Although a PHS 398 face page must not be used for each individual research project, a cover page should be included that indicates the project title, the name of the investigator supervising the project, the name of the mentor(s) if applicable, whether human subject/human subject materials will be used in the project, and whether vertebrate animals will be used in the project.
 - A Description page that provides an Abstract of the proposed project is required, and should immediately precede each project's Research Plan. As necessary, each project section can be concluded with letters of commitment from mentors and, as needed, letters of commitment from collaborators and/or consultants. Do not place these letters in the Appendix.
- Consecutively number the pages throughout the application. Do not include unnumbered pages and do not use suffixes, such as 5a, 5b, *et cetera*.
- The main body of the application should be self-contained, and the Appendix must not be used to circumvent page limitations. Applicants must adhere to the guidelines described in the PHS 398 document instructions regarding the preparation and presentation of materials that can be included in the Appendix.

REVISED APPLICATIONS

Applicants submitting a revised application should follow the instructions for revised applications described in the PHS 398 document instructions. The revision must include an Introduction of not more than three pages that summarizes substantial additions, deletions, and changes. The Introduction must include responses to the criticisms and issues raised in the Summary Statement. Insert the Introduction just before the very beginning of the Research Plan. Identify within the Research Plan the changes made by clearly bracketing, indenting, or changing typography, unless the changes are so extensive as to include most of the text. This exception should be explained in the Introduction. Do not underline or shade changes.

Individual projects and core descriptions that are retained in the revision must each include a separate section of not more than one page entitled “Response to Previous Review” that summarizes the substantial additions, deletions, and changes from the project that was originally submitted with the prior COBRE application. The Response to Previous Review should be inserted just before the very beginning of the individual project’s Research Plan section. Revised text should be marked as described above.

BUDGETS

Individual research projects and core facilities that are proposed to begin in year one should have corresponding individual budgets. Although an applicant can propose research projects and/or core facilities to begin in later years, each year’s budget should include costs for those projects or cores that will be active in that year only. Individual project and core facility budgets should be grouped together with justifications and prefaced by a summary or composite budget for the entire Center.

CONSORTIUM ARRANGEMENTS

When a grant application includes research activities that involve institutions other than the grantee institution, it is considered a consortium effort. Such activities may be included in the COBRE grant application, but it is imperative that a consortium application be prepared so that the programmatic, fiscal, and administrative considerations are explained fully. In addition, the thematic scientific focus of the COBRE must be evident in applications that include consortia arrangements. Applicants for COBRE grants should exercise great diligence in preserving the interactions of the participants and the integration of the consortium project(s) with those of the parent institution because synergism and cohesiveness can be diminished when projects are located outside of the group at the parent institution. Facilities and administrative costs requested by consortium participants are not included in the direct cost limitation (see NOT-OD-05-004; <http://grants.nih.gov/grants/guide/notice-files/not-od-05-004.html>).

EXTERNAL ADVISORY COMMITTEE (EAC)

The PI must select and name in the application at least three, but no more than five scientists who will serve as EAC members. Furthermore, the participation of each member in the EAC must be confirmed by inclusion in the application of a letter of acceptance and a current biographical sketch of each proposed member. The PI may recruit additional members or remove members to the EAC after an award is made. The PI must communicate the selection of additional EAC members or the removal of EAC members to the NCRP for Programmatic Review.

RESEARCH PLAN

Each application must describe an overall research plan to justify support of a thematic multi-disciplinary COBRE program for five years.

The Research Plan section of the application describing the Center, but not including the individual investigators' research projects and core facilities, is limited to no more than 25 pages, including all text, tables, graphs, figures, diagrams and charts. The Research Plans for the investigators' research projects and core descriptions are limited to no more than 10 pages each. These limitations do not include the sections describing Human Subject Research, Vertebrate Animals, Literature Cited, Consortium/Contractual Arrangements, Consultants, and/or supporting letters. Each Biographical Sketch is limited to no more than four pages. If not specifically cited in the PHS 398 document instructions, no page limit is in place for any other section. However, applicants are strongly urged to be succinct.

Ideally, it is recommended that the research plan contain the descriptions of three to five individual research projects. However, the research plan cannot contain fewer than three individual research projects. In addition, an administrative core providing a detailed plan for development and mentoring junior investigators must be included. The establishment of research core facilities necessary to carry out the objectives of a multi-disciplinary, collaborative program may be proposed.

The overall research plan should describe the unique research opportunities that will be provided to the junior investigators and to the institution. If the proposed COBRE research is closely related to ongoing research or an existing center, an explanation how the research activities of the COBRE will complement but not overlap with existing research should be described. In addition, the application should describe how the efforts of each junior investigator will assist in the establishment of a multi-disciplinary research center.

Although no non-Federal matching funds are required for these applications, clear evidence of institutional commitment must be included with the application. The level of institutional commitment will differ among applicant institutions because of the variability of resources available among institutions. At a minimum, a letter of support from a senior institutional official (e.g., President or Dean) should outline the commitment of resources and facilities to sustain and

support the COBRE throughout the period of funding and to maintain these resources beyond the period of grant support.

The institutional environment and resources that are available to investigators must be briefly described. Available resources (e.g., laboratory facilities, patient populations, geographic distributions of space and personnel) and collaborative resources should be described. If core facilities are included for support, the relationship of each component research project to the core(s) should be described.

INDIVIDUAL RESEARCH PROJECTS

Each COBRE program should ideally include three to five individual research projects that stand alone, but share a common thematic scientific focus. Each program must propose a minimum of three individual research projects. Each research project should be supervised by a single junior investigator who is responsible for ensuring that the Specific Aims of that project are met. An initial minimum commitment of 50 percent effort is required for this individual. It is recognized that during the development of a junior investigator's career (for example, the acquisition of other research support) it may be necessary to reduce this effort. Investigators should consult with NCRR Program staff regarding appropriate reductions.

