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-11-286
Related Notices	• NOT-OD-16-004 - NIH & AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications (November 18, 2015) • NOT-OD-16-006 - Simplification of the Vertebrate Animals Section of NIH Grant Applications and Contract Proposals (November 18, 2015) • NOT-OD-16-011 - Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications (November 18, 2015) • November 04, 2014 - See Notice NOT-GM-14-133. Notice of Change in Next Application Due Date for PAR-14-035 "Centers of Biomedical Research Excellence (COBRE) (P20)" • June 4, 2014 - Notice NOT-14-074 supersedes instructions in Section III.3 regarding applications that are essentially the same. • March 26, 2014 - See Notice NOT-GM-14-111. Notice of Clarification of Information for NIGMS Prior Approval of Pilot Projects Proposed for Support by IDeA Program Grants.
Funding Opportunity Announcement (FOA) Number	**PAR-14-035**
Companion Funding Opportunity	None
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.859
Funding Opportunity Purpose	The National Institute of General Medical Sciences (NIGMS) 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.

Key Dates

Posted Date	December 12, 2013
Open Date (Earliest Submission Date)	January 26, 2014
Letter of Intent Due Date(s)	30 days before the application due date.
Application Due Date(s)	February 26, 2014, ~~January 28, 2015~~ and January 28, 2016, by 5:00 PM local time of applicant organization. Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.
AIDS Application Due Date(s)	Not Applicable
Scientific Merit Review	May/June 2014, ~~May/June 2015~~ and May/June 2016
Advisory Council Review	October 2014, ~~October 2015~~ October 2016
Earliest Start Date	December 2014, ~~December 2015~~ December 2016
Expiration Date	January 29, 2016
Due Dates for E.O. 12372	Not Applicable

** ELECTRONIC APPLICATION SUBMISSION REQUIRED**

NIH's new Application Submission System & Interface for Submission Tracking (ASSIST) is available for the electronic preparation and submission of multi-project applications through Grants.gov to NIH. Applications to this FOA must be submitted electronically; paper applications will not be accepted. ASSIST replaces the Grants.gov downloadable forms currently used with most NIH opportunities and provides many features to enable electronic multi-project application submission and improve data quality, including: pre-population of organization and PD/PI data, pre-submission validation of many agency business rules and the generation of data summaries in the application image used for review.

Required Application Instructions

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*) and where instructions in the Application Guide are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. 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.**

There are several options to submit your application to the agency through Grants.gov. You can use the ASSIST system to prepare, submit and track your application online. You can download an application package from Grants.gov, complete the forms offline, submit the completed forms to Grants.gov and track your application in eRA Commons. Or, you can use other institutional system-to-system solutions to prepare and submit your application to Grants.gov and track your application in eRA Commons. Learn more.

Apply Online Using ASSIST Problems accessing or using ASSIST should be directed to the eRA Service Desk.

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Program Description and Objectives

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.

Section II. Award Information

Funding Instrument	Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed	New Resubmission The OER Glossary and the SF424 (R&R) 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	The annual budgets must not exceed $1.5 million in direct costs. Additional direct costs in year one only of up to $300,000 as a one-time expenditure for Alteration and Renovation may be requested.
Award Project Period	The scope of the proposed project should determine the project period. The maximum project period is 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
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

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)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Eligible IDeA States to participate in the COBRE competition: 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.

Eligible Institutions: 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 active COBRE awards, including phase 1, phase 2 and/or IDeA program for Clinical and Translational Research (IDeA-CTR). The COBRE Phase 3, Transition Center award, does not count into total number of COBRE awards.

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

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (formerly CCR) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
- NATO Commercial and Government Entity (NCAGE) Code – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account and should work with their organizational officials to either create a new account or to affiliate an existing account with the applicant organization's eRA Commons account. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

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(s)/Principal Investigator(s) (PD(s)/PI(s)) 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.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

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 that is essentially the same as one already reviewed within the past thirty-seven months (as described in the *NIH Grants Policy Statement*), except for submission:

- To an RFA of an application that was submitted previously as an investigator-initiated application but not paid;
- Of an investigator-initiated application that was originally submitted to an RFA but not paid; or
- Of an application with a changed grant activity code.

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants can access the SF424 (R&R) application package associated with this funding opportunity using the "Apply for Grant Electronically" button in this FOA or following the directions provided at Grants.gov.

