

COBRE Center on Opioids and Overdose

Research Project Leader Award Program

Program Description

The COBRE on Opioids and Overdose offers a unique and innovative mentoring strategy that, in addition to primary project advising, will provide COBRE-funded Research Project Leaders specialized mentorship and services, empowering investigators to influence policy and practice through their research. This COBRE will prepare Research Project Leaders to achieve independently funded research projects in this field and position them as future leaders in opioid-related or overdose research.

The long-term goals of the Center are to develop and sustain a critical mass of investigators specializing in research related to opioids and overdose that benefits affected populations, and to support the research activities of junior investigators interested in conducting opioid-related research to ensure their transition to independent R01 level-funded investigators.

Awardees will gain 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. The four Cores include Administrative, Data and Research Methods (DRM), Translational and Transformative (T2), and Special Populations (SP).

COBRE Faculty are available to meet with applicants to discuss how to strengthen an application. We strongly encourage you to email 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 2-year duration.
- The Project Leader must commit 6 person months annually for the duration of the project.
- The Project Leader must identify a senior faculty member who can serve as a mentor for the duration of the project. Mentors should show a record of external funding.
- The Project Leader must submit an application for an R01 or equivalent grant by the end of their second year.

Award Budget

Rhode Island Hospital Applicants:

Annual support between \$100,000 and \$164,000 in direct costs per year may be requested. Funding includes applicable indirect costs. Total costs (direct and indirect) should not exceed \$264,000 annually.

Applicants from other Rhode Island Institutes:

Annual between \$100,000 and \$155,000 in direct costs per year may be requested. Funding includes applicable indirect costs. Total costs (direct and indirect) should not exceed \$249,000 annually.

Use of Funds

The budget request may include salary/fringe benefits support for the 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.)

Mentors from non-IDeA states ([Click here](#) for more information about the IDeA Network.) will be compensated as consultants or via a fee-for-service arrangement. Capital equipment expenses are permissible following your institute's guidelines for these expenses.

Renovation expenses are not permitted.

Award Project Period

The project period is 24 months.

Eligibility

The research 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 Research 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 Research 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.

IDeA program investigators are not eligible to receive simultaneous research funding as COBRE project investigators. Similarly, COBRE investigators may not receive simultaneous research project support from any other IDeA programmatic funding. Awardees will be required to relinquish any other NIGMS sponsored IDeA programmatic funding. [Click here](#) for more information about the COBRE program. [Click here](#) for more information about the IDeA program.

Foreign components are not allowed. [Click here](#) for more information on foreign components.

Special Considerations

While the best science will be prioritized and the ability of the investigator to meet the goals of the center, special consideration will be given to those investigators who:

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

Application Process and Timeline

Applicants must 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 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/scope 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.

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

Project Summary statement due no later than September 30, 2019

Applications Due: November 8, 2019

COBRE Committee Review Date: ~November 14, 2019

External Advisory Committee Review Date: ~November 21, 2019

Prospective awardees will be asked to prepare their Just in Time Documentation on or around November 25, 2019.

NIGMS Review and Approval – Final Approval

NIGMS Submission Date:	Pending Just-in-Time Documentation, e.g. IRB/IACUC approval
Estimated Application Award Date:	Approximately 4-6 weeks after submission to NIGMS

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

- NIH Face Page (PHS 398 Face Page)
- NIH Project Summary Page (PHS 398 Form Page 2)
- Research Strategy Section (12-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.
 - Mentoring Plan: Briefly describe the mentoring plan for the applicant.
 - Project Timeline: Includes milestones and plans for submitting 1 manuscript in Year 1 and 2 manuscripts and an R01 or equivalent grant application in Year 2.
- 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
- Other Support Documentation following NIH guidelines (Click [here](#) for format and instructions)
- Detailed budget and budget justification using PHS 398 forms for 2 years.
- Checklist Format Page with F&A cost break down
- Support letters from your mentors
- PHS 398 detailed budget forms for up to 0.5 calendar month effort for Mentor salary and fringe benefits. Mentors are paid through the Administrative core budget.
- Mentor 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
- Updated Other Support which includes COBRE award
- Face Page signed by Institute representative
- Checklist pages for Mentor if they are from an IDeA state but not from RI Hospital
- Revised 24-month project budget to match grant year
- Revised 24-month budget for mentor 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 COBRE
- 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
- Strength of the potential investigator to become a leading independent researcher

Expectations

Upon acceptance into the program, Awardees will be expected to:

- Work with their mentors to develop an Individual Development Plan (forms provided).
- Submit at least 2-4 abstracts and 3 manuscripts by the end of their second year
- Apply for independent R01 level funding during the two-year period of support
- Attend and present at internal COBRE Research and Practice meetings
- Attend and present at the COBRE Symposium and Annual Retreat
- Attend regular COBRE events and meetings
- Work with the Special Populations core to engage the Community Advisory Board (CAB) on your project.
- Attend writing group meetings
- Present at external conferences

- Submit quarterly reports to the Program Administrator including an Annual Progress Report.
- Once independent funding is achieved the Research Project Leader is required to transition off the COBRE (graduated). Research Project Leaders will be expected to remain engaged with the COBRE by attending research meetings, collaborate scientifically, mentor, and speak at the annual COBRE symposium.

Mentors are expected to:

- Develop an IDP with their Research Project Leader upon acceptance into the program
- Meet with their Research Project Leader on a weekly basis
- Ensure the Research Project Leaders are meeting their project milestones and assist with professional development
- Review and comment on Research Project Leaders quarterly reports, updated IDPs and their annual progress reports.
- Attend the COBRE annual retreat

Contact

Address inquiries regarding the COBRE on Opioid and Overdose Junior Investigator Project Award to gfraser@lifespan.org.