Each individual research project should describe the Specific Aims in the selected area of research and the goals for the first year and for the long term. The design principles supporting the research or the hypotheses to be tested should be delineated. Preliminary studies are not required for COBRE applications, but applicants with preliminary results should describe them. In the absence of preliminary results, applicants should describe the rationale and scientific basis for the proposed research. Furthermore, each research project should describe the area of multi-disciplinary research that is the focus of the COBRE and critically assess the existing knowledge and approaches that have been or are being directed in the area with an emphasis on specifically how the multi-disciplinary COBRE approach will advance the field. Moreover, the importance and health-relevance of the proposed research to the Specific Aims should be concisely stated.

CRITERIA FOR ELIGIBILITY OF JUNIOR INVESTIGATORS

For the purpose of eligibility, a junior investigator is defined either as (1) an individual who does not have or has not previously had an external, peer-reviewed Research Project Grant (RPG) or Program Project Grant (PPG) from either a Federal or non-Federal source that names that investigator as the PI or (2) an established investigator who is making a significant change to his/her career. Senior funded investigators who are not making a significant career change must not be proposed as leaders for individual research projects.

With respect to item (1), grants that name an individual as a co-investigator, collaborator, consultant, or to a position other than PI do not disqualify that investigator. Starter grants (such as NIH's FIRST award mechanism, R29), Academic Research Enhancement Award grants

(AREA, R15), exploratory/pilot project grants (such as NIH R03 and R21 awards), career development awards (such as NIH K01 and K08 awards), or other Federal or non-Federal funding whose purpose is to provide preliminary support in anticipation of a RPG or PPG also do not disqualify the investigator. The intent of this initiative is not to disallow promising investigators whose early career support consists of awards geared toward initiating their intended area of research. However, investigators who have managed to obtain significant support in the form of a RPG or PPG (e.g., NIH R01 or P01, NSF, or other Federal or non-Federal agency awards) are not eligible.

Investigators who propose to develop a new or alternate line of research, but whose intention is to maintain support through an active RPG or PPG in a different area of research are also not eligible. Investigators should indicate in the Biographical Sketch their current and previous history of peer-reviewed research support.

A junior investigator must hold a faculty appointment (or equivalent at a research institute) at the time that the award is made. Moreover, a clear commitment to support this appointment independent of the outcome of this application must be demonstrated from the institution by a letter(s) from the appropriate senior institutional official(s). Postdoctoral fellows or other positions that do not carry independent faculty status will disqualify that individual and his/her research project from further consideration.

With respect to item (2), support may be provided to an established investigator who is making a significant change to his/her career goals by initiating a new line of research that is distinctly and significantly different than his/her current investigative program. The current or previous history of independent peer-reviewed research support, which may be indicated in the Biographical Sketch, in a different investigative area than that proposed in this application does not disqualify the investigator. Furthermore, this individual can be of any faculty rank. The intent of this initiative is to allow established investigators the opportunity to initiate and develop a new line of research. However, investigators whose current research is already supported by a RPG or PPG and who are not changing their current research program are not eligible.

This initiative is not intended to replace support for ongoing investigator-initiated research programs of established investigators. Instead, established investigators should serve as mentors to advance the junior investigators' careers.

The PI of the COBRE is not eligible for research project support, nor can he/she use COBRE funds to supplement research activities within his/her laboratory.

ADMINISTRATIVE CORE

A clear plan for the development of junior investigators and for their transition to and attainment of independent status must be included. This plan should detail the long-term goals as to how the institution intends to make the transition from the research support of multi-disciplinary COBRE projects to competitive grant support through applications submitted by its faculty members to

relevant NIH Institutes and Centers or to other appropriate Federal or non-Federal agencies or organizations. Each junior investigator must submit an investigator-initiated RPG application by the end of two years of support to maintain continued funding through the COBRE award.

The development plan must include both formative and summative evaluation strategies with specific milestones, including, but not limited to, the acquisition of independent status by the investigators, competition for complementary NIH, Federal or non-Federal external peer-reviewed research grant support, and publication in peer-reviewed journals. Faculty development should include a mentoring plan that involves oversight by established senior faculty members assigned as mentors, constructive evaluations by members of the External Advisory Committee (EAC) and coordinated management of all of these individuals by the PI of the COBRE program. Additional oversight may be augmented through the use of an internal advisory committee, but this committee should not act as a substitute for the EAC.

Each junior investigator should have at least one mentor. The mentor must be an established investigator who has demonstrated the ability to advise others through the acquisition of external support and the maintenance of an independent research laboratory. In some instances a suitable mentor may not be available within the applicant's institution and it is therefore acceptable to enlist appropriate mentors from outside institutions. Mentors may be provided 10 to 15 percent effort, and should be listed in the Administrative Core's budget section of the application and not in the individual projects' budget sections. The junior investigators should clearly designate in the text the identity of their mentors and describe their qualifications, both scientific and advisory, that make them appropriate to assist in the oversight of the project.

The award of a Research Project Grant (RPG) to a junior investigator should be viewed as a milestone and a criterion for changing the status of an investigator from mentored support to independent investigator. A junior investigator may also be considered for a status change if independence is indicated by the acquisition of sufficient skills and knowledge. However, it is stressed that the goal of the COBRE program is to promote the development of an independent and sustainable center. Investigators who have acquired independent status or completed a research project should not be excluded from Center activities. These investigators should be allowed access to core facilities and should be encouraged to participate in collaborative research efforts. If appropriate, an investigator who has acquired independent status may direct a core facility or serve as a mentor.

COBRE support cannot be provided in instances where a junior investigator's new award overlaps or is significantly similar to that described in the COBRE program. However, if the specific aims of the junior investigator's RPG are significantly different from the project described in the COBRE, then the junior investigator has an obligation to remain in the program to complete his/her COBRE project. In this latter case, continued support for personnel (e.g., postdoctoral associates, graduate students, technicians, etc.) associated with the COBRE project but also listed on the other award can be provided. However, the percent efforts of these individuals must be appropriately adjusted.

A junior investigator who has achieved independent status and no longer supervises a research project may be replaced by a new investigator. Replacement investigators and new research projects may be substituted following review by the PI and the EAC. The PI must communicate the EAC's recommendation to the NCRR for Programmatic Review.

In some instances, a junior investigator may be placed on probation or considered for removal from the COBRE program if a review by the EAC indicates a failure by the investigator to make significant progress toward achieving the specific aims of his/her project or, as noted above, to submit an investigator-initiated RPG application by the end of two years of COBRE support.

