

# **COBRE Center on Opioids and Overdose**

## **Pilot Project Award Program**

### **Program Description**

The COBRE on Opioids and Overdose aims to increase the quantity and quality of research in the area of opioids and overdose in Rhode Island. One means of attaining this goal is by identifying and nurturing talented young investigators and enabling established investigators to create a new research line. The Pilot Program supports the COBREs growth by encouraging additional scholarship in the COBREs thematic areas and developing potential new COBRE Project Leaders.

The COBRE awards 3-5 pilot project awards annually for research related to opioids and overdose depending on available funding. We particularly welcome projects that are interdisciplinary and cross areas of study such as behavioral health and anthropology. We aim to enable an investigator(s) to collect preliminary data in support of grant applications for independent external research funding, especially from the NIH. Pilot project leaders can take advantage of the COBRE community to help guide their science and career development.

Pilot project leaders will have access to the COBRE's four interdisciplinary cores. These cores will provide infrastructure, consultation, and additional support services to ensure the successful career development of the funded junior investigator and help them apply for external, independent funding. The four Cores include Administrative, Data and Research Methods (DRM), Translational and Transformative (T2), and Special Populations (SP).

We encourage interested applicants to submit a one project summary/scope statement, a copy of their CV and Other Support documentation and Biosketch if available to Gayle Fraser at [gfraser@lifespan.org](mailto:gfraser@lifespan.org) before beginning the application process to ensure the proposed research fits with the mission of the COBRE.

**COBRE Faculty** are available to meet with applicants to discuss how to strengthen an application. We strongly encourage you to email [gfraser@lifespan.org](mailto:gfraser@lifespan.org) to schedule a meeting with a faculty member.

### **Program Requirements**

- Research must be opioid and/or overdose related
- The proposed research project should be of 1 year duration

### **Award Budget**

Single Investigator:

Support of up to \$40,000 in direct costs may be requested. Only direct costs will be awarded.

Multidisciplinary Application/Multi-investigator:

Support of up to \$60,000 in direct costs may be requested. Only direct costs will be awarded.

## **Use of Funds**

The budget request may include salary/fringe benefits support for the Pilot Project Leader and a research assistant or postdoctoral fellow, and other federally allowable research expenses and supplies. ([Click here](#) for information on allowable costs and activities.) Costs for equipment (>\$1,000) and renovation expenses are not permitted.

## **Award Project Period**

The project period is 12 months.

## **Eligibility**

The research Pilot Project Leader must be a junior investigator employed in Rhode Island. The 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 (R01) 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 focus. Senior, funded investigators who are not making a significant career change are not eligible; if such a project is submitted, it will be deemed as non-compliant and will not be reviewed.

With respect to item (1), grants that name an applicant as a co-investigator, collaborator, consultant, or a position other than PD/PI, do not disqualify the applicant. 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 applicant. 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. Each Pilot Project Lead 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. 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, unless evidence is provided that a faculty appointment is forthcoming.

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 from serving as a Pilot Project Lead. Furthermore, this individual can be of any faculty rank. 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.

Because the pilot project funds derive, in part, from our NIGMS-funded COBRE, awarding of a COBRE-funded Pilot Project will require one to relinquish any other NIGMS sponsored NIGMS IDEa programmatic funding.

Foreign components are not allowed.

### **Special Considerations**

While the best science will be prioritized and the ability of the investigator to contribute to and meet the goals of the center, special consideration will be given to those investigators who (in no particular order):

1. Take a multi-disciplinary approach to addressing the opioid epidemic
2. Are RI Hospital based faculty.
3. Consider NIGMS priority areas such as incorporating basic science and community engagement into their research.
4. Employ use of COBRE Core services
5. Are women and/or underrepresented minorities

### **Awardee Responsibilities**

Upon acceptance into the program, Awardees will be assigned a COBRE mentor who will ensure that the pilot-funded activities serve the dual-function of supporting the themes of the Center and the development of the pilot project awardee.

#### **Awardees will be expected to:**

- Work with mentor(s) to develop an Individual Development Plan (forms provided).
- Submit at least 1 abstract by Q4
- Attend and present at COBRE symposium and Annual Retreat
- Work with the Special Populations core to engage the Community Advisory Board (CAB) on their project
- Present at other COBRE sponsored events
- Acknowledge sponsorship from the COBRE on Opioids and Overdose supported by the grant in all research publications during the performance period. Future publications related to this research must also acknowledge COBRE sponsorship.
- Complete quarterly progress reports
- Provide annual progress reports to the Program Administrator for 24 months following end of award.