Most applicants will use NIH's ASSIST system to prepare and submit applications through Grants.gov to NIH. Applications prepared and submitted using applicant systems capable of submitting electronic multi-project applications to Grants.gov will also be accepted.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed in this funding opportunity announcement to do otherwise and where instructions in the Application Guide are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. 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.

For information on Application Submission and Receipt, visit Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.

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 activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Yanping Liu, MD., PhD.
National Institute of General Medical Sciences
Telephone: (301) 594-3900
Email: liuyanp@mail.nih.gov

Page Limitations

Component Types Available in ASSIST	Research Strategy/Program Plan Page Limits
Overall	12
Admin Core	12
Core (use for Research Cores)	12
Project (use for Research Projects)	12
Alt and Renov (use for Alteration and Renovation)	12

Additional page limits described in the SF424 Application Guide and the Table of Page Limits must be followed.

Instructions for the Submission of Multi-Component Applications

The following section supplements the instructions found in the SF424 (R&R) Application Guide, and should be used for preparing a multi-component application.

The application should consist of the following components:

- Overall: required
  - Administrative Core: Required
  - Research Cores: Optional
- Research Projects: Required; minimum of 3, maximum of 5
- Alteration and Renovation: Optional

Overall Component

When preparing your application in ASSIST, use Component Type 'Overall'.

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Overall)

Complete entire form.

PHS 398 Cover Page Supplement (Overall)

Note: Human Embryonic Stem Cell lines from other components should be repeated in cell line table in Overall component.

Research & Related Other Project Information (Overall)

Follow standard instructions.

Project/Performance Site Location(s) (Overall)

Enter primary site only.

A summary of Project/Performance Sites in the Overall section of the assembled application image in eRA Commons compiled from data collected in the other components will be generated upon submission.

Research & Related Senior/Key Person Profile (Overall)

Include only the Project Director/Principal Investigator (PD/PI) and any multi-PDs/PIs (if applicable to this FOA) for the entire application.

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.

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.

A summary of Senior/Key Persons followed by their Biographical Sketches in the Overall section of the assembled application image in eRA Commons will be generated upon submission.

Budget (Overall)

The only budget information included in the Overall component is the Estimated Project Funding section of the SF424 (R&R) Cover.

A budget summary in the Overall section of the assembled application image in eRA Commons compiled from detailed budget data collected in the other components will be generated upon submission.

PHS 398 Research Plan (Overall)

Introduction to Application: For Resubmission applications, an Introduction to Application is required in the Overall component

Specific Aims: The SF424 application Guide must be followed.

Research Strategy: Each application must describe an overall center organization and management plan. The important elements that need to be included in the section are the following:

- Justification of a five-year support for a thematic multidisciplinary COBRE program.
- A description of the unique research opportunities that will be provided 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.

Detailed Requirements

The overall center organization and management 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.

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 application. 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 institutions, including non-doctoral degree-granting and research-performing institutes, is encouraged. 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.

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.

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.

Consortium/Contractual 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.

Letters of Support: A letter of support from a senior institutional official (e.g., President or Dean) must be included, outlining the institutional 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 level of institutional commitment will differ among applicant institutions because of the variability of resources available among institutions. In addition, any letter of support for the proposed center may also be included.

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 SF424 (R&R) Application Guide.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Administrative Core

When preparing your application in ASSIST, use Component Type 'Admin Core.'

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Administrative Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Administrative Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Administrative Core)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete.

Project /Performance Site Location(s) (Administrative Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Administrative Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Administrative Core)

Budget forms appropriate for the specific component will be included in the application package.

If items are requested as direct costs that are normally treated as F&A costs (for example, computers and general office supplies), the applicant must provide a strong justification for those items and demonstrate that the cost is commensurate with the benefit that particular item of cost will have on the associated project.

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.

The PD/PI of the COBRE is not eligible for research project support from the COBRE award, nor can he/she use COBRE funds to supplement research activities within his/her laboratory. Mentors may be compensated for up to 1 person month of effort and should be listed in the Administrative Core's budget section of the application and not in the individual research projects' budget sections. Mentors from non-IDeA states can be compensated as a consultant or fee for service.

Funds may 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. These funds may be used for salary, supplies, and/or equipment costs.

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 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.

Funds for research activities must not 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.