RESEARCH CORE FACILITIES

Funds may be requested to establish core facilities. The applicant must demonstrate that each proposed core will serve the scientific needs of the individual research projects and must show how each core will impact the development of the Center. Although the COBRE award is not intended to replace support for ongoing investigator-initiated research projects of established investigators, both the mentors, as well as other investigators at the institution, may use these facilities. Additional justification may be offered by showing how a core facility will benefit these individuals and improve the research infrastructure of the institution. Each core's description should indicate the qualifications of personnel selected to manage the facility and/or plans to recruit personnel to operate the core, if needed. Furthermore, the PI should indicate any institutional commitment to support and maintain the proposed facilities.

ALTERATION AND RENOVATION

Up to \$500,000 in direct Alteration and Renovation (A&R) costs – only in year one of the award, as a one-time cost expenditure – are allowed to improve existing research laboratories or animal facilities. Direct costs requested for A&R are not subject to facilities and administrative costs (F&A). Although this amount will be provided only in year one, the proposed A&R work does not have to be completed in year one. However, PIs are strongly encouraged to complete all A&R work in an expeditious manner and all A&R work must be completed before expiration of the award. Alteration and Renovation projects must be relevant to the scope of the proposed research. Sufficient detail must be provided to estimate the cost and suitability of the project. Failure to adequately justify an A&R request will likely result in its deletion from the requested budget. Support will not be provided for new construction, including the completion of shell space, or for movable research equipment/instrumentation, or for equipment intended for teaching or other non-research related purposes.

Alteration and Renovation costs will be approved only for facilities improvements at the applicant's organization. Proposed improvements at consortia sites are not allowed.

The expenditure of funds for all A&R projects in excess of \$300,000 is restricted until project documentation/architectural drawings have been reviewed and approved by NIH staff. A&R projects of less than \$300,000 that support the installation of fixed equipment or other structural

alterations should not be initiated until the project documentation/architectural drawings have been reviewed and approved by NIH staff.

For any proposed A&R, a narrative summary, line drawings, and cost estimates must be provided.

PLAN FOR SHARING RESEARCH DATA

All applicants must include a plan for sharing research data in their application. The data sharing policy is available at http://grants.nih.gov/grants/policy/data_sharing. All investigators responding to this funding opportunity should include a description of how final research data will be shared, or explain why data sharing is not possible.

The reasonableness of the data sharing plan, or the rationale for not sharing research data, will be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score.

The precise content of the data-sharing plan will vary, depending on the data being collected and how the investigator is planning to share the data. Applicants who are planning to share data may wish to describe briefly the expected schedule for data sharing, the format of the final dataset, the documentation to be provided, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any conditions will be placed on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal website, through a data archive or enclave, *et cetera*). Investigators choosing to share under their own auspices may wish to enter into a data-sharing agreement. References to data sharing may also be appropriate in other sections of the application.

SHARING RESEARCH RESOURCES

NIH policy expects that grant recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication. Investigators should include a plan for sharing research resources addressing how unique research resources will be shared or explain why sharing is not possible. The adequacy of the resources sharing plan and any related data sharing plans will be considered by Program staff when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (PHS 2590).

REVIEW PROCEDURES

Upon receipt, applications will be reviewed for completeness by the Center for Scientific Review (CSR) and for responsiveness by NCRR staff. Applications that are incomplete and/or

non-responsive, or exceed the maximum first-year direct cost limit of \$1.5 million, excluding F&A costs for consortium budgets, will be returned to the applicant without further consideration.

Applications that are complete and responsive will be evaluated for scientific and technical merit by a initial review group convened by NCRR using the review criteria stated below. As part of the initial merit review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score.
- Receive a written critique.
- Receive a second level of review by NCRR's National Advisory Research Resources Council (NARRC).

REVIEW CRITERIA

TRADITIONAL REVIEW CRITERIA

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:

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?

Each of the preceding criteria will be addressed and considered in assigning the overall score, weighting them 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 high 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.

ADDITIONAL REVIEW CRITERIA

The review of a COBRE application is not only based on the traditional review criteria (Significance, Approach, Innovation, Investigator, Environment), but also on the qualifications of the PI to provide both scientific and administrative leadership and on the feasibility and potential for investigators to become competitive for independent funding. Specifically, the Scientific Review Group will evaluate the 1) administrative leadership and overall potential for enriching the intellectual milieu for doing research, 2) effectiveness in training and promoting junior investigators, and 3) scientific merit of the individual biomedical research projects.

Administrative Leadership and Overall Potential for Enriching the Intellectual Milieu for Doing Research

Does the PI have the qualifications to provide scientific and administrative leadership in developing and directing the COBRE, and establishing thematic collaborative research efforts? As noted previously, the PI must demonstrate that he/she is an established biomedical or behavioral research scientist, that he/she has an active research laboratory, that he/she has relevant peer-reviewed funding (either NIH, NSF or other Federal or non-Federal investigator-initiated support), and that he/she has shown administrative leadership and mentoring experience.

Does the application describe how institutional biomedical research capacity will be augmented and strengthened? How will basic and/or clinical research be encouraged? How will a scientific thematic focus be established and maintained? Have appropriate and suitable evaluation strategies and specific milestones to measure progress toward attaining long-range goals been selected, and how will these be employed?

Are the nature, scope, and effectiveness of the plans for coordination and cooperation among research project investigators appropriate, and will they contribute to the establishment of the Center? Are the strengths, academic qualifications and biomedical expertise of the project investigators appropriate and sufficient for research productivity?

Is the level of institutional commitment sufficient to provide support for the development of a thematic multidisciplinary center? Has the application demonstrated that the resources and facilities to sustain the COBRE program are present (including, but not restricted to, existing relevant equipment, animal, and/or computer resources, and departmental or interdepartmental cooperation)? Has the applicant demonstrated the need for the proposed core facilities and the effectiveness of these facilities to enhance the research effort? Has the applicant demonstrated that each proposed core will serve the scientific needs of the individual research projects and has he/she shown how each core will impact the development of the Center?

Has the PI selected a suitable External Advisory Committee and does he/she describe plans to make effective use of this committee to achieve the objectives of the Center? Has the PI selected appropriate and suitable evaluation strategies and specific milestones to measure progress, not only of the junior investigators, but of the Center as a whole, toward attaining its long-range goals?

