Part I Overview Information

Department of Health and Human Services

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

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

Title: IDeA Networks of Biomedical Research Excellence (INBRE) [P20]

Announcement Type
This is a modification of RFA-RR-03-010.

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

Program Announcement (PA) Number: PAR-08-150

Catalog of Federal Domestic Assistance Number(s)
93.389

Key Dates
Release Date: April 17, 2008
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Application Receipt Date(s): July 22, 2008, July 22, 2009, and July 22, 2010
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Council Review Date(s): January 2009, January 2010 and January 2011
Earliest Anticipated Start Date(s): May 2009, May 2010 and May 2011
Additional Information To Be Available Date (Url Activation Date): Not Applicable
Expiration Date: July 23, 2010

Due Dates for E.O. 12372

Not Applicable

Additional Overview Content

Executive Summary

- **Purpose.** The National Center for Research Resources (NCRR) of the National Institutes of Health (NIH) invites applications for competing continuation of Institutional Development Award (IDeA) Networks of Biomedical Research Excellence (INBRE) grants to independent biomedical research institutes and/or biomedical research institutions that award doctoral degrees in the health sciences or sciences related to health within IDeA-eligible states. INBRE applications must represent a collaborative effort to sponsor research with undergraduate institutions, community colleges, and tribal colleges and universities (TCUs).
- The size, structure, and operational principles of the INBRE networks have been established during previous INBRE and the planning phase of INBRE project periods. The competitive renewal application should describe progress and accomplishments made to achieve the goals of the statewide research network.
- This Funding Opportunity Announcement (FOA) is to provide an opportunity to build on the successes of the current INBRE to augment and strengthen the state's biomedical research capacity. The objectives of INBRE program are to: 1) continue to build on the established multi-disciplinary research network with a scientific focus to strengthen the lead and partner institutions' biomedical research expertise and infrastructure; 2) build and increase the research base and capacity by providing support to faculty, postdoctoral

fellows and graduate students at the participating institutions; 3) provide research opportunities for students from undergraduate institutions, community colleges and TCUs and serve as a "pipeline" for these students to continue in health research careers within IDeA states; 4) enhance science and technology knowledge of the state's workforce.

- **Mechanism of Support.** This FOA will utilize the NIH exploratory grant mechanism (P20).
- **Funds Available and Anticipated Number of Awards.** The NCRR intends to commit approximately $60 million in fiscal year (FY) 2009 to fund up to 18 competing continuation awards in response to this FOA.
- **Budget and Project Period.** An applicant may request a project period of up to 5 years and may request a budget for direct costs of up to $2.5 million per year, excluding facilities and administrative (F&A) costs on consortium arrangements. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the NCRR provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1.A. are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support. The Principal Investigator (PI) of the INBRE application must be an established biomedical or behavioral research scientist who has the administrative abilities to carry out effectively the objectives of the INBRE program. The PI must have strong scientific credentials.
- **Number of PDs/PIs.** Multiple PDs/PIs are not allowed.
- **Number of Applications.** Each eligible IDeA state may submit only one application.
- **Resubmissions.** Resubmission applications will be accepted. Such applications must include an Introduction addressing the previous peer review critique (Summary Statement).
- **Renewals.** Applicants may submit a renewal application for this FOA. Competing continuation applications will be accepted from institutions that currently hold an INBRE award; only those INBREs that will be in the final year of funding in FY 2008 should apply in response to July 2008 submission date.
- **Special Date(s).** See Receipt, Review and Anticipated Start Dates
- See Section IV.1 for application materials.
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY 301-451-0088

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Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

The National Center for Research Resources (NCRR) of the National Institutes of Health (NIH) invites applications for competing continuation of Institutional Development Award (IDeA) Networks of Biomedical Research Excellence (INBRE) grants to independent biomedical research institutes and/or biomedical research institutions that award doctoral degrees in the health sciences or sciences related to health within IDeA-eligible states. INBRE applications must represent a collaborative effort to sponsor research with undergraduate institutions, community colleges and tribal colleges and universities (TCUs).

This Funding Opportunity Announcement (FOA) is to provide an opportunity to continue building on the successes of the INBRE program to further augment and strengthen the state's biomedical research capacity. The objectives of INBRE program are to: 1) continue to build on the established multi-disciplinary research network with a scientific focus to strengthen the lead and partner institutions' biomedical research expertise and infrastructure; 2) build and increase the research base and capacity by providing support to faculty, postdoctoral fellows and graduate students at the participating institutions; 3) provide research opportunities for students from undergraduate institutions, community colleges and TCUs and serve as a "pipeline" for these students to continue in health research careers within IDeA states; 4) enhance science and technology knowledge of the state's workforce.

The INBRE 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, encompassing the full spectrum of basic, clinical and translational sciences. 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 this FOA is to continue assisting these institutions to implement and use the technologies and other resources needed to conduct state-of-the-art biomedical and behavioral research and provide research experiences to students at baccalaureate institutions, community colleges, and TCUs.

Competing continuation applications will be accepted from institutions that currently hold an INBRE award (http://grants.nih.gov/grants/guide/notice-files/NOT-RR-03-008.html). The size, structure, and operational principles of the INBRE networks have been established during previous INBRE and the planning phase of INBRE project periods. The competitive renewal application should describe progress and accomplishments made to date to achieve the goals of the statewide research network. Progress should include

accomplishments in the following areas:

- Research Infrastructure as measured by improved research facilities and support services, including bioinformatics in the research network; acquisition and utilization of new and major instrumentation;
- Research Environment as evidenced by successful recruitment of science faculty from different disciplines at the institutions in the network; increased collaboration among researchers and institutions;
- Development of science curriculum (courses and programs) offered at the network institutions;
- Development of research laboratories and facilities in the network institutions;
- Students majoring in science and health-related fields;
- Students and faculty participating in research activities;
- Research Productivity as measured by scientific publications in the peer-reviewed journals and presentations at scientific meetings and other conferences;
- Grant applications from research intensive institutions for NIH and other research grants submitted and awarded;
- Number of undergraduate students pursuing science and health-related careers;
- Impact on the state's workforce and economy.

Background:

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 from 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 grant applications to the NIH historically has been low. Disparate funding distributions may stem in part from having relatively few competitively supported biomedical and behavioral investigators in IDeA states. Statewide IDeA Networks of Biomedical Research Excellence (INBRE) supported through this FOA are intended to develop the research resources and modern laboratories needed to attract established investigators, and to develop and enhance the research skills of talented investigators and promising students within each state.