The COBRE PD/PI should budget for a biennial one-day meeting in Bethesda, Maryland, with NIGMS staff.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Administrative Core)

Introduction to Application: For Resubmission applications, an Introduction to Application is allowed for each component

Specific Aims: The SF424 application Guide must be followed.

Research Strategy: The important elements that need to be included in this section are the following:

- 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.

Detailed Requirements

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. 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 or other COBRE 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 NIGMS for programmatic and administrative review.

Each COBRE application must include an 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 NIGMS 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 NIGMS. The applicant should not contact potential EAC members or provide the names of potential EAC members during the preparation or review of the application as this complicates the peer review process. Describing the expertise that will be included is appropriate.

A pilot project program may be proposed. The description of a pilot project program must include a plan for the solicitation of proposals, their review and funding prioritization, oversight and evaluation procedures, and assurance of full compliance with all applicable federal policies, rules, and guidelines for research involving human subjects, vertebrate animals, and/or biohazards. The scientific merit of pilot project(s) must be reviewed by EAC. The pilot project(s) and recommendation from EAC must be submitted to NIGMS for programmatic and administrative review. Research plans for individual pilot research projects should not be included in the application.

Letters of Support: Letters indicating institutional commitment and any letter of support for the proposed administrative core should be included.

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 SF424 (R&R) Application Guide.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Planned Enrollment Report (Administrative Core)

When conducting clinical research, follow all instructions for completing Planned Enrollment Reports as described in the SF424 (R&R) Application Guide.

PHS 398 Cumulative Inclusion Enrollment Report (Administrative Core)

When conducting clinical research, follow all instructions for completing Cumulative Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

Research Core

When preparing your application in ASSIST, use Component Type ‘Core.’

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Research Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Research Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Research Core)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete.

Project / Performance Site Location(s) (Research Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior / Key Person Profile (Research Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Research Core)

Budget forms appropriate for the specific component will be included in the application package.

Funds may be requested to establish core facilities. In addition to personnel and supply costs, the acquisition of new equipment and modernization of instrumentation may be proposed.

Core facilities should have a detailed budget for the entire proposed project period (5 years). Although the applicant may propose support for core facilities to begin in later years, each year's budget should include costs for only cores that will be active in that year.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Research Core)

Introduction to Application: For Resubmission applications, an Introduction to Application is allowed for each component

Specific Aims: The SF424 application Guide must be followed.

Research Strategy: If the research core(s) is proposed, the important elements that need to be included in this section are the following:

- 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.

Detailed Requirements

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 and charge-back fees for non-COBRE users.

NIGMS 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 the institution or other COBRE or INBRE awards.

Letters of Support: Letters indicating institutional commitment and any letter of support for the proposed research core should be included.

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 SF424 (R&R) Application Guide.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Planned Enrollment Report (Research Core)

When conducting clinical research, follow all instructions for completing Planned Enrollment Reports as described in the SF424 (R&R) Application Guide.

PHS 398 Cumulative Inclusion Enrollment Report (Research Core)

When conducting clinical research, follow all instructions for completing the Cumulative Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

Research Project

When preparing your application in ASSIST, use Component Type 'Project.'

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Research Project)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Research Project)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Research Project)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete.

Project / Performance Site Location(s) (Research Project)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior / Key Person Profile (Research Project)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

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 and 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 (AREA) grants, 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. 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.

Budget (Research Project)

Budget forms appropriate for the specific component will be included in the application package.

The applicants should propose a 5-year budget for proposed research projects and replacement projects.

Junior investigators must make an initial minimum commitment of 6 person months annually. It is recognized that during the development of an investigator's career (for example, the acquisition of other research support) it may be necessary to reduce these levels of commitment. PD/PIs should consult with NIGMS program staff regarding appropriate reductions.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Research Project)

Introduction to Application: For Resubmission applications, an Introduction to Application is allowed for each component

Specific Aims: The SF424 application Guide must be followed. The Specific Aims should describe the selected area of research and the goals for the first year and for the long term.

Research Strategy: The important elements that need to be included in this section are the following:

- 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 propose research projects of 2-3 year duration. The nature and scope of any scientific research collaborations within or cross institution should be described in the application.

Detailed Requirements

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. 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 strategy 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.

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.

Letters of Support: Letters indicating institutional commitment and any letter of support for the proposed research project should be included. Since a junior investigator must hold a faculty appointment (or equivalent at a research institute) at the time that the award is made, 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).