Effectiveness in Training and Promoting Junior Investigators

Are plans to direct and manage the research training, career development and mentoring of junior investigators well-described, and will these plans be effective in transitioning these investigators toward independent status? If the PI plans to recruit new faculty to the Center, are these plans suitable and consistent with the effective growth and development of the Center?

Scientific Merit of the Individual Biomedical Research Projects

Has the PI shown effective judgment in the selection of research projects? Are the projects related to and consistent with the overall goals of the Center? Although the Scientific Review Group will evaluate the qualifications of each junior investigator using the traditional criteria and considerations indicated in this PA, do the junior investigators have the potential and ability to achieve independent status?

ADDITIONAL REVIEW CONSIDERATIONS

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

Resubmission Applications (formerly “revised/amended”)

Are the responses to comments from the previous scientific review group adequate? Are the improvements in the resubmission application appropriate?

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 E on Human Subjects in the PHS Form 398).

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 E on Human Subjects in the PHS Form 398).

Care and Use of Vertebrate Animals in Research

If vertebrate animals are to be used in the project, the five items described under Section F of the PHS Form 398 research grant application instructions 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.

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.

Data Sharing Plan

The reasonableness of the data sharing plan or the rationale for not sharing research data may be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score. The funding organization will be responsible for monitoring the data sharing policy (http://grants.nih.gov/grants/policy/data_sharing).

AWARD CRITERIA

The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review
- Availability of funds
- Relevance of program priorities

In addition, the final selection of awards will depend upon the National Advisory Research Resources Council, geographic distribution, program balance, and the enhancement of the research competitiveness of the institution.

AWARD CONDITIONS

An award will not be made unless the institution has appointed a COBRE Director who is an established biomedical scientist with an active research program that is supported by peer-reviewed NIH, NSF, or other investigator-initiated research support in the scientific area of the Center and has the professional skills needed to direct the Program. If this individual is not in place at the institution at the time of review or award, a plan to recruit such an individual must be included in the application. The administrative and leadership skills of the established investigator, research productivity, and capacity to obtain and use the resources effectively will be assessed by NCCR staff.

REPORTING REQUIREMENTS

A Non-Competing Grant Progress Report (NIH form 2590) is required annually as part of the non-competing continuation award process, as described in the NIH Grants Policy Statement, http://grants1.nih.gov/grants/policy/nihgps_2003/index.htm. Instructions for the NIH form 2590 can be found at: <http://grants.nih.gov/grants/funding/2590/2590.htm>.

For NCCR-supported Center and Resource grants, the PHS form 2590 incorporates an Annual Progress Report (APR), which provides information in greater detail than the standard NIH form 2590. The NCCR uses the information contained in the APR to facilitate programmatic stewardship of the grant, and to respond to inquiries from other governmental agencies and the public. Specific instructions for completing an APR and including it with the NIH form 2590 can be found at <http://aprsis.ncrr.nih.gov>.

INQUIRIES

Written and telephone inquiries concerning the COBRE program are strongly encouraged, especially during the planning/budgeting phase of application development. Please contact:

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COBRE Program Officer
Division of Research Infrastructure
National Center for Research Resources
National Institutes of Health
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IDeA NETWORKS OF BIOMEDICAL RESEARCH EXCELLENCE (INBRE)

PURPOSE

The IDeA Networks of Biomedical Research Excellence (INBRE) program is one of the approaches taken by the National Center for Research Resources (NCRR) to implement the Institutional Development Award (IDeA) program. INBREs enhance the research capacity of institutions through collaborative partnerships, the development of areas of potential research, staff development, and access to research resources, so they can participate more fully in the competition for NIH awards.

RESEARCH OBJECTIVES

For many years, the NIH has made a special effort to stimulate research at educational institutions that traditionally have not received significant levels of competitive research funding through the NIH. The IDeA program was established for the purpose of broadening the geographic distribution of NIH funding for biomedical and behavioral research by enhancing the competitiveness for research funding of institutions located in states in which the aggregate success rate for applications to the NIH historically has been low. A major factor, which may contribute disparately to the funding distribution, is that there are relatively few investigators in the IDeA states who conduct competitively supported biomedical and behavioral research. The statewide IDeA networks are intended to develop the research resources and modern laboratories needed to attract established investigators, as well as the research skills of talented investigators and promising students.

The purpose of each INBRE is to promote the development, coordination and sharing of research resources and expertise that will expand the research opportunities and increase the number of competitive investigators within the IDeA states. The size, structure, and operational principles of the emerging networks were essentially established during phase one of INBRE – Biomedical Research Infrastructure Networks (BRIN) – by the very nature of which support, NCRR staff fully recognized that some networks are more advanced than others.

INBREs augment and strengthen the state's biomedical research capacity and investigator pipeline through flexible support to further expand and develop the competitive biomedical research capability for faculty; in addition, support via INBRE is used to further enhance the research infrastructure through support of a multi-disciplinary network, led by an established peer-reviewed investigator with expertise directly related to the research theme(s) of the INBRE. Each INBRE must include a scientific focus in one to three thematic areas, such as neuroscience, cancer, genomics, proteomics, developmental biology and genetics, toxicology or any of the biomedical and behavioral scientific areas relevant to the mission of NIH, and may include basic, and/or translational, and/or clinical research approaches to attain the goals of the network. The scientific leadership provided by one or more established biomedical research faculty members is critical to the success of this initiative, especially for the mentoring of promising investigators, postdoctoral fellows, and students. The network is intended to support investigators from several

complementary disciplines at the grantee's and partner graduate and undergraduate institutions. The network may extend to appropriate institutions in other IDeA states if the grantee state has no other appropriate institutions to include within its boundaries. The faculty at these institutions may receive support to establish their research laboratories, acquire specialized equipment, and hire postdoctoral fellows, students and technical assistance, enabling them to develop a critical mass of investigators and to enhance their competitiveness in a specific research area that positions those investigators to successfully compete for their own competitive NIH research grant awards. It is also anticipated that, in some instances, support through this initiative will facilitate the development of new disease-specific research networks or augment the capability of existing networks.