The INBRE program began in 2001 by providing planning grants for three years. These programs were re-competed in 2004 to establish inclusive statewide multidisciplinary research networks with scientific foci 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 in the IDeA-eligible states. INBREs also were intended to enhance the caliber of scientific faculty at research institutions and undergraduate schools, thereby attracting more promising students to these organizations.

Program Description:

The purpose of INBRE program is to:

- 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; and
- provide undergraduate faculty and students research support to serve as "pipeline" to health research careers and to provide hands-on research experience to students at undergraduate institutions, community colleges, and TCUs.

The FOA is intended to strengthen the basic science departments of undergraduate institutions and TCUs. This Program provides opportunities for undergraduate institutions, community colleges, and TCUs to support and retain current productive faculty and recruit outstanding faculty who conduct research in the specific proposed thematic areas and can attract promising students to health-related science through both didactic training and research experiences. Students who are well trained in science and technology can enhance the quality of the workforce, which in turn can attract biotechnology industries and enhance the economies within IDeA states. With better employment opportunities, more students may choose to stay within the state. The undergraduate institutions also serve as an important pipeline to the science departments of graduate schools within IDeA states for students to pursue graduate education. With access to promising, biomedically-trained students, the graduate schools in the IDeA states can more readily build a critical mass of investigators to conduct biomedical research by recruiting competitive investigators from other institutions as well as recruiting some of their own graduates.

The application must include a scientific focus in one or more 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, clinical, and/or translational research approaches to attain the goals of the proposed network. The broad thematic areas will encourage and facilitate interactions and cross-collaborations among INBRE, COBRE and RCMI investigators and programs; and will promote data and resource sharing within the statewide network and the region. It is also anticipated that, in some instances, support through this FOA will facilitate the development of new disease-specific research networks or augment the capability of existing programs.

Some applicant 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, collaborators, and scientific members of a multidisciplinary steering committee. The focus of the planned research network will determine the need for core research facilities and modern instrumentation.

Scientific leadership provided by one or more established biomedical research faculty members is critical to the success of the INBRE 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 and partner graduate and undergraduate institutions, community colleges and TCUs. Faculty at participating institutions will receive support to establish or enhance existing research laboratories, acquire specialized equipment, and hire postdoctoral fellows, students and technical assistants.

The NIH is committed to working toward elimination of health disparities among racial and ethnic minority populations. Investigators proposing research that involves human subjects are strongly encouraged to include representation from the unique and diverse populations within the IDeA states for valid analyses of factors that may influence health disparities. INBRE PIs are encouraged to interface and collaborate with other appropriate programs in this regard such as the Clinical and Translational Science Award (CTSA) program to address health disparities and health issues in underserved communities.

Since the NIH is also very concerned about the under-representation of minorities in biomedical and behavioral research, the inclusion of investigators and institutions that serve these populations within the INBRE is strongly encouraged.

Under this FOA, INBRE PIs are strongly encouraged to collaborate and interface with K-12/pre-college level programs such as Science Education Partnership Award (SEPA), for developing a continuous pipeline of students to provide for the INBRE program to train future generation of biomedical research workforce.

INBRE Network Characteristics:

The statewide network is to be composed of baccalaureate, master's level degree-granting institutions, non-profit research institutes, community colleges and/or TCUs that will provide the sites for the conduct of thematic, multidisciplinary, biomedical and behavioral research. An INBRE scientific network must include a doctoral degree-granting institution or research institute as the applicant institution in the eligible IDeA states and ideally six to eight baccalaureate, master's level degree-granting institutions and community colleges or TCUs participating in the thematic research activity. 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. New undergraduate institutions that have not been a part of the network previously but contribute to the thematic research effort may be included, if appropriate, in the proposed 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 proposed in the application may include partner institutions from other IDeA states. The inclusion of minority-serving institutions is encouraged as well as diversity among faculty and students included in the INBRE. Inclusion of minority-serving institutions is an effective means of developing a diverse scientific and academic workforce.

The six to eight baccalaureate, master's level degree-granting institutions, community colleges or TCUs that participate in the thematic multidisciplinary research activity can 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 sciences, 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 and community colleges or TCUs that have not been a part of the original network but could contribute to the proposed thematic research and/or efforts to address the health needs of the community may be included in the scientific network.

The network may extend to appropriate institutions in other IDeA states if the applicant’s state has no other appropriate institutions to include within its boundaries. 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-eligible institution may be transferred via subcontract to a consortium partner institution in a non-IDeA state. However, IDeA funds may be used in other IDeA and non-IDeA states for fee-for-service type of activities that include activities associated with collaborative projects, research education and training, sample and data analysis, workshops, etc.

It is the responsibility of INBRE leadership to define an effective statewide partnership and collaboration. The network is to include undergraduate and graduate students and postdoctoral fellows, undergraduate and graduate science department faculty and faculty and students from community colleges and TCUs if these institutions are part of the statewide network. 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. This FOA strongly encourages forging interactions and cross-collaborations among INBRE and COBRE programs to enhance communication among programs, leverage resources where appropriate, and provide students a broad continuum of research opportunities.

Principal Investigator:

The goals of this program are accomplished through the direction provided by a Principal Investigator (PI), who provides leadership to investigators and has the primary responsibility for administering the program and for overseeing the scientific network and its associated core facilities. The PI of the INBRE application must be an established biomedical or behavioral research scientist with expertise directly related to the research theme(s) of the grant proposal. The PI will ensure that high-quality research is performed and has the experience to administer effectively and integrate all components of the program. The PI must have the requisite administrative experience and leadership skills to direct this multi-faceted program.

The PI at the lead institution will serve as the director of the INBRE and will coordinate its activities. This person must devote a minimum time commitment for mentoring and administrative oversight of the INBRE of 3.6 person months per year, however up to 6.0 person months will be supported. The PI will also direct the Administrative Core and will establish an administrative structure that will ensure 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 will, in consultation with the Steering Committee, select the core directors.

Other Key Personnel:

Support will be provided at 3.6 - 6.0 person months annually for an additional faculty member within the INBRE network to serve as a Program Coordinator (PC). The PC will complement the administrative efforts of the PI and act 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.

While the PI and PC positions are considered important for carrying out the INBRE mission, support for other scientific or staff positions can also be requested as long as their role in the program is justified.

Developmental Research Projects and Investigators:

Each INBRE program should include multidisciplinary, collaborative, developmental mentored 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 research projects.

