

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Institute of General Medical Sciences (NIGMS)
Funding Opportunity Title	Centers of Biomedical Research Excellence (COBRE) [P20]
Activity Code	P20 Exploratory Grants
Announcement Type	Reissue of PAR-09-079
Related Notices	<ul style="list-style-type: none"> • December 20, 2012 - See Notice NOT-GM-12-118. Notice of Change in Contact Information. • September 28, 2012 – See Notice NOT-OD-12-161. NIH Announces Plans to Transition to Electronic Submission of Multi-Project Applications • February 22, 2012 - See Notice NOT-OD-12-065. Notice of Change of Participation of NIH Institutes and Centers.
Funding Opportunity Announcement (FOA) Number	PAR-11-286
Companion FOA	None
Number of Applications	Applications will be accepted from eligible institutions that hold two or less active COBRE awards at the time of submission. Only one application per institution per fiscal year is allowed as defined in Section III. 3. Additional Information on Eligibility .
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.859
FOA Purpose	The National Center for Research Resources (NCRR) of the NIH invites applications for Centers of Biomedical Research Excellence (COBRE) from investigators at biomedical research institutions that award doctoral degrees in the health sciences or sciences related to health or at independent biomedical research institutes within Institutional Development Award (IDeA) eligible states. The objective of the COBRE initiative is to strengthen an institution's biomedical research infrastructure through the establishment of a thematic multi-disciplinary center and to enhance the ability of investigators to compete independently for complementary National Institutes of Health (NIH) individual research grant or other external peer-reviewed support. COBRE awards are supported through the IDeA Program, which aims to foster health-related research by increasing the competitiveness of investigators at institutions located in states with

	historically low aggregate success rates for grant awards from the NIH.
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Key Dates

Posted Date	August 1, 2011
Letter of Intent Due Date	January 20, 2012, January 21, 2013, and January 21, 2014
Application Due Date(s)	February 21, 2012, February 21, 2013, and February 21, 2014
AIDS Application Due Date(s)	Not Applicable
Scientific Merit Review	May/June, 2012, May/June, 2013 and May/June, 2014
Advisory Council Review	October 2012, October 2013, and October 2014
Earliest Start Date(s)	December 2012, December 2013, and December 2014
Expiration Date	February 22, 2014
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the [PHS398 Application Guide](#) except where instructed to do otherwise (in this FOA or in a Notice from the [NIH Guide for Grants and Contracts](#)). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. While some links are provided, applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in [Section IV](#). When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

Looking ahead: NIH is committed to transitioning all grant programs to electronic submission using the SF424 Research and Related (R&R) format and is currently investigating solutions that will accommodate NIH's multi-project programs. NIH will announce plans to transition the remaining programs in the [NIH Guide to Grants and Contracts](#) and on NIH's Applying Electronically [website](#).

Note: A new version of the paper PHS 398 application form and instructions (revised 8/2012) must now be used. Download the new application form and instructions from <http://grants.nih.gov/grants/forms.htm>.

Table of Contents

[Part 1. Overview Information](#)

[Part 2. Full Text of Announcement](#)

[Section I. Funding Opportunity Description](#)

[Section II. Award Information](#)

[Section III. Eligibility Information](#)

[Section IV. Application and Submission Information](#)

[Section V. Application Review Information](#)

[Section VI. Award Administration Information](#)[Section VII. Agency Contacts](#)[Section VIII. Other Information](#)

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Program Description: The COBRE program seeks to promote the initiation and development or expansion of unique, innovative state-of-the-art biomedical and behavioral research centers at institutions in IDeA-eligible states. Research supported by this program spans the full spectrum of basic and clinical sciences and encompasses all areas of health-related investigation. The NIH recognizes that contributions from 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 assist these institutions to implement and use the technologies and other resources needed to conduct state-of-the-art research.

The objectives of this program are (1) to strengthen an institution's biomedical research infrastructure through the establishment of a thematic multi-disciplinary center and (2) to enhance the ability of investigators to compete independently for complementary NIH individual research grant or other external peer-reviewed support. The application must have a thematic scientific focus in a specific research area and may use basic, clinical, and/or translational research approaches, including community engagement and outreach research, to attain the goals of the proposed center. The center is intended to support investigators from several complementary disciplines. It will enable the institution to develop a critical mass of investigators and enhance their competitiveness in a specific research area that accelerates the rate at which those investigators compete for other complementary NIH, Federal or non-Federal external peer-reviewed research grant support. It is also anticipated that, in some instances, the support through this FOA will facilitate the development of new disease-specific research centers or augment the capability of existing centers.

Although the individual career development of the junior investigators is an important part of this program, the primary objective of the COBRE initiative is to build and develop thematic multi-disciplinary research centers. This is accomplished through the leadership of a peer-reviewed, funded investigator with expertise central to the research theme of the proposal. The scientific leadership provided by one or more established biomedical research faculty is critical to the success of this FOA, especially for the mentoring of promising junior investigators.

