

O'Donnell Brain Institute Human Neuroscience Collaborative Research Program

This program will provide resources for clinical research interdisciplinary teams pursuing hypothesis-driven projects in human neuroscience. For the purposes of this mechanism, “human neuroscience” is broadly defined as experimental work with human participants, inclusive of obtaining biospecimens from a well-characterized cohort of human subjects for laboratory analyses. These clinical research teams may include investigators within an individual department or, ideally, across departments. Support will be for two to four years with an opportunity for competitive renewal. Support may be used in whatever way the research team deems appropriate to address their scientific questions (e.g., equipment and supply purchases, data science and biostatistical assistance, study personnel needs).

The goals of this program are to (1) further scientific knowledge developed through human neuroscience research; (2) encourage clinical and translational interdisciplinary research team development; (3) develop a database and/or repository of well characterized specific patient cohorts; and (4) establish a sustainable plan to continue interdisciplinary clinical research efforts.

Each application should be designed to address a significant clinical research question. The proposed hypothesis-based research should advance understanding of or answer this question. Several approaches responsive to this program include but are not limited to:

1. A focused clinical cohort study (including biospecimen collection) with clear research goals led by a dedicated interdisciplinary team. The initial project should result in a rigorously characterized clinical cohort with biospecimen and associated clinical data relevant to the clinical question. Proposals not focused on a *well-defined research question* or a proposal to collect patient data and biosamples for a specific condition based only on diagnosis (e.g., a patient registry) and not focused on a specific research question will be deemed non-responsive to this program.
2. A proof-of-concept clinical trial for any clinical intervention(s) (e.g., device, drug, neuromodulation, surgical, behavioral).
3. Hypothesis-driven research on human subjects directly relevant to advancement of new therapeutics or interventions (i.e., could include neuroimaging, EEG/MEG, etc. to inform underlying mechanisms).
4. Hypothesis-driven research on human subjects to enhance understanding of disease mechanisms.

Award Information

- Teams will include PIs from one or more OBI-affiliated departments. Applications may contain a single project or seek to support a team of investigators working on distinct projects around a common theme. In the latter case, the central goal

being pursued must be highlighted, and the details and contribution to the central goal of each project must be clearly outlined.

- Biorepository and/or clinical data banking is an expected component of all relevant projects. Independent of their research budgets, teams will have access to A) clinical informatic support to include assistance with definition and identification of patient cohorts, data base design and construction, and biostatistical analysis, and B) biorepository support to include sample collection and preparation, sample cataloging, and sample storage. This support will enhance data quality control and scientific rigor and is an added benefit of participation in PNTRC research.
- Teams selected to submit full applications will be required to attend a statistical planning meeting with the Chief Medical Informatics Officer (CMIO) of the Neurosciences and associated faculty members. The statistical planning recommendations and services that will need to be included in the full application are an added benefit of participation in PNTRC research.
- PNTRC-supported programs are expected to produce data for externally sponsored project submissions (e.g., federal grant application).
- All areas of human neuroscience study are eligible. Priority will be given to OBI's special emphasis areas of neurodegeneration/regeneration, neuroimmunology, and circuit neuroscience/neuromodulation.
- OBI will dedicate up to \$4M to support these programs for the initial round of funding. Individual projects may receive up to \$1M. Project scope and budgets will be scrutinized for appropriateness. Not all projects are expected to be large and to utilize the maximum budget. The primary goal is impactful human science performed responsibly and rigorously.
- Teams will be expected to submit annual progress reports and to present an annual update at the OBI Research Day.

Eligibility

All OBI Investigators are eligible to apply for this award. [Click this link](#) to learn more about the OBI Investigator program and to access the application.

Letter of Intent

By September 3, 2024, prospective applicants are required to submit a letter of intent (2 pages):

1. Summary statement: Concise summary of project and clinical impact
2. Statement of need: Description of the interdisciplinary team and overall goals
3. Research activity: Major activities of the research project(s)
4. Administrative support and biorepository component
5. Outcomes: Expected achievements and "next steps" to apply for external support
6. Acknowledgement of application by current department chair (not included in page limit)

7. Appendix: Biographical sketch of PI and names/department information for proposed key personnel (not included in page limit).

Application Components

After LOI review by an internal advisory committee, selected applicants will be invited to submit a FULL APPLICATION to be reviewed by an external review committee:

1. Project summary/ Overall Interdisciplinary Team Design
2. Research Project(s) - Specific aims
3. Innovation and Significance
4. Research strategy and team synergy
5. Key references
6. Budget
7. Budget justification
8. Biographical sketches from PI/Co-PI 5 pages per NIH Biosketch template
9. All documents will be single-spaced, no less than 11-point Arial font, 1" margins on all document sides. Page limits denote maximums.

1. Project Summary/Overall Team Design (750 words)

Include a summary of the project's broad, long-term objectives and specific aims, and a description of the research design and methods. In this section, use nonexpert terminology for a short, succinct description of the proposed work. Avoid both descriptions of past accomplishments and the use of the first person. Please be concise.

2. Research Project - Specific Aims (1 page)

State concisely the goals of the proposed research with expected outcomes, including the impact the results of the proposed research will have on the research fields involved. List succinctly the specific aims/objectives of the proposed research study.

3. Innovation and Synergy (1 Page)

Highlight the specific expertise, including unique departments and disciplines, brought by the different investigators and how joining forces brings synergistic value to the project. For study team key personnel, include information such as departmental affiliation, discipline, area of expertise, and the study team role.

4. Research Strategy (3 Page)

The research strategy needs to include relevant methodologic information for how the study will address the aims and hypotheses. Depending on the study design, such information may include details such as human subject inclusion and exclusion criteria, biobehavioral and biospecimen outcome metrics, interventions, and biostatistical plan. This section also needs to include information regarding how the study will ensure scientific rigor and reproducibility.

5. Key References (1 Page) This attachment should include any references cited in the Research Strategy (#4). References should include PubMed Central (PMC) reference number. References should be limited, relevant, and concise.

6. Budget

As part of the grant's progress report, the PI is required to estimate carry-over balance (including prior-year carryover). For carry-over greater than 25 percent of the current year's total approved budget, the PI must request an exception to carry-over all funds.

7. Budget Justification

This form includes details for all expenditures and budget line items (i.e., personnel time and effort, materials, supplies, travel) needed to support the research project.

8. Biographical Sketches

Biographical sketches are required for all key personnel following non-Fellowship NIH Biosketch template, found here: <https://grants.nih.gov/grants/forms/biosketch.htm>