The award of a Research Project Grant or a major grant award to an investigator from lead or primarily undergraduate institutions should be viewed as a milestone. Investigators who have completed a research project should not be excluded from Network 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 research support may direct a core facility or serve as a mentor to other investigators and students. It is emphasized that INBRE support cannot be provided in instances where an investigator receives a new award and that award overlaps or is significantly similar to that described in the INBRE application. However, if the specific aims of the investigator's grant application are significantly different from the project described in the INBRE, then the investigator should complete his/her INBRE project and provide research experiences to the students. In this latter case, continued support for personnel (e.g., postdoctoral fellows, graduate and undergraduate students, technicians, etc.) associated with the INBRE project can be provided.

An investigator who leaves the Network may be replaced by a new investigator. Replacement investigators and new research projects may be substituted following review by the PI and the External Advisory Committee (EAC). The PI must communicate the EAC's recommendation along with the research project to the NCRR for Programmatic Review.

In some instances, an investigator may be placed on probation or considered for removal from the INBRE 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 and/or achieving the goals and objectives of the INBRE program.

Attaining R01 support is not a criterion for evaluation of investigators located at primarily undergraduate institutions. Some research support may be attained by investigators at primarily undergraduate institutions, community colleges or TCU, i.e., Academic Research Enhancement Award (AREA, R15) grants, R03s, even R01s but that is not a requirement of this program.

Mentors:

Mentors should have research expertise relevant to the scientific area(s) to be developed within the INBRE. The mentor may be a collaborator on the faculty investigator's research project. Mentors will help oversee the proposed training and career development of promising investigators. Each project investigator should be assigned 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 up to 2.4 person months and should be listed in the Administrative Core's budget section of the application and not in the individual projects' budget sections. The faculty investigators should clearly designate in the text 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) investigators, where appropriate, may serve as mentors to INBRE investigators and/or students. Letters of commitment from mentors should be included in the application.

Cores:

Each network must have an Administrative Core and a Bioinformatics Core. Training and mentoring aspects of the program are to be included under the Administrative Core. Applications may include additional cores developed during previous INBRE or planning phase of INBRE project periods, such as centralized research facility and instrumentation cores. Several research projects may need access to one or more technologies included in such research core facilities, so each core facility is to include professional technical expertise to optimize use of the available technology.

The mandatory Administrative Core will be directed by the PI of the INBRE and will provide the logistical support for the network. Systematic communication among investigators within the research network is essential. The Administrative Core will also develop programs to meet the training and mentoring needs of the research faculty, fellows, and graduate, undergraduate, community and TCUs students. For example, special training may be designed for students, fellows and faculty to hone their investigative skills. Support also may 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 will be provided for mentors, based on their level of effort for mentoring promising students and investigators. Salary support may be provided for an administrative assistant if required and justified.

The Administrative Core will serve to oversee 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 provide electronic networking to inform investigators both within and outside the network of the availability of 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.

The Administrative Core may include a number of role-modeling and related training activities for four-year undergraduate institutions, junior/community colleges, and TCUs. INBRE programs are encouraged to develop mentoring/training activities designed to increase the number and quality of graduate program applications submitted by students. 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 or field sites (e.g., community sites).

The PI and PC should budget for an annual meeting in Bethesda, Maryland with NCRR staff. These meetings will provide a forum for the exchange of ideas, information and address their concerns, needs and problems that arise. In addition, NIH staff will provide updates on policies and regulations that relate to the conduct of research, including discussions of NIH Electronic Research Administration, ethics, and protection of human subjects to strengthen the program and the network. Applicants are to include in their requested budgets the cost of attending these meetings in the Bethesda area.

Required Committees under Administrative Core:

Steering Committee:

The PI will serve as Chairperson of the Steering Committee (SC), one of two required INBRE committees. The PI, PC and research network institutional representatives must agree to participate as members of the Network's SC, which will consist of no more than 20 members. The SC will include up to two members from each network partner institution; these members should include a senior administrative person and someone with scientific expertise and background. 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 will establish the policies and operating procedures of both itself and the INBRE. The SC will meet at least three times during the first year of the award and at least semi-annually thereafter. The SC will develop strategies as to how it will interact with the External Advisory Committee, the other mandatory committee described below. The members of the SC will

oversee the development of relevant workshops, lecture series, etc., and will regularly review the progress of student-mentor teams. The Administrative Core will provide logistical support to the SC. The PC, in conjunction with SC, will design an Evaluation Plan to determine the impact of their program on the development of the participating institutions and investigators' development.

External Advisory Committee:

Each INBRE application must include an External Advisory Committee (EAC). The Steering Committee (SC) should establish rules governing the composition of the EAC and the tenure of the Chairperson. The composition of the EAC is to include at least three to five members with appropriate scientific expertise in the thematic focus area (s), who can provide advice to the SC for scientific, administrative, and other matters. The members can monitor the progress of INBRE development. The Administrative Core will provide logistical support to the EAC. Expenses of the EAC, including honoraria, are to be included in the budget request. The EAC must meet at least twice per year. The EAC critiques the scientific progress of the INBRE and also offers advice on scientific matters to the INBRE 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 network, and evaluating the progress of the individual research projects. The PI will share the advice and critiques provided by the EAC with other INBRE investigators and the Steering Committee of the network. The EAC also will review and recommend candidate investigators for replacement/substitute projects, as required, before such requests are forwarded to the NCRR for Programmatic Review. 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.

Bioinformatics Core (Mandatory):

Bioinformatics includes organization and analysis of biological and related information, involving the use of computers to develop databases, retrieval mechanisms, and data analysis tools, especially in the fields of molecular biology, genomics, proteomics, structural biology, and genetics. The Bioinformatics Core will provide resources and tools that fall under three categories: Research, Training, and Education opportunities, through facilitated communication. For research, the Core will provide investigators access to the technical expertise and data management and analysis tools required for competitive, multidisciplinary 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 faculty and students participating in the network. This core may promote informatics training and education, and development of Bioinformatics curriculum and degree programs 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.

Access to and utilization of bioinformatics tools and resources relies on a comprehensive supporting infrastructure (often termed cyberinfrastructure) that integrates data-gathering facilities, computing hardware, data analysis and informatics tools, software and middleware, high-bandwidth network connectivity, and technical support. Robust network connectivity facilitates research collaboration and sharing of resources across geographical boundaries and provides access to rural areas and other hard to reach populations. Enhanced network connectivity also broadens access to education and training programs that further national efforts to strengthen the biomedical research workforce. Under this Core, applicants may request funds to enhance network connectivity within their state. Applicants within a common geographical region may also develop a multi-state plan to collectively address research cyberinfrastructure needs and gaps. Such efforts should seek to leverage funds from other federal, state, and local sources to the greatest extent possible. The Bioinformatics Core may also provide resources to enhance communications within the state and with the rest of the world, including but not limited to library access to research journals and video-teleconferencing services.

