

O'Donnell Brain Institute Clinical Investigator Development (CID) Program

Essential to the O'Donnell Brain Institute's (OBI) goal of developing impactful therapies for patients with brain disease is increasing the number of outstanding early career faculty who pursue clinical human neuroscience research. 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.

The CID program will cultivate a new cadre of early career scientists pursuing human neuroscience research and the development of research excellence. This program will support early career faculty to pursue prospective human neuroscience research, and additional research methodology and career development training as appropriate for a specific investigator's needs. Applicants are required to define a mentorship team and, if appropriate, to participate in relevant career development training and/or coursework (e.g., biostatistics, scientific writing). Applicants will have submitted at least one external grant proposal (i.e., foundation, federal, state) or one special internal grant proposal as PI (Principal Investigator) within the past three years, but a funded proposal is not required.

Award Information

- Excellence and the future promise of the candidate will be of paramount importance for review.
- The applicant must assemble a mentoring team that must meet at least two to three times per award year.
- The applicant should identify a relevant certificate or coursework to develop expertise in research methodology and career development training as it relates to their research and/or career advancement goals. If gaps in a candidate's training are identified in review, OBI may require additional educational training as a requirement for support (e.g. Responsible Conduct of Research, UT Southwestern's SOAR program, scientific/grant writing, and team management/administration)
- Up to three CID scholars will be awarded in the initial funding round.
- Awards are for four years and will provide \$150K/year support.
- The applicant will be required to submit research findings for scientific presentation and publication (in peer-reviewed journals), and may be required to present at the annual OBI Research Day
- Applicants 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.
- CID Scholars will be required to submit a federal (e.g., National Institutes of Health (NIH)) grant during year four of the award.
- The OBI will assist with the creation of a peer mentor group that can provide support in areas such as career development, leadership development, scientific writing, peer review, and best practices for team-based collaborative science.

- The OBI will provide resources to create a study monitoring and auditing plan to maximize human subject safety and data quality assurance throughout the entirety of the project, as well as ensure compliance with UT Southwestern policies as they relate to clinical research.

Eligibility

- Current UT Southwestern Assistant Professors or individuals being recruited (either internally or externally) into an Assistant Professor position
- Eligible candidates hold an M.D., Ph.D., or M.D.-Ph.D. degree.

Letter of Intent (LOI)

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

1. Summary statement: Concise summary of clinical research project and career goals. Briefly explain the impact of the proposed project and how it aligns with and advances the applicant's career goals in clinical neuroscience research.
2. Mentorship team plan: Identify proposed mentoring team and briefly state their title, affiliation, and expertise relevant to the proposed project. External mentors are acceptable and desirable if they contribute relevant expertise to the proposed program. At least one mentor of the mentoring team needs to be dedicated to career development mentorship.
3. Project activity: Major activities of the proposal including any certificate or coursework required to develop expertise needed for the proposal and/or for a candidate's future career success.
4. Outcomes: Expected research and career advancement outcomes
5. Acknowledgement of application by department chair (not included in page limit)

Application Components

- The LOIs will be reviewed by an internal advisory committee. Selected applicants will be invited to submit a FULL APPLICATION reviewed by an external review committee.
- These awards will provide the Early-Career Investigator support over four years. Candidates are required to devote at least 25% effort to CID activities.
- CID Scholars will have access to a) Clinical Informatics support to include assistance with definition and identification of patient cohorts, data base design and construction, and biostatistical analysis, b) biorepository support to include sample collection and preparation, sample cataloging, and sample storage, and c) support to create a study monitoring and auditing plan with regard to human subject safety and data quality control.
- 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 (750 words)

Include a summary of the project's 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. Specific Aims (1 page)

State concisely the goals of the proposed human neuroscience research with expected outcomes, including the impact that the results of the proposed research will have on the research fields involved. List succinctly the specific aims/hypotheses/objectives of the proposed research. Proposals not focused on a *well-defined research question* or a proposal to collect patient data and bio samples 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.

3. Mentorship (1 page)

Applicants must identify a team of mentors who are qualified and committed to supervise, guide, and advise the applicant over the project. Please list each member, their respective academic affiliation, and the specific expertise/guidance they will contribute to the project, and any facilities and/or resources they may contribute to the project. At least one mentor of the mentoring team needs to be dedicated to career development mentorship. The mentorship team is required to meet at least 2-3 times per year. A summary from mentoring team meetings will be incorporated into the annual progress reports.

4. Career Development Plan (1 – 2 pages)

Applicants need to provide a career development plan and a career development timeline (figure or table) that outlines their activities across the project's four years. The career development plan should list goals/objectives and the methods (e.g., mentorship, didactics/courses, training at professional organization, etc.) by which those goals/objectives will be achieved. The career development plan should align with the research project to help the applicant eventually transition to an independent investigator.

5. Responsible Conduct of Research Training (1 page)

Applicants need to include a plan for training in the responsible conduct of research. Following the NIH requirements, the application needs to include the following information for the plan: a) *Format* - the required format of instruction (e.g., face-to-face lectures, coursework, and/or real-time discussion groups). A plan with only on-line instruction is unacceptable; b) *Subject Matter* - the breadth of subject matter (e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics); c) *Faculty Participation* - the role of the mentor(s) and other faculty involvement in the applicant's instruction; d) *Duration of Instruction* - the number of contact hours of instruction (at least eight contact

hours are required); and e) *Frequency of Instruction* -instruction must occur at least once a year for each period of the project.

For additional information, see: NIH Notice NOT-OD-22-055; Requirement for Instruction in the Responsible Conduct of Research

6. Research Strategy/Methodology/Expected Outcomes (3 pages).

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.

7. 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.

8. 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 career development and research project.

9. NIH Biographical Sketches

Biographical sketches are required for the applicant, mentoring team members, and any other key personnel, following non-Fellowship NIH template, found here:
<https://grants.nih.gov/grants/forms/biosketch.htm>

10. Key References (1 page)

This should include any references cited in Research Strategy (#6). References should include PubMed Central (PMC) reference number. References should be limited, relevant, and concise.