



#### SCHOOL OF MEDICINE AND NC TRACS TRANSLATIONAL TEAM SCIENCE AWARDS 2021-22 REQUEST FOR PROPOSALS

#### I. Summary of Award

The School of Medicine's Strategic Plan includes an annual award jointly administered by the Office of Research and NC TraCS—the Translational Team Science Award (TTSA). This award is aimed at capitalizing on the "culture of collaboration" at UNC Chapel Hill to foster new synergistic interdisciplinary teams of basic science and clinical investigators. "Translational" is defined broadly and is not restricted to human subjects and tissues. Proposals may include research using cellular and animal model systems; however, the project should clearly translate across basic and clinical disciplines.

Interested teams that fit the eligibility criteria below should submit an initial Concept paper and selected teams will be invited to submit a full proposal for review. If awarded, the TTSA will provide an initial 12-month period (Phase I, up to \$50,000) to begin to fully engage team members in the project. For larger projects, an application for Phase II funding (12 months, up to \$75,000) can be submitted for competitive review upon completion of Phase I. Phase II will consist of additional distinct aims that are necessary to get the project to the point where it is competitive for external funding. Funding for Phase II is contingent on the merit of the proposed plan and progress in the prior period relative to the stated milestones.

The intent of TTSA awards is to provide the planning time and initial funds for support of early stage de novo research teams that would otherwise not be possible. TTSA supported research should lead to submission of novel interdisciplinary program project grants and R01s by UNC SOM investigators. This call is meant to capture the broad interdisciplinary expertise of SOM faculty and is not restricted to any programmatic area; however, projects that are responsive to NIH programmatic areas of interest (for example BRAIN, Precision Medicine, etc.) are encouraged to apply.

Since the inaugural cycle of the TTSA in October 2013, 28 teams have been selected for funding. A summary of these awards can be found on the Office of Research websitehttps://www.med.unc.edu/oor/ttsa-teams-and-projects/.

#### **III. Eligibility and Awards Administration**

- Pilot grant awards are not meant as bridge funds or as supplementary funding for existing grants. The proposed project should represent a new project and not significantly overlap with the aims of existing funding (external or internal awards). This must be **clearly** evident in the application.
- Review of applications (Phase I and Phase II) will be provided by the NC TraCS review panel with equal consideration for proposals across the translational spectrum.

- TTSA grants will support the development of <u>new</u> research teams. Project Teams should include at a minimum two PIs: one basic and one clinical. To qualify as a <u>new team,</u> the two PIs should not have previously submitted a successful grant proposal.
- Teams should consist of at least 1 basic and 1 clinical faculty member, and the **team leaders must hold a primary appointment in the School of Medicine**. Cross departmental teams are prioritized.
- Researchers whose appointments allow them to serve as PI on externally sponsored research projects are eligible to apply as PI. This generally means permanent faculty (not adjunct appointments) and includes those with non-faculty appointments like "research scientist" and investigators from research institutes and centers who are eligible to apply for investigator-initiated awards and R01-level funding.
- Applications may also include collaborators or co-investigators from NC TraCS' partner institutions; please contact <u>Mary Beth Cassely</u> to discuss guidelines for expending pilot funds at other institutions, and for other questions regarding investigator eligibility. If research is performed outside the US, no more than 50% of the funding can be expended outside the US or to support research on samples obtained outside the US.
- If projects involve collaborations or activities at other institutions should generally be funded by that institution. Funds cannot be subcontracted from one institution to the other. More information is available in the Pilot Program FAQ.

# **IV. Application Process**

#### 1. **Concept Submission** (required)

The Concept paper should include:

- Title Page and Team Description (1 page)
  - Include names and affiliations of the clinical and basic PIs as well as other key players. The basic and clinical PI(s) must be clearly identified.
  - Definition of how this is a 'new' team, and why a new team is needed for this project.
- Hypothesis, specific aims, and overall goals for the project (Phase I). Include the scientific and translational impact. (1 page)
- Current NIH biosketch and other support for each PI and key team member; *must indicate all internal pilot funding, including pending proposals.*
- Margins should be at least 0.5. Please use single or 1.5 spacing and 11pt Arial font.

Upon review of the Concept papers, teams will be selected to submit a full proposal. The Phase I grant awards up to \$50,000 for a 12-month period. These funds can be used to obtain whatever data/approvals are needed for proof of concept and can be used to support trainees and/or for reagents and other costs. Salary support for faculty is <u>not</u> an allowable cost.

Resubmissions of Concepts or Phase I proposals <u>are not permitted</u> unless <u>substantially different</u> <u>than the previous submission</u> or <u>by invitation</u>.