Optional Core:

Under this FOA, institutions may also request additional cores such as a Community-Based Participatory Research (CBPR) Core to facilitate the conduct of new research projects or to expand ongoing projects in community-based research, with an emphasis on those diseases that disproportionately affect racial and ethnic minorities and rural and other medically underserved populations. A community-based participatory collaborative approach involves partners – community residents and scientists- in the research process and recognizes the unique strengths that each brings to research. The CBPR Core can help develop critical infrastructure in medically underserved communities to increase their involvement in clinical and translational research and mentor investigators in the conduct of this research modality.

Evaluation Plan and Milestones:

An evaluation component is to be included in the application to assess whether the effectiveness of the approach taken will meet the goals or benchmarks for building an effective institutional and statewide scientific network. The application is to describe 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 and retention of outstanding faculty and students at

participating undergraduate and graduate institutions, community colleges and TCUs. There may be other novel elements that the applicant may choose to include in the evaluation plan, such as quality and number of students, productivity of the mentors and investigators, and impact on state's biotechnology industry and workforce.

All the Networks must have an independent, external evaluation in addition to the monitoring and formative evaluation process provided internally and by the External Advisory Committee. Funds for the external evaluation, up to 5% of the total direct costs, if appropriately justified, may be requested in the Administrative Core budget. As a part of the evaluation process, students who are receiving biomedical research experiences and training should be tracked, for example total number of students who had research experiences, have gone to graduate and professional schools or have entered the workforce.

One of the objectives of INBRE is to provide undergraduate faculty and students research support and serve as a “pipeline” for undergraduate students to continue in health research careers. The mission of the most undergraduate institutions and liberal arts colleges is teaching and in some cases teaching and research to provide students experiences and exposure to research. The intent of INBRE is not to transform liberal arts undergraduate institutions into biomedical research centers but rather to augment the science curriculum. Obtaining R01 support by investigators at these institutions is not expected and is not a criterion for evaluation. However, these investigators may seek and obtain research support via mechanisms such as Academic Research Enhancement Award (AREA) and Research Infrastructure in Minority Institutions (RIMI) grants, and even R01s but that is not a requirement of the INBRE program. However, at the lead institutions, investigators may apply for and obtain R01 and Program Project grant support and in some cases faculty at the primarily undergraduate institutions (PUIs) may participate as investigators in these Program Project grants.

INBREs that include TCUs as partners are encouraged to develop activities that focus on enhancing the quality of instruction and providing research experiences relevant to students and their communities. This may include activities that focus on preserving the culture of their tribes, incorporating new courses in science curricula, and involving their students in research projects that are linked to reducing health disparities and developing interventions to improve the health status of their communities.

The success of PUIs, community colleges and TCUs researchers may be measured by attainable metrics that are appropriate to the missions of their institutions. Criteria for evaluating the progress of these researchers may include evidence of scholarly activities including publications, offering of new courses and programs, providing research experiences to students, impact on the community, attending and presenting research findings at scientific meetings and conferences, and submission of external grant applications to NIH and other Federal and non-Federal agencies and acquisition of awards such as Academic Research Enhancement Award (AREA, R15), exploratory/pilot project grants (R03 and R21), career development awards (K01 and K08) or other Federal or non-Federal Agency awards.

Allowable Costs:

Funds will be provided to continue building and strengthening research infrastructure and capacity at the lead and partner institutions, including Alteration and Renovation (A&R) of research laboratories, instrumentation for Core laboratories, optional cores such as for Community Based Participatory Research, and staffing (investigators, postdoctoral fellows, graduate and undergraduate students, students from community colleges and TCUs, and technical assistants).

The maximum allowable direct cost for the INBRE program is $2.5 million per year of which $1.0 million is available to 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.

The remaining direct costs, up to a maximum of $1.5 million, are to be distributed among the participating network partner institutions including baccalaureate/masters degree institutions, community colleges, and TCUs as consortium arrangements and/or subcontracts to build infrastructure and research capacity for the proposed multidisciplinary research projects. Funds allocated to partner institutions are to cover expenses including but not limited to salary, research support, and equipment acquisition. Individual research projects may be funded at a level not to exceed $125 thousand per year in direct costs. A maximum of 15% of the total direct cost requested at each partner institution may be used for administrative costs. Funds allocated to community colleges and TCUs may be used to establish science programs/courses and conduct meaningful research projects relevant to their communities during the summer and academic year. A Memorandum of Understanding (MOU) must clearly describe the arrangements between the network partner institutions and the grantee institution and must provide for release time for investigators and consideration of research accomplishments in any advancement/tenure criteria.

This FOA will provide an additional one time cost of up to $250 thousand in direct costs in year one for A&R to improve existing core laboratories and/or research laboratories at the lead institution, undergraduate institutions, and community colleges and TCUs.

It is not required or expected that each applicant will request the categorical maximum allowable costs stated herein. These numbers are

provided as a guide for purposes of developing the INBRE proposed network. The actual costs requested will 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.

Sharing resources among INBRE and COBRE investigators is strongly encouraged. If a core facility already exists for equipment and instrumentation supported by a COBRE program, these should not be proposed de novo in the INBRE application. However, if duplicate equipment is to be requested under this FOA, it should be appropriately justified. Under this FOA, COBRE investigators are not eligible for research funding from INBRE as project investigators. Similarly, INBRE investigators may not receive simultaneous research project support from a COBRE program. COBRE investigators may serve and be supported as mentors in INBRE programs as appropriate.

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, may consider the budgetary allocation guidelines regarding the available $2.5 million direct costs to be flexible.

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 research project investigators at the awardee and network partner institutions will devote at least 50 percent of their professional effort (equivalent to 6.0 person months) to career development and research activities. Institutions must provide release time for project investigators, thus permitting a significant time commitment to the research enterprise. To allow flexibility to investigators who cannot devote 6.0 consecutive months throughout the year, the effort can be distributed over the year to achieve a total of 6 person months; (for example, 3.0 person months during academic year and 3.0 person months in summer (up to three months) to account for a yearly 6.0 person months effort).

Annual Meeting Costs. There will be an annual meeting of the leadership of the grantee networks. The costs to support and attend this meeting should be included in the budget section (travel) of the application. Estimate the costs for key staff to attend this meeting annually. The key staff may include PI, PC and Bioinformatics Core Director.