Collaboration with other non-doctoral degree-granting and research-performing institutes or institutions is encouraged. Funds for research activities cannot be used at collaborative institutions in non-IDeA states. However, 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, attending instructional activities and learning new techniques, sample and data analysis, and workshops etc. It is the responsibility of the PD/PI to define an effective partnership and collaboration. These centers are expected to engage in future growth through the promotion of collaborative interactive efforts among researchers with complementary backgrounds, skills and expertise and to compete independently for external peer-reviewed center or program project grant support. This goal is accomplished through the direction provided by a PD/PI, who provides leadership to junior investigators (defined below) and has the primary responsibility for administering the program and for overseeing the development of the center and its associated core facilities.

Qualifications and Responsibilities of the PD/PI: The PD/PI must be an established biomedical or behavioral research scientist, who has an active research laboratory, peer-reviewed funding (NIH, NSF or other Federal or non-Federal investigator-initiated support) that is relevant to the scientific theme of the proposed COBRE, and administrative leadership and mentoring experience to effectively carry out the objectives of the COBRE program and to meet its goals. A minimum time commitment of 3 person months is required for the PD/PI. However, up to 6 person months will be supported for mentoring and administrative oversight of the COBRE. Multiple PD/PIs are not allowed.

If the PD/PI is not in place at the institution at the time of review or award, a plan to recruit such an individual must be included in the application that will result in having that individual on the full-time faculty within one year

of the peer-review of the institution's application. An award will not be made until the institution has appointed a permanent COBRE PD/PI.

Overall Center Organization and Management plan: Each application must describe an overall center organization and management plan to justify support of a thematic multi-disciplinary COBRE program for five years. The plan should describe the unique research opportunities that will be provided to the junior investigators and to the institution. If the proposed COBRE research is closely related to ongoing research or to an existing center, an explanation of how the research activities of the COBRE will complement but not overlap with existing research should be included. In addition, the application should describe how the efforts of each junior investigator will contribute to the establishment of a multi-disciplinary research center.

For applications that propose community engagement and outreach research, clear and detailed plans for identifying a health issue that fits community priorities and academic capacity to respond, for developing a coalition of community and academic stakeholders, and for implementing evaluation strategies for the proposed projects must be included. Pilot project(s) may be proposed, but they will not be subject to peer review.

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

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

Utilizing existing core facilities and sharing research resources among IDeA programs are strongly encouraged. Applicants should describe plans (if applicable) for utilizing equipment and instrumentation supported by institution, existing COBRE or IDeA Networks of Biomedical Research Excellence (INBRE) awards.

Administrative Core: An administrative core must be included in the application. A clear plan addressing the development of junior investigators and for their transition to and attainment of independent investigator status must be included. This plan should detail the long-term goals as to how the institution intends to make the transition from the research support of multi-disciplinary COBRE projects to competitive grant support through applications submitted by its faculty members to relevant NIH Institutes and Centers or to other appropriate Federal or non-Federal agencies or organizations. Each junior investigator must submit an investigator-initiated Research Project Grant (RPG) application by the end of two years of COBRE support in order to be eligible to receive continued funding through the COBRE award.

The faculty development plan must include both formative and summative evaluation strategies with specific milestones, including, but not limited to, acquisition of independent status by the junior investigators, competition for complementary NIH, Federal or non-Federal external peer-reviewed research grant support, and publication in peer-reviewed journals. Plans for faculty development should include the mentoring plan that identifies established senior faculty members who will provide mentoring and oversight to the junior investigator; constructive evaluations by members of the External Advisory Committee (EAC, see details below); and how the COBRE PD/PI will coordinate the management of all of these individuals. An internal advisory committee may provide additional oversight and input, but this committee may not act as a substitute for the EAC.

Each junior investigator should have at least one mentor. The mentor must be an established investigator who has demonstrated the ability to advise others through the acquisition of external support and the maintenance of an independent research laboratory. In some instances a suitable mentor may not be available within the applicant's institution and it is therefore acceptable to enlist appropriate mentors from outside institutions. Mentors may receive up to 1.8 person months of salary support, which should be listed in the Administrative Core's budget section of the application and not in the individual projects' budget sections. Mentored junior investigators should clearly designate in the text of their individual research plans the identity of their mentors and describe the mentor's qualifications, both scientific and advisory, to assist in the oversight of the project.

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

It is emphasized that COBRE support cannot be provided in instances where a junior investigator's new award overlaps or is significantly similar to that described in the COBRE program. However, if the specific aims of the junior investigator's RPG are significantly different from the project described in the COBRE, then the junior investigator has an obligation to remain in the program to complete his/her COBRE project. In this latter case, continued support for personnel (e.g., postdoctoral associates, graduate students, technicians, etc.) associated with the COBRE project but also listed on the other award can be provided. However, the percent efforts of these individuals must be appropriately adjusted. Under this FOA, IDeA Networks of Biomedical Research Excellence (INBRE) investigators are not eligible to receive simultaneous research funding as COBRE project investigators. Similarly, COBRE investigators may not receive simultaneous research project support from an INBRE award.

