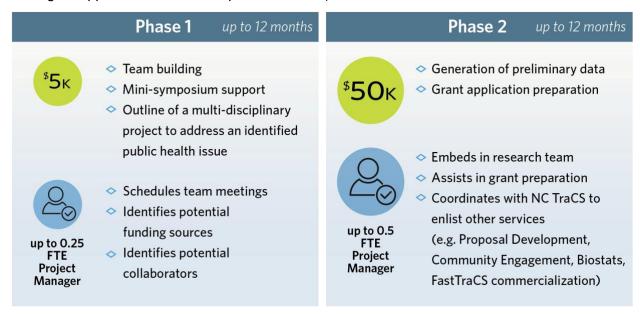
NC TraCS/UNC Chapel Hill Advancing Collaborative Team Research (ACTeR) – Phase 2 Program Request for Applications (RFA)

The North Carolina Translational and Clinical Sciences Institute (NC TraCS) is the academic home of the NIH Clinical and Translational Science Award (CTSA) at UNC Chapel Hill (UNC-CH). Our mission is to accelerate clinical and translational research from health science to discovery to dissemination to patients and communities.

I. Purpose

The overall goal of the **NC TraCS Team Science** program is to promote multidisciplinary translational research across the UNC campus, the NC TraCS partnership, and the larger Clinical and Translational Science Award (CTSA) program network. Such broad-based research is intended to bring together investigators from a variety of disciplines to address specific public health issues or knowledge gaps, and to transcend the conventional 'section- or division-based' structure of research universities. Recognizing the logistical hurdles that such an approach can entail, the **Advancing Collaborative Team Research (ACTeR)** program will support the formation and maintenance of multidisciplinary research teams that comprise investigators, with complementary expertise, from across the campus, from NC TraCS partner institutions, and from other regional institutions. Support is provided through a combination of competitively reviewed *graduated* direct funding and logistical support awarded in two phases: **Phase 1** (up to 0.25 FTE Project Manager support + \$5,000, for up to 12 months) and **Phase 2** (up to 0.5 FTE Project Manager support + \$50,000, for up to 12 months). See Section II below for more details.



Bringing an idea from concept to completion can be challenging for teams, especially when there is limited bandwidth among team members. Support through the ACTeR program will reduce the organizational and administrative burden of grant preparation on Principal Investigators (Pls), freeing them to focus on research and team-building. Support through the full ACTeR program enables (i) the recruitment of additional team members to augment the team's existing expertise, (ii) the formulation and incubation of ideas and plans for a novel project and eventual research program that addresses a research issue in clinical or translational medicine, which (iii) may include the collection of preliminary data, and (iv) Project Manager assistance to facilitate the

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preparation of a *large, multidisciplinary proposal* (e.g., a "P," or "U"-scale grant application or a large multiple-PI R01) from concept to submission. This program is intended to support teams seeking continued programmatic growth and sustainability. While complementarity of the proposed research group to existing institutes, units, programs, or centers on campus will be considered a strength, emphasis will be placed on the novelty and interdisciplinarity of the research project. The overarching expectation is for the teams to develop a new and sustainable program or center.

Applications to the ACTeR program are encouraged from **Teams** of investigators drawn from different disciplines, institutions, and diverse communities. Therefore eligible teams will initially comprise ≥3 investigators drawn from ≥2 schools or institutions. We are interested in research that spans the full <u>Translational Science Spectrum</u>, and in supporting Teams working to address as many of the following topics that apply:

- Research on a clearly identified medical problem or knowledge gap that lends itself to a multidisciplinary approach.
- Research that **generates initial or basic discoveries** relevant to human health or disease regardless of whether the context of the discovery is the laboratory or the field.
- Research that applies or accelerates discovery into testing in clinical or population settings.
- Development and/or evaluation of the evidence base that **changes practice**.
- Research that investigates how practice improves health policy, health outcomes, and the health of populations.

II. ACTeR Graduated Support Structure

The ACTeR program is designed to encourage and facilitate novel clinical and translational research in its many forms, by providing *graduated multi-phased support* to investigators:

- 1. <u>Phase 1 Support</u> (team identification & idea generation). For up to <u>12 months</u>, ACTeR will provide Team Science Project Manager support (up to 0.25 FTE dedicated to the team) plus \$5,000. More details on the Phase 1 funding can be found in the <u>Phase 1 ACTer RFA</u>.
 - <u>Goal:</u> By the end of Phase 1, applicants are expected to have developed their initial idea into a fleshed-out plan for obtaining extramural funding, and to have strengthened their team's existing expertise commensurate with this research goal.
- 2. <u>Phase 2 Support</u> (generation of preliminary data & preparation of grant application). If and when the team becomes eligible for Phase 2, and once they have identified a specific goal (e.g., funding opportunity) at the end of their Phase 1 support, the team can apply for Phase 2 support. This can include, but is not limited to, the submission of a large, multi-component federal grant application (e.g., P, U, large R01), the development of a patentable product, acquisition of state funding, etc. For up to <u>12 months</u>, this phase will include:
 - (a) Team Science Project Manager Support. The Project Manager from Phase 1 will transition to serve as an embedded *Proposal Manager* (up to 0.5 FTE dedicated to the team) who will provide logistical support for the application and preparation effort. This includes scheduling meetings to ensure the team meets regularly and productively, working with the PIs and team to clarify FOA requirements, assigning writing/reviewing responsibilities and timelines, aiding in preparation of the application, overseeing version control, assembling ancillary documentation, and coordinating with NC TraCS to identify appropriate services (e.g., Proposal Development, Biostatistics) that will aid in creating a more competitive application.