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 support for mentors is allowed as long as the mentors are members of the established investigator pool, and interact directly with and mentor the faculty and investigators at the undergraduate institutions, community colleges and TCUs. The mentor may request up to 2.4 person months if he/she will be extensively involved in this INBRE activity.

Salary and research support will be provided for participating graduate, undergraduate and community college and TCUs students, and postdoctoral fellows.

Alteration and Renovation: Alteration and Renovation (A&R) costs to improve existing core laboratories and/or research laboratories are allowed. This FOA will provide an additional one time cost of up to $250 thousand in direct costs in year one for alteration and renovations. A&R costs will be approved for facilities improvements at the awardee institution as well as at the consortia sites (the undergraduate institutions, community colleges and TCUs). A&R projects must be relevant to the scope of the proposed research and at the institutions involved in the research network. Sufficient detail must be provided to estimate the cost and suitability of the project. All alteration and renovation must be complete within the first three years of the award. Direct costs requested for A&R are not subject to F&A. Failure to adequately justify A&R requests will likely result in their deletion from the requested budget. Proposed renovations in successful applications will subsequently require the submission of design documents for review and approval by NIH staff before the renovation project may commence. This FOA will not provide support for new construction, including the completion of shell space. Applicants interested in seeking additional funds for animal facilities improvements are referred to the NCRR Animal Facilities Improvement Program (G20). Please refer to the Program Announcement: http://grants.nih.gov/grants/guide/pa-files/PAR-07-342.html for more information.

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 and other scientific or staff positions;
- K-12 activities at institutions participating in the statewide INBRE network.

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

Section II. Award Information

1. Mechanism of Support

This funding opportunity announcement (FOA) will use the P20 award mechanism. The applicant will be solely responsible for planning, directing, and executing the proposed project.

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

A detailed categorical budget for the “Initial Budget Period” and the “Entire Proposed Period of Support” is to be submitted with the application.

2. Funds Available

The NCRR intends to commit approximately $60 million to fund up to 18 competing continuation grant awards in response to this FOA contingent upon the availability of funds. An applicant may request a project period of up to 5 years and may request a budget for direct costs of up to $2.5 million per year, excluding facilities and administrative (F &A) costs on consortium arrangements. In addition, this FOA will provide one time cost of up to $250 thousand in direct costs in year one for A&R to improve existing core laboratories and/or research laboratories at the lead institution, primarily undergraduate institutions (PUIs), and community colleges, and TCUs.

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

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

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

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

The following organizations/institutions are eligible to apply:

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

An eligible institution must be within an IDeA state. An eligible institution must either be (1) a domestic, public or private, or non-profit research institution that awards doctoral degrees in health sciences or sciences related to health, or (2) an independent biomedical research institute.

Criteria for Eligibility of an IDeA State: In making its assessment for eligibility, NCRR includes all states/commonwealths that received less than $120 million annually NIH funding averaged over the five-year period 2002-2006. Under this criterion, the following states/commonwealth

are eligible IDeA states:

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

Criteria for Institutional Eligibility: Applications will be accepted from institutions in IDeA states that currently hold an IDeA Networks of Biomedical Research Excellence (INBRE) award (http://grants.nih.gov/grants/guide/notice-files/NOT-RR-03-008.html).

1.B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with his/her institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support. The Principal Investigator (PI) of the INBRE application must be an established biomedical or behavioral research scientist who has the administrative abilities to carry out effectively the objectives of the INBRE program. The PI must have strong scientific credentials.

2. Cost Sharing or Matching

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

Although no cost sharing or matching funds are required for the submission of these applications, clear evidence of institutional and state commitments should be included with the application. The level of institutional commitment will differ 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 should be submitted.

3. Other-Special Eligibility Criteria

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

Applicants may submit a renewal application.

Each eligible IDeA state may submit only one application.

Section IV. Application and Submission Information

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1. Address to Request Application Information

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

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

2. Content and Form of Application Submission

Applications must be prepared using the most current PHS 398 research grant application instructions and forms. Applications must have a D&B Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The D&B number can be obtained by calling (866) 705-5711 or through the web site at http://www.dnb.com/us/. The D&B number should be entered on line 11 of the face page of the PHS 398 form.

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

3. Submission Dates and Times

See Section IV.3.A. for details.

3.A. Receipt, Review and Anticipated Start Dates

Letter of Intent Receipt Date(s): June 22, 2008, June 22, 2009 and June 22, 2010
Application Receipt Date(s): July 22, 2008, July 22, 2009, and July 22, 2010
Peer Review Date(s): October/November, 2008, October/November 2009 and October/November 2010
Council Review Date(s): January 2009, January 2010 and January 2011
Earliest Anticipated Start Date(s): May 2009, May 2010 and May 2011

3.A.1. 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 this funding opportunity

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 listed in Section IV.3.A.

Office of Review
National Center for Research Resources
National Institutes of Health
6701 Democracy Boulevard, Room 1070
Bethesda, MD 20892-4874
Bethesda, MD 20817-4874 (for express/courier service)
Telephone: (301) 435-0811

3.B. Sending an Application to the NIH

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

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)
Bethesda, MD 20817 (for express/courier service; non-USPS service)

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

At the time of submission, two additional copies of the application and all copies of the appendix materials must be sent to:

Office of Review
National Center for Research Resources
National Institutes of Health
6701 Democracy Boulevard, Room 1070
Bethesda, MD 20892-4874
Bethesda, MD 20817-4874 (for express/courier service)
Telephone: (301) 435-0811

3.C. Application Processing

Applications must be **received** on or before the application receipt/ date(s) described above (Section IV.3.A.). If an application is received after that date, it will be returned to the applicant without review.

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

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

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

4. Intergovernmental Review

This initiative is not subject to intergovernmental review.

5. Funding Restrictions

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

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

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

6. Other Submission Requirements and Information

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 network, followed by the individual budgets for all cores, consortia, contractual arrangements, and projects. 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 network should be followed with letters indicating institutional commitment and any letters of support for the proposed network (if applicable). Do not place these letters in the Appendix. The Research Plan for the network (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, etc.

The PI, PC, core directors, research project investigators and mentors must provide a biographical sketch as indicated in the PHS 398 instructions. This section must not exceed four pages per person.

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 (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-031.html.) Lack of adherence to these guidelines may result in the application being considered as non-responsive and returned to the applicant.

Applicants submitting a resubmission application should follow the instructions for resubmission applications described in the PHS 398

document instructions. The resubmission must include an Introduction of not more than three pages that summarizes the 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 resubmission must each include a separate section of not more than one page titled Response to Previous Review that summarizes the substantial additions, deletions, and changes from the project that was originally submitted with the prior INBRE application. Insert the Response to Previous Review just before the very beginning of the individual project's Research Plan section. Changed text should be marked as described above.