A junior investigator who has achieved independent status and no longer leads a research project may be replaced by a new junior investigator. Replacement junior investigators and new research projects may be substituted following review by the PD/PI and the EAC. In some instances, a junior investigator may be placed on probation or considered for removal from the COBRE program if a review by the EAC indicates a failure by the investigator to make significant progress toward achieving the specific aims of his/her project or, as noted above, to submit an investigator-initiated RPG application by the end of two years of COBRE support. The PD/PI must communicate the EAC's recommendation for adding or removing junior investigators to the NCRR for Programmatic and Administrative Review.

Each COBRE application must include an External Advisory Committee (EAC) comprised of 3-5 scientists with national scientific reputations in their fields. Their expertise must be directly relevant to the scientific theme of the COBRE. The EAC critiques the scientific progress of the COBRE and also offers advice on scientific matters to the COBRE PD/PI. The EAC activities include developing and planning concepts and programs, encouraging and assisting faculty development and mentoring, identifying resources, evaluating the development of the center, evaluating the progress of the individual research projects, and evaluating the junior investigators' progress toward acquiring independent status. The PD/PI will share the advice and critiques provided by the EAC with other COBRE investigators at the center. 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. The EAC must meet at least twice per year. Video-, teleconferencing or other means may be used in situations where it would be difficult to hold an in-person meeting. A summary of the issues discussed at each EAC meeting, recommendations made, and actions taken must be included in the yearly progress reports submitted to the NCRR. The applicant should not contact potential EAC members or provide the names of potential EAC members during the preparation or review of the application.

The COBRE PD/PI should budget for a biannual two-day meeting in Bethesda, Maryland, with NCRR staff.

Research Core Facilities: Funds may be requested to establish core facilities. The applicant must demonstrate that each proposed core will impact the development of the center and how it will serve the scientific needs of the individual research projects. Although the COBRE award is not intended to replace support for ongoing, investigator-initiated research projects of established investigators, mentors and other investigators at the institution may use these facilities. Additional justification may be offered by showing how a core facility will benefit these individuals and improve the research infrastructure of the institution. Each core description should indicate the qualifications of personnel selected to manage the facility and/or plans to recruit personnel to operate the core, if needed, and the proposed business plan for operation of the core including prioritization of the service requests, charge back fees for non-COBRE users. Furthermore, the PD/PI should indicate any institutional commitment to support and maintain the proposed facilities.

NCRR strongly encourages adding equipment/personnel to existing core facilities rather than creating new core

facilities. As much as practicable, applicants should seek to utilize existing equipment and instrumentation supported by institution, other COBRE or INBRE awards.

Individual Research Projects: The COBRE center must contain at least three and up to five individual research projects. The individual research projects should stand alone, but share the COBRE's common thematic scientific focus. Each research project should be led by a single junior investigator who is responsible for ensuring that the Specific Aims of that project are met. An initial minimum commitment of 6 person months is required for this individual. It is recognized that during the development of a junior investigator's career (for example, the acquisition of other research support) it may be necessary to reduce this effort. Each individual research project should describe the Specific Aims in the selected area of research and the goals for the first year and for the long term. The design principles supporting the research or the hypotheses to be tested should be delineated. Preliminary studies are not required for projects in a COBRE application, but applicants with preliminary results should describe them. In the absence of preliminary results, applicants should have a strong research plan that includes a description of the rationale and scientific basis for the proposed research. Furthermore, each research project should describe its relationship to the thematic area of multi-disciplinary research that is the focus of the COBRE and critically assess the existing knowledge and approaches that have been or are being directed in the area with an emphasis on specifically how the multi-disciplinary COBRE approach will advance the field. In addition, how the Specific Aims relate to the importance and health relevance of the proposed research should be concisely stated.

Pilot project(s) may be proposed, but they will not be subject to peer review.

Criteria for Eligibility of Junior Investigators: For the purpose of eligibility, a junior investigator is defined either as (1) an individual who does not have or has not previously had an external, peer-reviewed Research Project Grant (RPG) or Program Project Grant (PPG) from either a Federal or non-Federal source that names that investigator as the PD/PI or (2) an established investigator who is making a significant change to his/her career. Senior, funded investigators who are not making a significant career change must not be proposed as leaders for individual research projects; if such a project is included, it will not be reviewed or counted in the minimum required 3 projects.