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 SF424 (R&R) Application Guide.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Planned Enrollment Report (Research Project)

When conducting clinical research, follow all instructions for completing Planned Enrollment Reports as described in the SF424 (R&R) Application Guide.

PHS 398 Cumulative Inclusion Enrollment Report (Research Project)

When conducting clinical research, follow all instructions for completing Cumulative Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

Alteration and Renovation

When preparing your application in ASSIST, use Component Type 'Alt and Renov.'

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Alteration and Renovation)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Alteration and Renovation)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Alteration and Renovation)

Other Attachments: Line drawings should be submitted as described below:

- Submit line drawings. (DO NOT SUBMIT BLUEPRINTS.). All floor plans must be legible, with the scale clearly indicated.
- 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.
- The floor 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 that will be demolished.

Project Narrative: Do not complete.

Project /Performance Site Location(s) (Alteration and Renovation)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Alteration and Renovation)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Alteration and Renovation)

Budget forms appropriate for the specific component will be included in the application package.

Alteration and Renovation is allowed 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.

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.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Alteration and Renovation)

Introduction to Application: For Resubmission applications, an Introduction to Application is allowed for each component

Specific Aims: The SF424 application Guide must be followed.

Research Strategy: Alteration and Renovation (A&R) projects must be relevant to the scope of the proposed research. A narrative summary as outlined below must be provided:

- 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.
- 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.
- 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.
- 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. A list of allowable fixed equipment can be found at http://dpcpsi.nih.gov/orip/diic/instru_fixed_equip_s10.aspx (refer to: Allowable as "Fixed Equipment" under C06/G20) .
- 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.

Letters of Support: Letters indicating institutional commitment and any letter of support for the proposed alteration and renovation should be included.

Resource Sharing Plan: Not Applicable

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Planned Enrollment Report (Alteration and Renovation)

Not Applicable

PHS 398 Cumulative Inclusion Enrollment Report (Alteration and Renovation)

Not Applicable

3. Submission Dates and Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications to Grants.gov (the online portal to find and apply for grants across all Federal agencies) using ASSIST or other electronic submission systems. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, NIH's electronic system for grants administration.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

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 submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

For information on how your application will be automatically assembled for review and funding consideration after submission go to: http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-

project_Application_Image_Assembly.pdf.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically.

Important reminders:
All PD(s)/PI(s) and component Project Leads must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

See more tips for avoiding common errors.

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-13-030.

Section V. Application Review Information

NEW **Important Update: See NOT-OD-16-006 and NOT-OD-16-011 for updated review language for applications for due dates on or after January 25, 2016.**

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 score to reflect their assessment of the likelihood for the project 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 project proposed).

Scored Review Criteria - Overall Center Application

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 center address an important problem or a critical barrier to progress in the field? If the aims of the center 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(s)/PI(s), 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?

Does the PD/PI have the qualifications and skills to provide scientific and administrative leadership in developing and directing the COBRE and establishing thematic collaborative research efforts? Does the PD/PI have the experience and ability to implement and manage an effective mentoring plan to move investigators toward independent status?

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 center? 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 center involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion 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?

Is the infrastructure necessary for the proposed center (e.g., facility improvements, modernization/acquisition of equipment, implementation of administrative resources, etc.) in place? Is the institution is committed to support the resources and infrastructure?

Does the application describe the institutional commitment to provide support for the development of a thematic multidisciplinary center? Has the applicant described the environment and resources available to investigators, and indicate how COBRE support will improve facilities or make available new and collaborative resources (e.g., laboratory facilities, patient populations, laboratory space and personnel)? 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?

Review Criteria for Cores

Reviewers will score each core based on the criteria provided.

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?

Does the development plan include a mentoring plan that involves oversight by established senior faculty members assigned as mentors, constructive evaluations by members of the External Advisory Committee? Is there coordinated management of all of these individuals by the PD/PI of the COBRE program?

Milestones and Evaluation: Has the PD/PI selected appropriate and suitable evaluation strategies? Does the development plan include both formative and summative evaluation strategies detailing specific milestones for the acquisition of independent status by the investigators? Are specific milestones identified and supported to measure progress toward attaining long-range goals?

Is the External Advisory Committee properly constituted with the scientific expertise to critique the scientific progress of the COBRE and offer advice on scientific matters to the COBRE PD/PI?