Supplemental Instructions:

An application for an INBRE award should include the following:

- A discussion of accomplishments made during the current INBRE or the planning phase of INBRE period (if previously did not have an INBRE award); the strongest and most relevant parts of the network accomplishments should be identified and included in the application. Provide a summary of the evaluation report and provide recommendations and corrective actions taken.
- A discussion of the organizational structure established for various cores and network during INBRE or planning phase of INBRE.
- A discussion of the required plan for networking, sharing of resources and cross-collaborations with Centers of Biomedical Research Excellence (COBREs), other INBREs, and other appropriate NCRR programs such as CTSAs, Biomedical Technology Research Centers and other NIH-supported Centers; Provide a description of how resources will be shared and collaborations formed within the Network, programs and regions.
- A discussion of the plan how INBRE will interface with K-12/pre-college level programs such as SEPA for developing a continuous pipeline of students to provide for the INBRE program to train future generation of biomedical research workforce
- With respect to the overall program, a description of the unique research opportunities that will be provided to the project investigators at the lead and partner institutions. If the proposed research is closely related to ongoing research or an existing center, explain how these research activities will complement but not overlap with existing research.
- A description of how the efforts of project investigators will assist in the establishment of a multi-disciplinary research network.
- A clear description of the qualifications of the PI. The Principal Investigator must be an established biomedical or behavioral research scientist.
- A description of the External Advisory Committee, including the number and types of individuals to be included and their professional qualifications, along with a budget estimate to support EAC activities.
- Presentation of an overall plan to justify support of the thematic scientific network for the next five years, which includes the proposed organization and component functions of the INBRE. The plan should demonstrate the applicant's knowledge, ingenuity, practicality, and commitment to developing a significant, productive, research program.

(1) Discuss the priorities and objectives of the scientific network to be developed in the INBRE.

(2) Describe the statewide network of baccalaureate/master's level degree-granting institutions and community colleges and TCUs that will provide the sites for the conduct of the thematic, multidisciplinary, biomedical or behavioral research.

(3) Address the establishment of core facilities necessary to carry out the objectives of a multi-disciplinary, collaborative program.

(4) Justify requested funds to develop the several components, including support for promising but not yet established investigators.

(5) Describe the potential impact of the proposed network on the research capacities of participating institutions, faculty, and students within the host state.

(6) Describe the roles of the INBRE Steering Committee and External Advisory Committee in establishing the approaches to be used to set priorities for future research efforts in undergraduate and graduate institutions, community colleges, and TCUs.

(7) Prioritize the needs within the proposed scientific network and how those needs will be met.

(8) Describe the anticipated impact on students and faculty from undergraduate institutions, community colleges, and TCUs on the workforce and as a pipeline into the graduate science programs within the state.

- Description and justification of the proposed individual research projects (up to ten pages for the Research Plan Section for each project) and core service facilities that collectively will contribute to the network. Senior, funded investigators must not be proposed as research project leaders, but they may serve as mentors for faculty investigators and students.

(1) For each research project (up to 10 pages):

- Describe the specific aims of the research project in an area that is focus of the INBRE. Delineate the hypotheses to be tested. Preliminary studies are NOT required for INBRE 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 and provide a strong research plan. Concisely state the importance and health relevance of the proposed research to the specific aims.
- Describe the nature and scope of any scientific research collaborations.

(2) The proposed research plan for each project should also address:

- The candidate
- Career development plan, including plans for developing a sustainable research program
- Research plan
- Mentor/collaborator
- Research environment
- Institutional commitment
- Technical support
- Budget
- A description of the research and research training or career development goals.
- A discussion of how proposed cores are integrated into the proposed project.

Cores:

(1) Administrative Core (Required):

- Discuss the qualifications and role of the PI and PC. The PC may be selected from among the participating institutions in the proposed scientific network.
- Describe the administrative structure of the network and arrangements and the mechanisms to be used to resolve differences of opinion.
- Discuss training and mentoring plans. Include a clear plan for career development, a mentoring plan that involves oversight by established senior faculty members assigned as mentors, constructive evaluations by members of the SC and EAC, and coordinated management of all of these individuals.
- Research project investigators should clearly designate in the text 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, COBRE investigators, where appropriate, may serve as mentors to INBRE investigators and/or students.
- Describe the network's plan to develop the research skills of both graduate and undergraduate students and faculty.
- Describe the role of undergraduate faculty.
- Describe how faculty will be protected for research time.
- Describe plans to attract and retain promising students into biomedically-related science majors and opportunities for exposure to cutting-edge research.
- A description of the infrastructure -- equipment and facilities -- available at the lead and network institution to support studies aimed at developing a nationally competitive biomedical research program and research capacity. Describe available resources (e.g., laboratory facilities, patient populations, geographic distributions of space and personnel) and collaborative resources. Describe the infrastructure needs at the INBRE partner institutions and how the Administrative Core will prioritize those infrastructure needs.

(2) Bioinformatics Core (Required):

- Describe the progress made by the Bioinformatics Core in creating infrastructure and other related tools for investigators in the network during INBRE and/or planning phase of INBRE period.
- Describe the new approaches to be undertaken within the proposed scientific network to provide access to bioinformatics tools for data mining and model development, database management of heterogeneous objects of varying size and the need for training investigators in the effective use of those tools.
- Describe the impact of the Core on multidisciplinary thematic research efforts and the environment in which to develop a new generation of researchers.

- If access to high-end computational power is required, describe how and where investigators can access this capability.

(3) Centralized Research/Instrumentation Core (Optional):

- Describe how core facilities will facilitate research for investigators in the network.
- Provide the impact of Research Core Laboratories, and how the Core Laboratories will be professionally staffed; provide the rationale for continuing the Core facilities or for adding new Core facilities.
- Include justification for the level of funds requested to support the Core Facilities.
- If core facilities are included for support, describe the relationship of each component research project to the core(s).
- Describe what research equipment is available and can be used by INBRE investigators and students; Describe and justify additional research instrumentation needs of the INBRE partner institutions and how those needs can be addressed through this program.

(4) Community-Based Participatory Research (CBPR) Core (Optional):

- Describe how this core facility will facilitate research for investigators in the network.
- Provide the rationale for proposing the Core facility with justification for the level of funds requested.
- Describe the quality of existing institutional research space as well as research facilities needed across the partner institutions to conduct the proposed CBPR for investigators within the INBRE.
- Describe what research equipment is available and can be used by INBRE investigators and students. Describe and justify additional research instrumentation needs of the INBRE and how those needs can be addressed through this Core.