The overarching objectives of the INBRE program are to:

- establish a multi-disciplinary research network with a scientific focus that will build and strengthen the lead and partner institutions' biomedical research expertise and infrastructure;
- build and increase the research base and capacity by providing research support to faculty, postdoctoral fellows and graduate students at the participating institutions;
- provide research opportunities for undergraduate students and serve as a "pipeline" for undergraduate students to continue in health research careers within IDeA states
- provide outreach activities to students at undergraduate institutions, community colleges, tribal colleges and K-12 institutions participating in the state's network [see "K-12 Institutions," below]; and,
- enhance science and technology knowledge of the state's workforce.

ELIGIBILITY REQUIREMENTS

Applications were accepted ONLY from institutions that currently held a Biomedical Research Infrastructure Network (BRIN) award (RFA: RR-01-005).

Under BRIN/INBRE, an eligible institution must be within an IDeA state, and be either a domestic, public or private, or non-profit research institution that awards doctoral degrees in health sciences or sciences related to health, or an independent biomedical research institute.

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research was invited to work with their institution, and each institution worked within its state, to develop one state-wide application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

MECHANISM OF SUPPORT

The administrative and funding instrument for INBRE is the P20 exploratory grant award mechanism.

Responsibility for planning, directing, and executing an INBRE project is solely that of the grantee. All current policies and requirements that govern the research grant programs of NIH apply to grants awarded for INBREs.

FUNDS AVAILABLE

An applicant could request a project period of up to five years and a budget of up to \$2.5 million per year in direct costs.

The maximum allowable direct cost for the INBRE program is \$2.5 million dollars per year. Up to \$1.25 million is available to the awardee institution. \$1.0 million of those funds may support the Administrative and Bioinformatics Cores, Core facilities, training and mentoring activities, and research activities at the awardee institution and at other research-intensive institutions in the network. Up to \$250 thousand of that \$1.25 million may be used to support the Outreach Core to sponsor outreach activities to other institutions in the state that are not part of the research network.

A maximum of \$1.25 million of the available direct costs may be expended at the baccalaureate/masters degree institutions that are part of the scientific network of INBRE, to build infrastructure and research capacity for the proposed multi-disciplinary research areas. These funds are to be allocated to these institutions as consortium arrangements and/or subcontracts, and are to cover expenses for including but not limited to salary and research support, alteration and renovation of the research and animal facilities, equipment. A memorandum of understanding (MOU) must clearly describe the arrangements between the baccalaureate institutions and the grantee institutions and must provide for release time for investigators and consideration of research accomplishments in any advancement/tenure criteria. A maximum of 15 percent of the total direct cost requested at each baccalaureate institution may be used for administrative costs. Individual research projects may be funded at a level not to exceed \$150 thousand/year in direct costs.

It was not expected that each applicant would request the categorical maximum allowable costs stated above. Those numbers were provided as a guide for purposes of developing the INBRE proposed network. The actual costs requested were to be based on the proposed INBRE network (i.e. number of participating institutions) and activities (i.e. number of proposed scientific projects, core support costs) providing the justification for the appropriate expenditure of proposed costs.

The applicant institution for an INBRE scientific network that is located in a state that has no medical school and fewer than four additional accredited undergraduate institutions that award degrees in both biology and chemistry, could consider the budgetary allocation guidelines regarding the available \$2.5 million direct costs to be flexible.

Funds are provided for building and strengthening the infrastructure and capacity-building at the lead and partner graduate and undergraduate institutions, including Alteration and Renovation

(A&R) of research laboratories and animal facilities, instrumentation for Core Laboratories, and staffing (investigators, junior investigators, postdoctoral fellows, graduate and undergraduate students, and technical assistance).

F&A costs for the parent institution and consortium organization(s) are excluded from the limit on the amount of direct costs that can be requested for the entire project. Grantees are encouraged to review the *NIH Grants Policy Statement* for policy and procedures applicable to consortium agreements.

FUNDING RESTRICTIONS

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 continuation award if such costs are necessary to conduct the project, and 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 continuation 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 (NIH Grants Policy Statement; http://grants.nih.gov/grants/policy/nihgps_2003/nihgps_part6.htm).

COST SHARING OR MATCHING

This program does not require cost sharing as defined in the current NIH Grants Policy Statement. Although no non-Federal matching funds were required for consideration of INBRE applications, clear evidence of institutional and state commitment had to be included with the application. The level of institutional commitment differed among applicant institutions because of the variability of resources available among institutions and states. At a minimum, a letter of support from a senior institutional official (e.g., President or Dean) outlining the commitment for resources and facilities to sustain and support the INBRE throughout the period of funding had to be submitted. This program does not require cost sharing as defined in the current NIH Grants Policy Statement. The most current Grants Policy Statement can be found at: http://grants.nih.gov/grants/policy/nihgps_2003/.

ALLOWABLE COSTS

SALARY

Salary costs are allowable to the extent that they are reasonable; conform to the established policy of the organization consistently applied regardless of the source of funds; and reflect no more than the percentage of time actually devoted to the NIH-funded project. If full-time 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary.

It is expected that the project investigators and junior investigators will devote at least 50 percent of their professional effort to career development and research activities. Institutions must provide release time for project investigators, thus permitting a significant time commitment to the research enterprise.

TUITION REMISSION

Tuition remission is allowable provided:

- the individual is performing activities necessary to the grant;
- tuition remission and other forms of compensation are provided in accordance with established institutional policy, consistently provided to students performing similar activities conducted in non-sponsored as well as in sponsored activities; and
- during the academic period, the student is enrolled in an advanced degree program at a grantee or affiliated institution and the activities of the student in relation to the federally sponsored research project are related to the degree program.

ANCILLARY PERSONNEL SUPPORT

Salary for mentors is allowed as long as the mentors are members of the established investigator pool, which is to interact directly with and mentor the junior investigators. The grantee may request 10-20 percent effort for mentors who are extensively involved in the INBRE activity. Salary and research support will be provided for participating graduate and undergraduate students, and postdoctoral fellows.

FACILITIES AND ADMINISTRATIVE COSTS

Facilities and Administrative Costs (F&A) will be reimbursed at the negotiated rate.