# 2. Phase I Application Components:

- **Title Page** (include project title and names, titles and affiliations of each team member and brief description of research team)
- Abstract (250 word max)
- Research Plan

- The Research Plan should include Specific Aims, Significance, Innovation, and Approach. The approach should include statistical analysis and justification. <u>Consultation with a TraCS biostatistician</u> is highly encouraged.
- For studies enrolling human subjects, include engagement and recruitment plans either in this section or in the Human Subjects section (number 7 below).
- Include where applicable clear evidence of how the application meets the review criteria.
- 1.5 line spacing, font Arial 11 pt., and 1-inch margins all around. (5-page limit, including tables and figures. References do not count towards the page limit.)
- **References** (no page limit)

# Detailed Budget and Justification

- Please use PHS 398 form page 4 for detailed budget.
- Budget should not exceed \$50,000 for Phase I.
- Funds may be allocated to support research staff, supplies, core facility fees, travel directly related to project goals (ie data collection), and small equipment. Salary support for faculty is <u>not</u> an allowable cost. Salary support for research staff, trainees, and technicians are permissible. Funds will support direct costs only.
- Human and Animal Subjects (no page limit)
  - Although Institutional Review Board (IRB) and/or Institutional Animal Care & Use Committee (IACUC) approval is not required at time of submission, the application should briefly describe any human and/or animal subject issues.
  - If human subjects will be involved in the research, provide a description of their involvement and characteristics, study procedures, materials used in the research, potential risks to subjects, the process for recruitment and informed consent, and protection against risks. Provide assurance that the project will be reviewed and approved by an IRB, use a single IRB if the project is multicenter, and comply with HIPAA.
  - If vertebrate animals will be used, provide a description of the proposed use of the animals in the work outlined and procedures for ensuring that discomfort, distress, pain and injury will be limited. Provide assurance that the project will be reviewed and approved by an IACUC.
  - Note that no funds will be released without the requisite approvals in place.

# • NIH Biosketches and Other Support for Key Personnel

- Include current and pending support and internal as well as external funding sources.
- Letters of Collaboration (if applicable).
  - Letters of Collaboration may be included if they clearly state a commitment of resources required for the project's success, for example biobank samples being made available to the investigator. Generic or non-specific letters of support are not required or encouraged. (No page limit)

At the end of Phase I, the team must submit a final progress report and may submit a proposal for an additional year of Phase II funding (up to \$75,000 for one year). Phase II proposals are competitively reviewed and an award is contingent on successful completion of Phase I milestones and a clear path for future funding.

Teams that received a Phase I Grant are not required to submit a proposal for Phase II funding, but they must submit a final report. <u>Investigators who do not submit a final report will be</u> ineligible for future funding from this award mechanism.

# V. Review Criteria

Applications should be presented in a clear and logical fashion, make a convincing case for the significance of the work, and describe the proposed methods in sufficient detail so that an adequate evaluation of the application can be made.

The primary review criterion is that the pilot work has the potential to lead directly to a fundable external proposal for disparities research, written and led by the pilot study PI, and submitted within a year following completion of the pilot project. Preliminary data are not required for the pilot proposal, but some specific evidence that the work has merit scientifically and that the proposed effort is feasible within the timeframe and funding level of the pilot program is required. It is strongly encouraged that the pilot proposal includes specific plans regarding the proposal for external funding following the pilot work.

#### The following review criteria will be considered:

- 1. Significance of the work
- 2. Novelty/innovation of the research idea
- 3. Existence of a genuine multidisciplinary team in place that is integral to the conduct of the research
- 4. Relevance of the proposed study to translational research
- 5. Soundness of the proposed methods
- 6. Feasibility of accomplishing the stated project goals within the 12-month study period
- 7. Potential for the project to lead to future external funding

# **VI. Other Guidelines**

- The budget period will begin when applicable IRB/IACUC documentation is provided to NC TraCS and the PI indicates everything is in place for the project to begin. If the PI is not ready to start within 4 months of notification of funding, NC TraCS reserves the right to withdraw the award. The expectation is that all funds will be expended by the end of the grant period. At the end of the 12-month project period, any unexpended funds will be retained by NC TraCS and/or returned to the matching entity.
- 2. Prior to receiving funds, research involving human subjects must have appropriate approvals from the UNC-CH IRB, and research involving animals must have the appropriate IACUC approval. Either an IRB approval letter or an IRB response to a "Determination Whether Research or Similar Activities Require IRB Approval" must be submitted to NC TraCS. Human subjects or animal research must be reviewed in accordance with the university's general assurances and HIPAA. In addition, if the research involves human subjects, all personnel named on the budget page must have certification of training in the protection of human subjects prior to the start of the grant period.
- 3. The NC TraCS Institute is funded through a CTSA grant from NIH's National Center for Advancing Translational Sciences (NCATS). NCATS requires that they review and approve all NC TraCS pilot grants involving human subjects research prior to funds being released. If your application is funded and involves human subjects research, NC TraCS will require additional documentation to send to NCATS. NCATS generally completes their review in less than 30 days.
- 4. NC TraCS staff will work closely with funded projects throughout the grant period to monitor progress and provide assistance where necessary. A 6-month interim progress report and a final progress report are required. NC TraCS expects the PI to report the outcomes achieved due to the pilot award over the lifetime of the work, e.g., subsequent external funding, publications, presentations and patents, and to <u>acknowledge NC TraCS research support</u> where appropriate.

# VII. Submission Dates

- TTSA Concept papers due: September 15, 2021 by 5pm. Email to <u>oor submissions@med.unc.edu</u>
- TTSA Phase I Proposals: December 7, 2021 by 5pm. Submit to the <u>NCTraCS online</u> <u>portal</u>.

If you have questions, please contact <u>Jennifer Brennan</u> or <u>Mary Beth Cassely</u> at NCTraCS.