With respect to item (1), grants that name an individual as a co-investigator, collaborator, consultant, or to a position other than PD/PI or PD/PI on research grants that allow multiple PD/PIs, do not disqualify that investigator. Academic Research Enhancement Award grants (AREA, R15), exploratory/pilot project grants (such as NIH R03 and R21 awards), mentored career development awards (such as NIH K01 and K08 awards), or other Federal or non-Federal funding whose purpose is to provide preliminary support in anticipation of a RPG or PPG also do not disqualify the investigator. The intent of this FOA is to support and develop promising investigators whose early career support consists of awards geared toward initiating their intended area of research. However, investigators who have managed to obtain significant support in the form of a RPG or PPG (e.g., NIH R01 or P01, NSF, or other Federal or non-Federal agency awards) are not eligible. Each project Investigator should indicate in his/her Biographical Sketch their current and previous history of peer-reviewed research support.

A junior investigator must hold a faculty appointment (or equivalent at a research institute) at the time that the award is made. Moreover, a clear commitment to support this appointment independent of the outcome of this application must be demonstrated from the institution by a letter(s) from the appropriate senior institutional official(s). Postdoctoral fellows or other positions that do not carry independent faculty status at the applicant institution will disqualify that individual and his/her research project from further consideration and will not be reviewed or counted towards the minimum required 3 projects.

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

RPG or PPG in a different area of research are also not eligible.

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

Alteration and Renovation: Alteration and Renovation (A&R) costs to improve existing research laboratories or animal facilities are allowed. This FOA will provide up to \$300,000 in direct costs only in year one of the award as a one-time cost expenditure. Direct costs requested for A&R are not subject to facilities and administrative costs (F&A). This amount will be provided only in year one. It is expected that the funds be expended within 3 years of award. Alteration and Renovation projects must be relevant to the scope of the proposed research. Sufficient detail must be provided to estimate the cost and suitability of the project. Failure to adequately justify an A&R request will likely result in its deletion from the requested budget. Funds designated for A&R under this FOA cannot support new construction, including completion of shell space, or the purchase of movable research equipment/instrumentation or equipment intended for teaching or other non-research related purposes. Please note that A&R costs will be approved only for facilities improvements at the applicant organization. Proposed improvements at consortia sites are not allowed.

For any proposed A&R, a narrative summary (as outlined below), line drawings, and cost estimates must be provided. The following sample format is suggested:

Narrative Summary

- (1) Relate the proposed renovations to the research projects that will use the facility. If renovations to animal facilities are proposed, they should be related to the projected animal populations (by species) in the proposed projects. If renovations to animal facilities are proposed, include the lines of authority and responsibility for administering the institution's animal care and use program. The role and composition of the Institutional Animal Care and Use Committee (IACUC) and how compliance with relevant laws, policies, and guidelines are achieved should also be included.
- (2) List the functional components, including the size (dimensions) and square footage of each component (room, alcove, or cubicle) that will be directly affected by the renovation project.
- (3) List engineering criteria applicable to each component (mechanical, electrical, and utilities). Include information such as the number of air changes per hour, electrical power, light levels, hot and cold water, and steam.
- (4) List appropriate architectural criteria (such as width of corridors and doors, surface finishes).
- (5) List and justify all fixed equipment items requested for the renovated area. A list of allowable equipment can be found at http://ncrr.nih.gov/research_funding/instruments/.

Line Drawings

- (1) 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. All floor plans must be legible, with the scale clearly indicated.
- (2) The 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 also be given.
- (3) The plan should indicate the location of the proposed renovation area in the building.
- (4) Include the as-built drawings of the proposed renovation area and indicate any areas that will be demolished.
- (5) 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.
- (6) Indicate the type(s) of new finishes to be applied to room surfaces.

Cost Estimates

Detailed cost estimates must be included. Provide vendor quotes when available.

Section II. Award Information

Funding Instrument	Grant
Application Types Allowed	New Resubmission Revision The OER Glossary and the PHS398 Application Guide provide details on these application types.
Funds Available and Anticipated Number of Awards	The number of awards is contingent upon NIH appropriations, and the submission of a sufficient number of meritorious applications.
Award Budget	Direct Costs of \$1.5 million per year per application. This FOA will provide an additional one time cost of up to \$300 thousand in direct costs in year one for A&R..
Award Project Period	Five years

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

Eligible Organizations

Higher Education Institutions

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

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

Criteria for Eligibility of an IDeA State to participate in this COBRE competition: In making its assessment for eligibility, NCRR included all states/commonwealths with a success rate for obtaining NIH grant awards (number of applications awarded vs. number of applications approved) of less than 20 percent over the period of 2001-2005 or received less than an average of \$120 million per year during that time period. Under these criteria, the following states/commonwealth are the IDeA states eligible to respond to this FOA:

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: An eligible institution must be within an IDeA state. Applications will be accepted from eligible institutions that hold two or less active COBRE awards at the time of submission. Eligible institutions that do not hold a current COBRE award are encouraged to apply. Please note that applications will NOT be accepted from institutions that hold three or more active COBRE awards (excluding COBRE Phase 3: Transition Center awards); these institutions cannot submit new applications.