Memorandum of Understanding:

- A memorandum of understanding (MOU) clearly describing the arrangements between the baccalaureate institutions, community colleges and TCUs and the awardee institution. Faculty at 4-year baccalaureate institutions must have a commitment for 50% release time (equivalent to 6.0 person months) for the conduct of research as part of the MOU. Women, minorities and individuals with disabilities are strongly encouraged to participate.

Alteration and Renovation:

- A narrative summary, line drawings and cost estimates must be provided for any proposed A&R project. The following sample format is suggested:

Narrative summary

- Relate the proposed renovations to the research projects that will use the facility.
- List the functional components, including the size (dimensions) and square footage of each component (room, alcove, cubicle) that will be directly affected by the renovation project.
- List engineering criteria applicable to each component (mechanical, electrical, and utilities), including information such as the number of air changes per hour, electrical power, light levels, hot and cold water, and steam.
- List appropriate architectural criteria (such as width of corridors and doors, surface finishes).
- List and justify all fixed equipment items requested for the renovated area.

Line drawings

- Submit line drawings on 8-1/2" x 11" paper only. (DO NOT SUBMIT BLUEPRINTS) These drawings will not be counted against the page limit for the Core facility or research project. All floor plans must be legible, with the scale clearly indicated.
- Line drawings of the proposed renovation must be at a scale adequate to explain the project. The drawings should indicate size (dimensions), function, and net and gross square feet of space for each room. The total net and gross square feet of space to be renovated should be given.
- The plan should indicate the location of the proposed renovation area in the building.
- Include the as-built drawings of the proposed renovation area and indicate any areas which will be demolished.
- Changes or additions to existing mechanical and electrical systems should be clearly described in notes made directly on the plan or attached to the plan.
- Indicate the type(s) of new finishes to be applied to room surfaces.

Cost estimates

- An itemized budget and justification of the impact that this alteration and renovation would have on the INBRE activities must be provided.
- Detailed cost estimates must be included, provide vendor quotes when available.

Applicants interested in seeking additional funds for animal facilities improvement are referred to the NCRR Animal Facilities Improvement Program which accepts applications for upgrading of animal facilities including renovation and equipment (e.g., cages and static racks). Please refer to the Program Announcement: http://grants.nih.gov/grants/guide/pa-files/PAR-07-342.html for more information.

Research Plan Page Limitations

The Research Plan section of the application describing the network, 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. 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.

Appendix Materials

All paper PHS 398 applications submitted for May 25, 2008 and subsequent due dates **must** provide appendix material on CD only, and include five identical CDs in the same package with the application. Paper applications submitted for due dates prior to May 25, 2008 may voluntarily provide the appendix on five identical CDs; if submitting CDs it is not necessary to include a paper appendix. (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-031.html.)

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

Resource Sharing Plan(s)

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

(a) *Data Sharing Plan*: Investigators seeking $500,000 or more in direct costs in any year are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Applicants are encouraged to discuss data-sharing plans with their NIH program contact. See Data-Sharing Policy or http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html.

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

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

Section V. Application Review Information

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1. Criteria

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

2. Review and Selection Process

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

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

- Undergo a selection process in which only those applications deemed to have the highest scientific and technical 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 the appropriate national advisory council or board.

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

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

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

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

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

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

Investigators: Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

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

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

The review of the INBRE application is additionally based not only on these traditional review criteria, but also on the qualification and stature of the Principal Investigator to provide both scientific and administrative leadership and on the feasibility and potential for investigators to obtain independent grant support and provide research experiences to students to develop a pipeline to health research careers.

The following criteria will be used to evaluate the 1) administrative leadership and overall potential for developing a research interest and culture, 2) scientific merit of the developmental biomedical research projects, and 3) effectiveness in training and promoting investigators and students at the lead and partner institutions.

1) ADMINISTRATIVE LEADERSHIP AND OVERALL POTENTIAL FOR DEVELOPING A RESEARCH INTEREST AND CULTURE:

Reviewers will be asked to consider the following:

- The qualifications of the Principal Investigator to provide scientific and administrative leadership in developing and directing the INBRE, and to continue building on the established thematic, multi-disciplinary research network with a scientific focus.
- Key personnel in other areas, for example, bioinformatics, well qualified to work in developing and enhancing activities of the Cores and network.
- Progress to date in achieving program goals and program impact in the following categories:
- Research Infrastructure as measured by improved research facilities and support services, including bioinformatics in the research network; acquisition and utilization of new and major instrumentation;
- Research Environment as evidenced by successful recruitment of science faculty from different disciplines at the institutions in the network; increased collaboration among researchers and institutions;
- Development of science curriculum (courses and programs) offered at the network institutions;
- Development of research laboratories and facilities in the network institutions;
- Students majoring in science and health-related fields;
- Students and faculty participating in research activities;
- Research Productivity as measured by scientific publications in the peer-reviewed journals and presentations at scientific meetings and other conferences;
- Grant applications from research intensive institutions for NIH and other research grants submitted and awarded;
- Number of undergraduate students pursuing science and health-related careers;
- Impact on the state's workforce and economy
- Organizational structure established for various cores and network during INBRE or planning phase of INBRE.
- The significance, approach, and innovation of the proposed developmental research projects and of the INBRE as a whole.
- The nature, scope, and effectiveness of the plans for coordination and cooperation among research project investigators.
- The level of institutional commitment with regard to assuring that the resources and facilities to sustain the INBRE program are present, including, but not restricted to, existing relevant equipment, animal, and/or computer resources, and departmental or inter-departmental cooperation.
- The need for the bioinformatics core and other proposed core facilities and the effectiveness of these facilities to enhance the network research effort.
- The ability to augment and strengthen the biomedical research capability at the lead and partner institutions.
- The ability to develop undergraduate and graduate educational opportunities, ranging from formal programs to courses and seminars, visiting scientist programs and other similar activities. Provisions made for familiarizing investigators and students with bioinformatics tools and resources.
- A letter of intent to establish a formalized agreement (MOU) among institutions that is to constitute the scientific network. The MOU must describe the recourse available to arbitrate differences in the event that disputes arise and cannot be resolved collegially. Issues such as tenure, promotion, release-time, and other personnel matters pertaining to the success of the INBRE must be addressed.
- If there are plans to recruit investigator(s) are those plans reasonable and necessary and can those efforts be completed in a timely manner, such that the recruited investigator(s) can make meaningful and significant contributions to building the network? Are the timelines for building the network's biomedical research capacity realistic and attainable with the level of support provided through this program? Will the INBRE Award contribute to salaries and start up funds for promising investigators? Are there other sources of support for salaries and start-up funds?
- The effectiveness of plans to reach institutions and programs outside the scientific network. Are plans for networking, sharing of resources and cross-collaborations with COBREs, other INBREs, and other NIH-supported Centers, as appropriate, described?
- The effectiveness of plans to interface and collaborate with K-12/pre-college level programs such as SEPA for developing a continuous pipeline of students to provide for the INBRE program to train the future generation of biomedical research workforce.
- The means by which basic, clinical and/or translational research across the network is encouraged.
- The structure, composition and organizational plans for the External Advisory Committee and Steering Committee to effectively provide advice and recommendations to the participating institutions in the network.
- The appropriateness and suitability of evaluation strategies to achieve the specific goals of the INBRE program. In addition to the SC and EAC, the application must identify an independent evaluator, not a part of the INBRE program, who will perform the evaluation.