If a pilot project program is proposed, is there an adequate plan to solicit proposals, prioritize the projects and review their methodology and research performance? Are plans adequate to assure compliance with applicable federal policies and guidelines for research and research protections?

Research Core Facilities

Has the PD/PI provided the necessary oversight to establish and maintain the necessary core resources and laboratory facilities to carry out the objectives of the application?

Do the core resources and facilities serve the scientific needs of the individual research projects?

Are the personnel who direct the core facility as well as the technical staff who operate the core facility well qualified?

Has the PD/PI obtained institutional commitments sufficient to ensure that the resources and facilities required to sustain the center are present?

Are requests of new core facilities justified in terms of the need related to the COBRE thematic research focus?

Review Criteria for Individual Research Projects

For each research project, reviewers will consider each of the review criteria below in determination of scientific and technical merit and provide an overall impact score, but will not give separate scores for the individual criteria.

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? Do they have appropriate experience and training? Do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Are the strengths, academic qualifications and biomedical expertise of the project investigator appropriate and sufficient for research productivity? Does the investigator publish his/her work in a timely manner?

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?

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?

If this project involves community engagement and outreach research, 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?

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?

Review Criteria for Alteration and Renovation (If included)

Reviewers will score Alteration and Renovation based on the criteria provided below

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, Research Cores and Research Projects

As applicable for the cores and project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact 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 ris 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 Guidelines for the Review of Human Subjects.

Inclusion of Women, Minorities, and Children

When the proposed cores and 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 Guidelines for the Review of Inclusion in Clinical Research.

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

Not Applicable

Additional Review Considerations - Overall, Research Cores and Research Projects

As applicable for the cores and projects 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 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 the National Institute of General Medical Sciences (NIGMS), in accordance with NIH peer review policy and procedures, using the stated review criteria. Assignment to a Scientific Review Group 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 score.
- Will receive a written critique.

Applications will be assigned to the appropriate NIH Institute or Center. 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 NIGMS Advisory Council or Board. 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.

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, SAM Registration, and Transparency Act requirements as noted on the Award Conditions and Information for NIH Grants website.

Prior Approval of Pilot Projects

Awardee-selected projects require prior approval by NIH prior to initiation (see the NIH Grants Policy Statement 8.1.3 Requests for Prior Approval for instructions on submitting a request). The awardee institution will provide NIH with following documents for administrative review:

- Full research proposal.
- Written evaluation and recommendation for scientific and technical merit by External Advisory Committee of COBRE center.
- Biographical Sketches.
- Detailed budget and justification.
- If clinical research or trial is proposed:
    - Clinical Research
    - Written study protocols that address risks and protections for human subjects in accordance with NIH's Instructions for Preparing the Human Subjects Section of the Research Plan.
    - IRB approval.
    - Certificate of training on human subjects protections for all personnel involved in the project.
    - Clinical Trial
    - Same documents required for clinical research.
    - Specific plans for data and safety monitoring, and will notify the IRB and NIH of serious adverse events and unanticipated problems, consistent with NIH DSMP policies.
- If live vertebrate animals are involved:
    - Written protocols addressing 5 points as indicated above (Additional Review Criteria, Vertebrate Animals).
    - IACUC approval.
- Updated other support.

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 or RPPR) 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

eRA Service Desk (Questions regarding ASSIST, eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Web ticketing system: https://public.era.nih.gov/commonshelp
TTY: 301-451-5939
Email: commons@od.nih.gov

Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading forms and application packages)
Contact Center Telephone: 800-518-4726

Web ticketing system: https://grants-portal.psc.gov/ContactUs.aspx
Email: support@grants.gov

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)
Telephone: 301-435-0714
TTY: 301-451-5936
Email: GrantsInfo@nih.gov

Scientific/Research Contact(s)

Yanping Liu, MD., PhD.
National Institute of General Medical Sciences (NIGMS)
Telephone: (301) 594-3900
Email: liuyanp@mail.nih.gov

Peer Review Contact(s)

Helen R. Sunshine, PhD
National Institute of General Medical Sciences (NIGMS)
Telephone: (301) 594-2881
E-mail: sunshinh@nigms.nih.gov

Financial/Grants Management Contact(s)

Ms. Christy Leake
National Institute of General Medical Sciences (NIGMS)
Telephone: (301) 594-7706
Email: Christy.leake@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

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