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as [defined](#) in the NIH Grants Policy Statement, **are not** allowed.

Required Registrations

Applicant organizations must complete the following registrations as described in the PHS398 Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- [Central Contractor Registration \(CCR\)](#) – must maintain an active registration, to be renewed at least annually
- [eRA Commons](#)

All Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization.

All registrations must be completed by the application due date. Applicant organizations are strongly encouraged to start the registration process at least four (4) weeks prior to the application due date.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director/Principal Investigator (PD/PI) is invited to work with his/her 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.

2. Cost Sharing

This FOA does not require cost sharing as defined in the [NIH Grants Policy Statement](#).

3. Additional Information on Eligibility

Number of Applications

Only one application per institution (normally identified by having a unique DUNS number or NIH IPF number) per fiscal year is allowed.

NIH will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application. NIH will not accept any application that is essentially the same as one already reviewed. Resubmission applications may be submitted, according to the NIH Policy on Resubmission Applications from the PHS398 Application Guide.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants are required to prepare applications according to the current PHS 398 application forms in accordance with the PHS 398 Application Guide.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the [PHS398 Application Guide](#), except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

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.

By the date listed in [Part 1. Overview Information](#), 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 PD(s)/PI(s)
- Names of other key personnel
- Number and title of this funding opportunity

The letter of intent should be sent to:

Steven Birken, PhD
Office of Review
National Center for Research Resources
National Institutes of Health
6701 Democracy Boulevard, Room 1078
Bethesda, MD 20892-4874
Bethesda, MD 20817-4874 (for express/courier service)
Telephone: (301) 435-0815
FAX: (301) 480-3660
E-mail: BirkenS@mail.nih.gov

Application Submission

Applications must be prepared using the PHS 398 research grant application forms and 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)

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

Steven Birken, PhD
Office of Review
National Center for Research Resources
National Institutes of Health
6701 Democracy Boulevard, Room 1078
Bethesda, MD 20892-4874
Bethesda, MD 20817-4874 (for express/courier service)
Telephone: (301) 435-0815
FAX: (301) 480-3660
E-mail: BirkenS@mail.nih.gov

Page Limitations

All page limitations described in the PHS398 Application Guide and the [Table of Page Limits](#) must be followed,

with the following exceptions or additional requirements:

The application should be organized and assembled in the order as follows:

Face Page

Use Form 1 of the PHS 398 and follow the Instruction.

Description Page

Use Form 2 of the PHS 398. An abstract describing proposed COBRE center is required and should be placed in the Project Summary area. The length of the abstract must not exceed the space provided.

Key Personnel including the principal investigator, core directors, research project leaders, and other key professional and administrative members of this Program should be placed in the area of Performance Sites and Key Personnel. Do not include names of external advisory committee members. Do not separate key personnel into each project section.

Table of Contents

Applicant should customize the PHS 398 Table of Contents to specifically indentify the section of the application.

Detailed Budget Pages for Initial Budget Period and Entire Proposed Period of Support

The Budget section should begin with the summary or composite budget for the center, followed by the individual budgets for all projects, cores, consortia and contractual arrangements. Individual research projects and core facilities that are proposed to begin in year one should have corresponding 5-year individual budgets with justifications. Do not separate the individual project budgets into each project section.

An applicant may request a budget for direct costs of up to and no more than \$1.5 million per year, excluding facilities and administrative (F&A) costs on consortium arrangements. The applicant may also request additional direct costs in year one only of up to \$300,000 as a one-time expenditure for Alteration and Renovation of laboratory or animal facilities. If Alteration and Renovation costs are requested, then the total budget request for year one must not exceed \$1.8 million in direct costs, excluding F&A costs on consortium arrangements. Regardless whether Alteration and Renovation costs are requested, budget requests for years two through five cannot exceed \$1.5 million per year, excluding F&A costs on consortium arrangements.

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

For those small and developing institutions where Offices of Sponsored Programs are not in place, funds may be used to develop Offices of Sponsored Programs.

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

Funds may also be used to develop or enhance appropriate community engagement including recruitment and retention efforts by increasing community buy-in and trust, enhancing the reliability and validity of measurement instruments through in-depth and honest feedback during pre-testing, improving data collection through increased response rates, increasing relevance of intervention approaches and thus likelihood for success, targeting interventions to the identified needs of community members, developing intervention strategies that incorporate community norms and values into scientifically valid approaches, increasing accurate and culturally sensitive interpretation of findings, facilitating more effective dissemination of research findings to impact public health and policy, and increasing the potential for translation of evidence-based research into sustainable community change that can be disseminated more broadly.