### **Mentor Responsibilities**

- Work with investigators on the development of an Individual Development Plan
- Ensure that pilot-funded activities support the theme of the Center
- Attend the COBRE Annual Retreat

### **Application Process and Timeline**

Interested applicants should submit a one page project summary/scope statement of their project, their CV and a Biosketch and Other support documentation if available to Gayle Fraser at [gfraser@lifespan.org](mailto:gfraser@lifespan.org) to ensure eligibility and the scope of the research is aligned with the COBRE mission. Please supply all information as one PDF file. The project summary statement should include:

- Contact and academic information
- One-page overview of aims, significance and approach

Although not required, we encourage you to speak with COBRE Faculty during the application process to help strengthen your application. To be paired with a faculty member, please contact Gayle Fraser at [gfraser@lifespan.org](mailto:gfraser@lifespan.org).

Applications must be submitted as one PDF and should use PHS 398 forms and instructions as described below. Upon receipt, applications will be evaluated for completeness and compliance with these instructions by the Center on Opioids and Overdose. Applications that are not compliant will not be reviewed.

## **COBRE Review and Approval**

Applications Due no later than 8:00 am: April 15, October 15

Note: Date restrictions can be overridden with recommendation from a COBRE Faculty member.

COBRE Committee Review Date: ~ 5 business days post application receipt

External Advisory Committee Review Date: ~ 10 business days post application receipt

## **NIGMS Review and Approval – Final Approval**

NIGMS Submission Date: Pending Just-in-Time Documentation, e.g. IRB/IACUC approval

Estimated Application Award Date: Approximately 4-8 weeks after submission to and approval by NIGMS.

## **Application Content** ([Click here](#) for PHS 398 forms and instructions):

- NIH Face Page (PHS 398 Face Page). This does not need to be signed by an institutional official the time of submission.
- NIH Project Summary Page (PHS 398 Form Page 2)
- Research Strategy Section (5-page limit including the Specific Aims page, no form). For more guidance on writing a strong Research Strategy click [here](#).
  - Specific Aims (1 page limit)
  - Significances: Overall significant of the project, including relevance to the goals of the COBRE on Opioids and Overdose and plans for use of the Cores in subsequent independently funded projects.
  - Innovation: Include both conceptual and technical innovations
  - Approach: Preliminary data (If applicable) and research plan including expected results.
- References: Not included in the page limit.
- PHS Human Subjects and Clinical Trials information ([Click here](#) for form and [here](#) for instructions). Note: All NIH funded studies that meet the [NIH definition for clinical research](#) must address plans for the [inclusion of women and minorities](#) within the application or proposal.

- Vertebrate Animals per PHS 398 Instructions (if applicable)
- NIH Biographical Sketch or CV
- Other Support Documentation following NIH guidelines (Click [here](#) for format and instructions)
- Detailed budget and budget justification using PHS 398 forms for 1 year. PI salary is allowable, but will be reviewed carefully considering the scope of the PI role.
- Mentoring statement – Please include your current mentor(s), their affiliation and their Personal Statement from their Biosketch.
- COBRE on Opioids and Overdose Applicant Questionnaire (Click [here](#) for the form).

### **Just-in-Time (JIT) Documentation**

Upon COBRE project approval from the EAC, the following additional and updated documentation will be required:

- IRB approval or IACUC approval
- Human subjects training certificates for all personnel involved in the work with human participants.
- Updated inclusion enrollment report for this study in HSS
- Face Page signed by Institute representative
- Revised 12-month budget to match grant year
- Project Summary and Specific Aims in Microsoft Word format.

### **Review Process and Selection Criteria**

Funding is dependent upon the review of the COBRE on Opioids and Overdose Executive and External Advisory Committee and final approval of the National Institute of General Medical Sciences.

The final selection will be made based on the following criteria:

- Contribution to the Center
- Scientific merit of the work
- Potential for the award to provide a basis for further research support from external sponsors
- Potential impact of the research on the opioid crisis
- Likelihood that the proposed work will be completed during the award period
- Interdisciplinary research proposed

### **Contact**

Address inquiries regarding the COBRE on Opioid and Overdose Pilot Project Award to [gfraser@lifespan.org](mailto:gfraser@lifespan.org).