2) SCIENTIFIC MERIT OF THE DEVELOPMENTAL BIOMEDICAL RESEARCH PROJECTS:

The review of developmental research projects is not based solely on the traditional considerations used for peer evaluation of scientific merit (preliminary data are not required). Reviewers also take into account the preliminary nature of the proposed studies, and in a broader sense, the extent to which the research activity will contribute to the goals and objectives of the INBRE program. To the extent appropriate, all developmental research projects' activities will be evaluated according to NIH review guidelines for scientific projects, i.e., the five criteria used

for scientific merit review: significance, approach, innovation, investigator, and environment.

Major factors to be considered in the evaluation of developmental research projects include:

- Significance and relevance of the proposed research problem
- Potential of the research to advance the concepts or methods that drive the field and scientific knowledge in general
- Approach, including appropriateness of research plan, specific aims, experimental design, methodology, consideration of alternatives, data analysis, scope, and timetable
- Innovation is a significant consideration in some, though not all, types of research projects; innovation is characterized by novel concepts, approaches, or methods, original and innovative aims, development of new methodologies, or paradigms challenged
- Investigator training and qualification, and the appropriateness of the research to the experience level of the Project Investigator and other personnel
- Environment in which the research will be performed
- adequacy of resources
- availability of any specialized facilities needed
- institutional support for the project
- extent to which the research takes advantage of any unique features of the scientific environment or employs productive collaborative arrangements

As warranted, explicit attention to human subject's protection and appropriate inclusion of women, minorities and children as noted in Instructions for the *Application for a Public Health Service Grant*, form PHS 398 (Rev. 11/2007).

- As warranted, explicit attention to use of animals in research as noted in Instructions for the *Application for a Public Health Service Grant*, form PHS 398 (Rev. 11/2007).

3) EFFECTIVENESS IN TRAINING AND PROMOTING INVESTIGATORS, POST-DOCTORAL FELLOWS AND STUDENTS:

The reviewers will be asked to use the following items in evaluating this criterion:

- The quality of the mentoring plans, mentor suitability, plans for recruitment, research training, and career development of investigators, postdoctoral fellows and students of the institutions involved in the network.
- The suitability of the plan for recruiting new faculty, if any.
- Plans to be undertaken for capacity building at the lead and participating institutions in the network.

OVERALL EVALUATION:

The review of the INBRE applications will be based on the review criteria described herein, the administrative qualifications of the Principal Investigator and the quality of the plan to develop an effective research network for faculty and students that will contribute significantly to the state's research base.

2.A. Additional Review Criteria:

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

Resubmission Applications (formerly "revised/amended" applications): Are the responses to comments from the previous scientific review group adequate? Are the improvements in the resubmission application appropriate?

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

Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated (see the Research Plan section on Human Subjects in the PHS 398 instructions).

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

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

2.B. Additional Review Considerations

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

2.C. Resource Sharing Plan(s)

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

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

3. Anticipated Announcement and Award Dates

Not Applicable

Section VI. Award Administration Information

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1. Award Notices

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

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

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

A formal notification in the form of a Notice of Award (NOA) will be provided to the applicant organization. The NOA signed by the grants management officer is the authorizing document. Once all administrative and programmatic issues have been resolved, the Notice of Award will be generated via email notification from the awarding component to the grantee business official (designated in item 14 on the Application Face Page). If a grantee is not email enabled, a hard copy of the Notice of Award will be mailed to the business official.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm) and Part II Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part9.htm).

3. Reporting

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

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

institutions or when an award is terminated.

Section VII. Agency Contacts

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

1. Scientific/Research Contacts:

Krishan K. Arora, Ph.D.
Division of Research Infrastructure
National Center for Research Resources
Democracy I, Room 938
6701 Democracy Blvd.
Bethesda, MD 20892
Telephone: (301) 435-0760
FAX: (301) 480-3770
Email: arorak@mail.nih.gov

2. Peer Review Contacts:

Office of Review
National Center for Research Resources
National Institutes of Health
6701 Democracy Boulevard, Room 1070
Bethesda, MD 20892-4874
Bethesda, MD 20817-4874 (for express/courier service)
Telephone: (301) 435-0811

3. Financial or Grants Management Contacts:

Ms. Judy Musgrave
Office for Grants Management
National Center for Research Resources
Democracy I, Room 1051
6701 Democracy Blvd.
Bethesda, MD 20892
Telephone: (301) 435-0841
FAX: (301) 480-3777
Email: Musgravj@mail.nih.gov

Section VIII. Other Information

Required Federal Citations

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

Human Subjects Protection:
Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the

importance of the knowledge gained or to be gained (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).

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

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

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

Policy for Genome-Wide Association Studies (GWAS):
NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease through a centralized GWAS data repository. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition. All applications, regardless of the amount requested, proposing a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. Data repository management (submission and access) is governed by the Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, NIH Guide NOT-OD-07-088. For additional information, see http://grants.nih.gov/grants/gwas/.

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

Access to Research Data through the Freedom of Information Act:
The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Applicants may wish to place data collected under this funding opportunity in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

Inclusion of Women And Minorities in Clinical Research:
It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and

the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

Inclusion of Children as Participants in Clinical Research:
The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects (http://grants.nih.gov/grants/funding/children/children.htm).

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

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

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

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

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

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

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

Authority and Regulations:
This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74

and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at http://grants.nih.gov/grants/policy/policy.htm.

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

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

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Office of Extramural Research (OER)
National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892
Department of Health and Human Services (HHS)

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, RealPlayer, Video or Flash files, see Help Downloading Files.