RENOVATIONS

A&R costs to improve existing research laboratories or animal facilities, and allowable fees associated with A&R projects at the lead and scientific network partner institutions are allowed. INBRE awards could provide up to \$750 thousand in direct costs (10 percent of awarded direct costs) over the period of the first three years. A&R costs could be approved for facilities

improvements at the awardee institution as well as at the partner institutions. No more than \$250 thousand of that \$750 thousand may be used for A&R at the awardee institution. Proposed improvements at consortia sites are allowed. A&R projects must be relevant to the scope of the proposed research and at the institutions involved in the research network, and sufficient detail must be provided to estimate the cost and suitability of the project. Proposed renovations in successful applications required subsequent submission of design documents for review and approval before the renovation project could commence. Support is not provided for new construction, including the completion of shell space.

Direct costs requested for A&R are not subject to F&A. Installation of fixed equipment or other structural alterations should not commence until architectural documents have been reviewed and approved by NIH staff. Expenditure of funds for all A&R projects in excess of \$300 thousand are restricted until project documentation/architectural drawings have been reviewed and approved by NIH staff.

OTHER ALLOWABLE COSTS INCLUDE:

- Research equipment and instrumentation for laboratories
- Supplies for research
- Salaries for support and technical staff as well as professional staff who will direct Cores
- Salary support for a Program Coordinator

MEETINGS

- The Principal Investigator and Program Coordinator could budget for an annual two-day meeting in Bethesda, Maryland with NCCR staff. These meetings will provide a forum for the exchange of IDeAs and information, and address problems that arise. In addition, NIH staff will provide updates on policies and regulations that relate to the conduct of research, including discussions of conflicts of interests, NIH Electronic Research Administration, ethics, and protection of human subjects to strengthen the program and the network.
- The Principal Investigator and Program Coordinator should budget for an annual a meeting of INBREs in the grantee's IDeA region.

CONSORTIA

When an INBRE includes research activities that involve institutions other than the grantee institution, it is considered a consortium effort. Such activities may be included in the INBRE, but it is imperative that a consortium agreement be prepared so that the programmatic, fiscal, and administrative considerations are explained fully. In addition, the emerging network's thematic scientific focus must be evident in consortia arrangements. INBREs should exercise great diligence in preserving the interactions of the participants and the integration of the consortium project(s) with those of the parent institution, because synergism and cohesiveness can be diminished when projects are located outside of the group at the parent institution.

UP-TO-DATE INFORMATION

All grantees must ensure they have the latest information about the IDeA and INBRE programs by visiting the IDeA and INBRE Web pages (http://www.ncrr.nih.gov/research_infrastructure/ and http://www.ncrr.nih.gov/research_infrastructure/institutional_development_award/idea_networks_of_biomedical_research_excellence/).

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (<http://grants.nih.gov/grants/policy/policy.htm>).

PROGRAM CHARACTERISTICS

PROGRAM OBJECTIVES

This program seeks to promote the development and expansion of unique, innovative, state-of-the-art biomedical and behavioral research at institutions in IDeA-eligible states. The research focus of this program encompasses the full spectrum of the basic and clinical sciences and includes cellular and molecular biology, biophysics and biotechnology, developmental biology and genetics, pharmacology, toxicology and others. The NIH recognizes that the contributions from the institutions in IDeA-eligible states are important and essential in fulfilling the promise of the NIH research agenda. The intent of INBRE is to assist these institutions to implement and use the technologies and other resources needed to conduct state-of-the-art biomedical and behavioral research.

Each INBRE program should include multi-disciplinary, collaborative, developmental research projects that stand alone, but share common scientific themes. A single investigator at the awardee or network institutions should supervise each research project. Each investigator is responsible for ensuring that the project's specific aims are met. The research excellence of these projects will be enhanced by effectively using the scientific and technical strengths of collaborating investigators and/or mentors. Promising investigators who are resident at institutions in IDeA states but are not a part of the scientific network of the INBRE may receive research support through an adjunct appointment at one of the partner institutions or as collaborators on sponsored research projects.

At the request of an INBRE grantee, the NCCR will identify one or more program staff from an NIH Institute or Center with a research mission directly relevant to the thematic research area(s) to be developed within the INBRE. This arrangement will provide additional advice by NIH staff in areas directly relevant to the scientific focus proposed in the application.

PRINCIPAL INVESTIGATOR (PI)

The goal of this program is accomplished through the direction provided by a PI, who provides leadership to investigators and has the primary responsibility for administering the program and

for overseeing the development of the scientific network and its associated core facilities. The INBRE PI must be an established research scientist and have administrative and leadership skills to direct this multi-faceted program. The PI at the lead institution serves as the director of the INBRE and coordinates its activities.

This person should devote a minimum time commitment of 30 percent, however up to 50 percent effort will be supported for mentoring and administrative oversight of the INBRE. This individual serves as a research advocate. The PI also directs the Administrative Core and establishes an administrative structure that ensures efficient utilization of the scientific facilities and investigators within the network. The PI is responsible for management, staffing and resource allocation, and for administering the award in accordance with NIH policies. The PI, in consultation with the Steering Committee, selects the directors for the mandatory cores.

PROGRAM COORDINATOR (PC)

Support will be provided at a 30-50 percent effort for an additional faculty member within the INBRE network to serve as a Program Coordinator (PC). The PC complements the administrative efforts of the PI and acts as a liaison between the lead institution and the partner institutions in the network. The PC must have demonstrated ability to organize, administer, and stimulate collaborative initiatives in the planned network.

INSTITUTIONS MAKING UP THE NETWORK

An INBRE scientific network must include a doctoral degree-granting institution or research institute (the previous BRIN grantee institution) and ideally three to five baccalaureate or master's level degree-granting institutions participating in the thematic multidisciplinary research activity. New undergraduate institutions that have not been a part of the original BRIN but contribute to the thematic research effort may be included, if appropriate, in the scientific network. The states that elect to do so, or states that do not have appropriate eligible undergraduate/graduate institutions with focus on the scientific area relevant to the thematic focus, may include partner institutions from other IDeA states. The inclusion of minority-serving institutions is encouraged as well as diversity among faculty and candidates included in the INBRE.