Consortium Arrangements: When a grant application includes research activities that involve institutions or communities other than the grantee institution, it is considered a consortium effort. Such activities may be included in the COBRE grant application, but it is imperative that a consortium application be prepared so that

the programmatic, fiscal, and administrative considerations are explained fully. In addition, the thematic scientific focus of the COBRE must be evident in applications that include consortia arrangements. Applicants for COBRE grants should exercise great diligence in preserving the interactions of the participants and the integration of the consortium project(s) with those of the parent institution because synergism and cohesiveness can be diminished when projects are located outside of the group at the parent institution.

Funds cannot be used at collaborative institutions in non-IDeA states. However, funds may be used in other IDeA and non-IDeA states for fee-for-service activities that include activities such as learning new techniques, sample and data analysis, workshops etc.

Biographical Sketches

All Biographical Sketches should be grouped together with the PD/PI's biographical sketch presented first followed by all other sketches in alphabetical order. Do not separate the biographical sketches into each project section.

Resources

Resources including existing equipment, instrumentation and laboratory space for cores and research projects should be described using the PHS398 Resources form page and instructions. Although there is no page limit for resource section, it should be concise and contain only information that is not included in the Research Strategy section for that corresponding core or research project. Do not include information required by the FOA, such as methods, that belongs in the page-limited Research Strategy sections. Do not include Resources form in individual projects and cores.

Research Plan

All instructions in the PHS398 Application Guide must be followed, with the following additional instructions:

The Research Plan for each section consists of the following components, as applicable. All page limits include all tables and figures. Do not use components without page limits (1, 2, and 6 to 14) to circumvent the page limits of the Research Strategy.

1. Cover page
2. Description page
3. Introduction (1 page, Resubmission and Revision Applications only)
4. Specific Aims (1 page)
5. Research Strategy (12 pages)
6. Bibliography and References Cited
7. Protection of Human Subjects
8. Inclusion of Women and Minorities
9. Targeted/Planned Enrollment Table
- 10 Inclusion of Children
11. Vertebrate Animals
12. Consortium/Contractual Arrangements
13. Letters of Support
14. Resource Sharing Plan

Specific Requirements for Individual Section:

Cover page (Do NOT use PHS 398 face page)

For each individual core and 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.

Description page (PHS 398 Form 2)

An Abstract of the proposed core or project is required. The length of the abstract must not exceed the space provided. Do not include a key personnel list in individual core or project section.

Introduction (Resubmission and Revision Applications only, 1 page for each section)

The Introduction must include responses to the criticisms and issues raised in the prior Summary Statement, which summarizes the substantial additions, deletions, and changes. Insert the Introduction before the Research Strategy of each section, identifying within the Research Strategy 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.

Overall Center Organization and Management Plan

- Specific Aims (1 page)
- Research Strategy (12 pages)
 - Justification of a five-year support for a thematic multidisciplinary COBRE program.
 - A description of the unique research opportunities that will provide to junior investigators and to the institution.
 - A research strategy that describes the organization and component functions of the COBRE. The plan should demonstrate the applicant's knowledge, ingenuity, practicality, and commitment to developing and maintaining a significant and productive research program.
 - A description of the existing equipment and instrumentation for conducting studies aimed at developing a nationally competitive biomedical research program. Sharing research resources among IDeA programs is strongly encouraged. Applicants should describe plans for utilizing equipment and instrumentation supported by existing COBRE or IDeA Networks of Biomedical Research Excellence (INBRE) awards.
 - A description of and justification for the proposed individual research projects and core service facilities that collectively will contribute to the center.
 - A description of how the efforts of each junior investigator will contribute to the establishment of a multi-disciplinary research center.

Administrative Core

- Specific Aims (1 page)
- Research Strategy (12 pages)
 - A clear and full explanation of the necessary administrative, fiscal, and scientific aspects of the proposed COBRE.
 - A description of the research and research training or career development goals and capabilities of the proposed COBRE.
 - A mentoring plan addressing the development of junior investigators for their transition to and attainment of independent investigator status.
 - A formative and summative evaluation strategy with specific milestones.

Research Cores

- Specific Aims (1 page for each core)
- Research Strategy (12 pages for each core)
 - The impact of proposed cores on the development of the center and how they will serve the scientific needs of the individual research projects.
 - The qualifications of personnel selected to manage the facilities.

- A description of how the cores will be operated.
- Institutional commitment, if any, to support and maintain the proposed cores.

Research Projects

- Specific Aims (1 page for each project)
- Research Strategy (12 pages for each project)
 - The experimental design principles supporting the research or the hypothesis to be tested should be clearly delineated.
 - Preliminary data is not required, but should be included if the data is available.
 - Applicants should describe the nature and scope of any scientific research collaborations within or cross institution.

Alteration and Renovation

- Specific Aims (1 page)
- Research Strategy (12 pages)
 - Relation of proposed renovations to the research projects.
 - The functional components.
 - Engineering criteria applicable to each component.
 - Appropriate architectural criteria.
 - Justification of all fixed equipment items requested for the renovated area.
 - Line Drawings (The line drawings do not count toward the 12 page limit).