The initiative is intended to strengthen the basic science departments of undergraduate institutions. INBRE provides opportunities for undergraduate institutions to support current productive faculty and recruit outstanding faculty who can conduct research in the specific proposed thematic area and pique the interest of their promising students in health-related science through both the didactic training and the research experiences. As a consequence, more students who are well trained in science and technology may enhance the quality of the workforce and help attract biotechnology industries that may enhance the economies within the IDeA states in the future. With better employment opportunities, more students may choose to stay within the state. The undergraduate institutions also serve an important "feeder" role to the science departments of graduate schools within IDeA states and Puerto Rico to pursue graduate

education. With access to promising, well-educated students, the graduate schools in the IDeA states can more readily build a critical mass of investigators by recruiting competitive investigators from other institutions as well as recruiting their own graduates.

The four to six baccalaureate or master's level degree-granting institutions that participate in the thematic multidisciplinary research activity serve as a pipeline for future independent biomedical investigators. Principally undergraduate institutions are also eligible if they are a component of a university that includes a graduate school that confers doctoral degrees in one or more science, but are not research intensive or do not conduct biomedical research as a principal activity. Faculty at the undergraduate colleges of research-intensive institutions who do not have appointments in the graduate school may also receive research support via this initiative. Further, new undergraduate institutions that have not been a part of the original BRIN but contribute to the thematic research effort may be included, if appropriate, in the proposed scientific network.

K-12 Institutions

On October 16, 2006, NIH informed the scientific community that it was amending INBRE overarching objective 4 to include K-12 institutions [Notice Number: NOT-RR-07-002]. No additional funds will be provided to support this activity. Those grantees who have an interest in expanding outreach activities to K-12 institutions may rebudget funds available in the Outreach Cores of their INBRE Networks to accomplish this activity.

NETWORK CHARACTERISTICS

A network within a state should have a research institute or doctoral degree-granting institution serve as the network's lead institution and also serve as the grantee institution on behalf of the INBRE. One or two additional biomedical research-intensive institutions may participate in the network and share in the portion of the budget dedicated to the lead institution. The statewide network is to be composed of baccalaureate or master's level degree-granting institutions or non-profit research institutes that will provide the sites for the conduct of the thematic, multidisciplinary, biomedical and behavioral research.

The research capacity-building may focus on clinical, and/or translational, and/or basic types of research in a creative, integrated approach. Collaborations between or among IDeA-eligible states as well as collaborations with institutions in other states is allowable, but no IDeA grant funds awarded to an IDeA state may be used for activities in a non-IDeA state. It is the responsibility of the leadership of the INBRE to define an effective partnership and collaboration. The network is to include undergraduate and graduate students and postdoctoral fellows as well as undergraduate and graduate science department faculty. Special efforts must be undertaken to enhance the recruitment and career development of participating students, fellows and faculty. Collaborations with investigators from outside an IDeA state are permissible, but must be agreed upon by the INBRE Steering Committee (see below).

Some grantee institutions may have faculty who hold significant peer-reviewed funding from either Federal or private sector sources to conduct research. Those faculty members may be included as mentors and scientific members of a multi-disciplinary steering committee. The focus of the research network will determine the need for core research facilities and modern instrumentation. The research plan for proposed projects may be in basic, and/or translational, and/or clinical areas of research, but must be relevant to the proposed thematic focus. There are unique populations within the IDeA states and investigators are strongly encouraged to include representations of those populations for valid analyses of differences that may affect health disparities. The NIH is committed to working toward elimination of health disparities among racial and ethnic minority populations. Since the NIH is concerned about the under-representation of minorities in biomedical and behavioral research, the inclusion of institutions that serve these populations is encouraged.

CORES

Each network must have at least three cores; Administrative, Bioinformatics, and Outreach. In addition, a network must include a research network with a multi-disciplinary thematic science focus. Training and mentoring aspects of the program are to be included under the Administrative Core. Applications may include additional cores, such as a Centralized Research Facility Core – several research projects may need access to one or more technologies included in the Centralized Research Facility Core; the Core Laboratory is to include professional technical expertise to optimize use of the Core Laboratory's technology. All INBREs must include an evaluation component, described below.

Mandatory Cores

Administrative Core

The Administrative Core is directed by the PI of the INBRE and provides the logistical support for the network. Systematic communication among investigators within the research network is essential. The Administrative Core also develops programs to meet the training and mentoring needs of the junior research faculty, fellows, and graduate and undergraduate students. For example, special training may be designed for students, fellows and junior faculty to hone their investigative skills. Support may also be provided for attending national scientific meetings and workshops to interact with the scientific leaders in the field and learn about the most current research advances in the field. Salary support is provided for mentors, based on their level of effort for mentoring students and promising investigators. Salary support may also be provided for an administrative assistant if required.

The Administrative Core also serves as a clearinghouse for ongoing research activities, any clinical studies, analysis of research results, other funding sources, and other information relevant to the thematic scientific focus that is being investigated within the Network. The Administrative Core may also provide electronic networking to inform investigators both within and outside the

network of the availability and access to modern technologies at research core facilities both within the network and located at other NIH-supported sites around the country.

Additionally, regional scientific grantsmanship and scientific presentation workshops, seminar and lecture series, and visiting faculty programs can be organized as a part of the Administrative Core's scope of training and mentoring activities. Those workshops can provide a forum for Federal and private sector agencies to present their missions and goals and provide updates on research funding opportunities for investigators within the INBRE.

Bioinformatics Core

The Bioinformatics Core is essential to provide investigators access to the technical expertise and data management and analysis tools required for competitive, multi-disciplinary biomedical research. Careful consideration must be given to optimizing access to bioinformatics and other related tools for investigators in the network. This core will have a substantial impact on enabling the pursuit of research areas by the multi-disciplinary research team of the network; and will promote informatics training and education as well as understanding of approaches and methods for data management, develop methods for multi-center research and resource sharing, and provide methods for secure and confidential data-sharing.

Outreach Core

The Outreach Core may include a number of role-modeling and related training activities for four-year undergraduate institutions, junior/community colleges and tribal colleges that are not part of the scientific network. A maximum of \$250 thousand of the total direct funds awarded to the grantee institution may be expended for the Outreach Core. This core can support research projects of faculty and some students to expose them to and provide them with research experiences. INBRE programs are encouraged to develop mentoring/training activities designed to increase the number and quality of graduate program applications submitted by students in the life and related sciences. Outreach activities to these institutions through mechanisms such as (but not limited to) seminars, lectures, workshops or short courses are encouraged. Activities could also include sponsorship of graduate school workshops and networking activities, career counseling, and laboratory/research experiences at active network research laboratories.

INBRE Committees

Steering Committee (SC)

The PI serves as Chairperson of the Steering Committee (SC), one of two required INBRE committees. The PI, PC and research network institutional representatives must form and agree to participate as members of the Network's SC. The Vice President for Research of the awardee institution, or their surrogate, must participate as a member of the SC. The members of the SC establish the policies and operating procedures of both itself and the INBRE. The SC meets at least three times during the first year of the award and at least semi-annually thereafter. The SC

also develops strategies as to how it will interact with the External Advisory Committee, the other mandatory committee described below. The members of the SC oversee the development of relevant workshops, lecture series, *et cetera*, and periodically review the progress of student-mentor teams. The Administrative Core provides logistical support to the SC. The PC, in conjunction with SC, designs an Evaluation Plan to determine the impact of their program on the development of the participating institutions and investigators' development.

External Advisory Committee (EAC)

Each INBRE includes an External Advisory Committee (EAC), comprising three to five scientists with national scientific reputations in their field; whose expertise must be directly relevant to the scientific themes of the INBRE. The SC establishes rules governing the composition of the EAC and the tenure of the Chairperson. The EAC critiques scientific progress of the INBRE and also offers advice on scientific matters to the PI. The EAC activities include concept development, program planning, encouraging and assisting with faculty development and mentoring, identifying resources, and evaluating progress toward stated goals. The PI will share the advice and critiques provided by the EAC with the PC and network investigators. The EAC also reviews and approves candidates for additional projects and investigators as required, before such requests are forwarded to NCRB for confirmation and approval. The members can monitor the longitudinal progress of INBRE development. The Administrative Core provides logistical support to the EAC. Expenses of the EAC, including honoraria, are included in the budget. The EAC must meet at least twice per year on average. A summary of the issues discussed at each EAC meeting, recommendations made, and actions taken must be included in the yearly progress reports submitted to the NCRB.

Mentors

Mentors must have research expertise relevant to the scientific area(s) to be developed within the INBRE. The mentor may be a collaborator on the junior investigator's research project. Mentors will help oversee the proposed training and career development of promising investigators. Each junior investigator should be assigned to at least one mentor. The mentor is an established faculty member who has demonstrated the ability to advise others through the acquisition of external support and the maintenance of an independent research laboratory. In some instances a suitable mentor may not be available within the investigator's institution; therefore it is acceptable to enlist appropriate mentors from outside institutions. Mentors may request between 10 and 20 percent effort and are included in the Administrative Core's budget, not in the individual projects' budgets. The junior investigators should clearly designate the identity of their mentors and describe the qualifications, both scientific and advisory, that make them appropriate to assist in the oversight of the project. In some cases, Center of Biomedical Research Excellence (COBRE) graduate investigators may serve as mentors to junior investigators and/or students.

Graduate and Undergraduate Students

Graduate and undergraduate students on various projects must be recruited in the first three years of the program. The NCRR Staff must administratively review the addition of students in Years four or five.

Evaluation Plan

An evaluation component is to be included in the INBRE to assess whether the effectiveness of the approach taken is meeting the goals or benchmarks for building an effective institutional and statewide scientific network. Grantees were required to include in their applications an evaluation plan describing the development and implementation of the plan for formative and summative evaluations of the network along with strategies for revisions, if deemed necessary. In addition, the evaluation plan is to set benchmarks for the network's impact on recruitment of outstanding faculty and students at participating undergraduate and graduate institutions. There may be other novel elements that the grantee may choose to include in the evaluation plan, such as quality and number of students, productivity of the mentors and junior investigators, and impact on state's biotechnology industry and workforce.

Plan for Sharing Research Data

All grantees had to include a plan for sharing research data in their application. The data sharing policy is available at http://grants.nih.gov/grants/policy/data_sharing. All applicants had to include a description of how final research data will be shared, or explain why data sharing is not possible.

The reasonableness of the data sharing plan, or the rationale for not sharing research data, was assessed by the reviewers. However, reviewers did not factor the proposed data sharing plan into the determination of scientific merit or the priority score.

The precise content of the data-sharing plan varied, depending on the data being collected and how the investigator is planning to share the data. Applicants who planned to share data were to describe briefly the expected schedule for data sharing, the format of the final dataset, the documentation to be provided, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any conditions will be placed on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal website, through a data archive or enclave, *et cetera*). Investigators choosing to share under their own auspices could enter into a data-sharing agreement.

Sharing Research Resources

NIH policy expects that grant recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication. Investigators were required to provide a plan for sharing research resources addressing how unique research resources will be shared or explain why sharing is not possible. The adequacy of the resources sharing plan and any related data sharing plans were considered by Program staff when making recommendations about funding applications. The effectiveness of the resource sharing is evaluated as part of the administrative review of each non-competing Grant Progress Report (PHS 2590).

REPORTING REQUIREMENTS

A Non-Competing Grant Progress Report (NIH form 2590) is required annually as part of the non-competing continuation award process, as described in the NIH Grants Policy Statement, http://grants1.nih.gov/grants/policy/nihgps_2003/index.htm. Instructions for the NIH form 2590 can be found at: <http://grants.nih.gov/grants/funding/2590/2590.htm>.

For NCRRC-supported Center and Resource grants, the PHS form 2590 incorporates an Annual Progress Report (APR), which provides information in greater detail than the standard NIH form 2590. The NCRRC uses the information contained in the APR to facilitate programmatic stewardship of the grant, and to respond to inquiries from other governmental agencies and the public. Specific instructions for completing an APR and including it with the NIH form 2590 can be found at <http://aprsis.ncrr.nih.gov>.

INQUIRIES

Written and telephone inquiries concerning the INBRE program are strongly encouraged, especially during the planning/budgeting phase of application development. Please contact:

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