Letters indicating institutional commitment and any letter of support for the proposed center and research core (if applicable) should be placed immediately after the Research Strategy of the overall center organization and management plan and corresponding core, respectively. 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.

Resource Sharing Plan

Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies; GWAS) as provided in the PHS398 Application Guide, with the following modifications:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix

No appendix material is allowed. If appendix material is included, the application will not be accepted for review.

3. Submission Dates and Times

[Part I. Overview Information](#) contains information about Key Dates.

Information on the process of receipt and determining if your application is considered “on-time” is described in detail in the PHS398 Application Guide.

Applicants may track the status of the application in the [eRA Commons](#), NIH’s electronic system for grants administration.

4. Intergovernmental Review (E.O. 12372)

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 only as described in the [NIH Grants Policy Statement](#).

6. Other Submission Requirements and Information

Applications must be received on or before the due dates in [Part I. Overview Information](#). If an application is received after that date, it will not be reviewed.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review, NIH. Applications that are incomplete will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [NOT-OD-10-115](#).

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the [NIH mission](#), all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact - Overall

Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the COBRE center to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the COBRE center proposed).

Scored Review Criteria - Overall

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or

novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Scored Review Criteria

Administrative leadership

Does the PD/PI have the qualifications to provide scientific and administrative leadership in developing and directing the COBRE, and establishing thematic collaborative research efforts?

Does the PD/PI demonstrate leadership by showing that the infrastructure necessary for the proposed center (e.g., facility improvements, modernization/acquisition of equipment, implementation of administrative resources, etc.) is in place, and that the institution is committed to support the resources and infrastructure?

Has the PD/PI shown the ability to lead, develop, and direct the COBRE to establish thematic collaborative research efforts? Has the PD/PI shown effective leadership in directing and managing the mentoring plan required to move the investigators toward independent status? Does the PD/PI present a plan for the continued development of investigators to independent status?

Has the PD/PI provided evidence of successfully mentoring graduate students, postdoctoral fellows and junior investigators as well as leading a large research group?

Project Investigators: Do the project investigators demonstrate the ability to compete successfully for investigator-initiated support? Do project investigators show career development potential and/or an ability to achieve independent status?

Overall Center Organization and Management Plan

Does the application describe how the institutional biomedical research capacity will be augmented and strengthened? How will basic and/or clinical research be encouraged? How will a scientific thematic focus be established and maintained? Are the nature, scope, and effectiveness of the plans for coordination and cooperation among research project investigators appropriate and will they contribute to the establishment of the center?

Is the level of institutional commitment sufficient to provide support for the development of a thematic multidisciplinary center? Has the applicant demonstrated that the resources and facilities to sustain the COBRE program are present, including, but not restricted to, existing relevant equipment, animal, and/or computer resources, and departmental or interdepartmental cooperation? Does the applicant detail the long-term goals as to how the institution intends to make the transition from the research support of the COBRE to competitive grant support?

Administrative Core

Does the administrative core include a clear plan for the transition to and attainment of independent status for junior investigators and for the continued development of early career investigators and describe how the center as a whole intends to make the transition from support of multi-disciplinary COBRE research projects to competitive grant support?

Has the PD/PI selected appropriate and suitable evaluation strategies and specific milestones to measure progress, not only of the junior investigators, but of the center as a whole, toward attaining its long-range goals? Have appropriate and suitable evaluation strategies and specific milestones to measure progress toward attaining long-range goals been selected and how will these be employed?

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

Will the External Advisory Committee be constituted to provide critical, stimulating, and thoughtful advice for the overall center performance?

Research Core Facilities

Has the applicant demonstrated the need for the proposed core facilities and the effectiveness of these facilities to enhance the research effort? Has the applicant demonstrated that each proposed core will serve the scientific needs of the individual research projects and has he/she shown how each core will impact the development of the center? Has the applicant selected qualified personnel to manage and operate the core facilities? Does the applicant indicate any institutional commitment to support and maintain the proposed core facilities?

Individual Research Projects

In addition to the traditional review criteria: Has the PD/PI shown effective judgment in the selection of research projects? Are the projects related to and consistent with the overall goals of the center? Can the individual projects stand alone? Although the Scientific Review Group will evaluate the qualifications of each junior investigator using the traditional criteria and considerations indicated in this PA, do the junior investigators have the potential and ability to achieve independent status? Are the strengths, academic qualifications and biomedical expertise of the project investigators appropriate and sufficient for research productivity?

Community Engagement and Outreach Research (If included)

Are there clear and detailed plans for identifying a health issue that fits community priorities and academic capacity to respond? Are there plans for developing a coalition of community and academic stakeholders and for implementing evaluation strategies for the proposed projects? Is the research characterized by substantial community input in the development of the proposed study? Are community members, persons affected by the health condition, disability or issue under study, or other key stakeholders in the community's health, full participants in each phase of the research, including conception, design, conduct, analysis, interpretation, drawing of conclusions and communication of results?

Alteration and Renovation (If included)

Are requested alteration and renovation projects relevant to the scope of the proposed research? Are the costs and suitability of the project justified? Do the proposed renovations relate to the research projects that will use the facility? If renovations to animal facilities are proposed, do the proposed renovations relate to the projected animal populations (by species)? If renovations to animal facilities are proposed, are the lines of authority and responsibility for administering the institution's animal care and use program indicated? Are there lists of the functional components, including the size (dimensions) and square footage of each component (room, alcove or cubicle) that will be directly affected by the renovation project? Are there appropriate descriptions of the 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, as well as the appropriate architectural criteria (such as width of corridors and doors, surface finishes)? Is justification provided for all fixed equipment items requested for the renovated area?

Are legible line drawings provided for all floor plans with the scale clearly indicated? Are the line drawings of the proposed renovation drawn to a scale adequate to explain the project? Do the drawings indicate size (dimensions), function, and net and gross square feet of space for each room? Are the total net and gross square feet of space to be renovated provided? Does the plan indicate the location of the proposed renovation area in the building? Does the plan include the as-built drawings of the proposed renovation area and indicate any areas that will be demolished? Do the plans indicate changes or additions to existing mechanical and electrical systems in notes made directly on the plan or attached to the plan? Do the plans indicate the type(s) of new finishes to be applied to room surfaces?

Additional Review Criteria - Overall

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the [Human Subjects Protection and Inclusion Guidelines](#).

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the [Human Subjects Protection and Inclusion Guidelines](#).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animal Section](#).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

Not Applicable.

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not for recommended approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations - Overall

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact/priority score.

Applications from Foreign Organizations

Not Applicable.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) [Data Sharing Plan](#); 2) [Sharing Model Organisms](#); and 3) [Genome Wide Association Studies \(GWAS\)](#).

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by NCRR, in accordance with [NIH peer review policy and procedures](#), using the stated [review criteria](#). Review assignments will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May 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 an overall impact/priority score.
- Will receive a written critique.

Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the

NCRR Advisory Council. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Special consideration will be given to eligible small and developing institutions, minority serving institutions and applications with strong collaborations to such institutions in IDeA states. Special consideration will also be made based upon geographic distribution throughout IDeA eligible states.

3. Anticipated Announcement and Award Dates

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](#).

Information regarding the disposition of applications is available in the [NIH Grants Policy Statement](#).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the [NIH Grants Policy Statement](#).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in [Section IV.5. Funding Restrictions](#). 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.

Any application awarded in response to this FOA will be subject to the DUNS, CCR Registration, and Transparency Act requirements as noted on the [Award Conditions and Information for NIH Grants](#) website.

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](#) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities](#). More information is provided at [Award Conditions and Information for NIH Grants](#).

Cooperative Agreement Terms and Conditions of Award

Not Applicable.

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 the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the *NIH Grants Policy Statement*.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at [www.fsrs.gov](#) on all subawards over \$25,000. See the [NIH Grants Policy Statement](#) for additional information on

this reporting requirement.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)

Telephone 301-435-0714

TTY 301-451-5936

Email: GrantsInfo@nih.gov

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues)

Phone: 301-402-7469 or 866-504-9552 (Toll Free)

TTY: 301-451-5939

Email: commons@od.nih.gov

Scientific/Research Contact(s)

Yanping Liu, MD., PhD.

Division of Research Infrastructure

National Center for Research Resources

National Institutes of Health

6701 Democracy Boulevard, Room 930

Bethesda, MD 20892-4874

Telephone: (301) 451-4217

FAX: (301) 480-3770

E-mail: liuyanp@mail.nih.gov

Peer Review Contact(s)

Steven Birken, PhD

Office of Review

National Center for Research Resources

National Institutes of Health

6701 Democracy Boulevard, Room 1078

Bethesda, MD 20892-4874

Bethesda, MD 20817-4874 (for express/courier service)

Telephone: (301) 435-0815

FAX: (301) 480-3660

E-mail: BirkenS@mail.nih.gov

Financial/Grants Management Contact(s)

Ms. Jenelle D. Wiggins

Grants Management Specialist

Office of Grants Management

National Center for Research Resources, NIH

6701 Democracy Blvd., Room 1050

Bethesda, MD 20892

Bethesda, MD 20817 (for courier service)

Voice: 301-435-0843

Fax: 301-480-3777

Email: jwiggins@mail.nih.gov

Section VIII. Other Information

Recently issued trans-NIH [policy notices](#) may affect your application submission. A full list of policy notices published by NIH is provided in the [NIH Guide for Grants and Contracts](#). All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](#).

Authority and Regulations

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 Part 52 and 45 CFR Parts 74 and 92.

[Weekly TOC for this Announcement](#)

[NIH Funding Opportunities and Notices](#)



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Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see [Help Downloading Files](#).