(b) Direct Funding, up to \$50,000. The fiscal support in Phase 2 increases substantially to support the generation of preliminary data, use of NC TraCS services, necessary travel and other project development activities (see also VII. Budget Guidelines below for specifics).

Goal: Submit a competitive large multidisciplinary grant application.

<u>Direct-to-Phase 2 Support</u> (generation of preliminary data & preparation of grant application). Multidisciplinary teams having already independently fulfilled the goals of Phase 1 (i.e., have a team largely in place and a firm plan for a grant application or other product) have the option to apply directly for Phase 2 funding, without having had Phase 1 ACTeR support. Investigators must meet the requirements to apply for Direct-to-Phase 2 Support. Applications will <u>not</u> be accepted for Direct-to-Phase 2 support without prior approval from the <u>ACTeR Team at NC TraCS</u>.

<u>Note:</u> Advancement to Phase 2 is by competitive application only and is not guaranteed to all projects that receive Phase 1 support. NC TraCS ACTeR awards are not meant to serve as bridge funds or as supplementary funding for existing grants.

III. Team and PI Eligibility

Eligible teams will comprise ≥3 investigators drawn from ≥2 schools or institutions. Such teams could include, but are not limited to, those that have already formed around a research idea, goal, or identified health problem (e.g., unfunded <u>Creativity Hub</u> applicants or School of Medicine (SOM) <u>Translational Team Science Award</u> awardees). We anticipate that most applications for Phase 2 support will come from those successfully established in Phase 1 of the ACTeR program.

Teams must identify one UNC-CH-affiliated PI as the **Contact PI**, who will have primary responsibility for the administrative aspects of the ACTeR program award. Only researchers whose appointments allow them to serve as PI on externally sponsored research projects are eligible to apply as **PIs.** This generally means permanent faculty (not adjunct appointments), but can also include those with non-faculty appointments like "research scientist," as well as investigators from research institutes and centers who are eligible to apply for investigator-initiated awards and NIH "R" funding. Applicants from NC A&T, RTI or NC State **are eligible to serve as co-PIs.** Please submit any questions regarding eligibility to the <u>ACTER team at NC TraCS</u>.

IV. Use of NC TraCS Services

NC TraCS offers investigators a variety of research services and expertise, and applicants are encouraged to propose the use of these services in their application and to use them during the project where appropriate. A full list of NC TraCS services can be found here. The cost of any desired NC TraCS services should be included in the budget. Note that, due to high workloads, some TraCS services require significant advanced notice of their need in the project. Therefore, any proposed TraCS Services should be consulted prior to submission to ensure that the application budget includes accurate information and timelines. NC TraCS Team Science Staff are available to offer general advice and assistance with applications prior to submission. Click here to schedule a consultation (choose "Submit a Request" and then "Team Science" from the menu).

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 plans in sufficient detail for an adequate evaluation to be made.

The following review criteria will be considered:

- 1. A multidisciplinary team and/or new collaboration initially comprising at least three investigators, drawn from at least two schools or institutions.
- 2. A clearly identified human health issue or knowledge gap that lends itself to a multidisciplinary approach that is novel and has the potential for high impact.
- 3. Relevance of the proposed study to translational research.
- 4. Evidence of productive ACTeR Phase 1-supported activities (if applicable).
- 5. Commitment to regular team meetings, which will be organized and scheduled by the PM.
- 6. Soundness of the Aims and Approach.
- 7. A plan for team sustainability and continued funding beyond the first external grant submission, including a timeline and milestones.
- 8. Potential for the project/topic to lead to future external funding or a commercialization opportunity.
- 9. Feasibility of the project goals being accomplished within the 12-month project period.

VI. Application Procedure

Before submitting an application, teams are **strongly encouraged** to <u>consult with NC TraCS</u> <u>Team Science</u>. Applications must be submitted using the <u>NC TraCS online grant portal</u>. Teams will need to identify a UNC-affiliated Contact PI and provide the names and affiliations of all other team members and their roles, and a Project Title.

NC TraCS strongly recommends involving a biostatistician in the application development process. For investigators without access to a biostatistician, biostatistical support can be obtained through the NC TraCS Biostatistics Service by completing the "Request a Consult" form. We require teams to contact Biostatistics at least 3 weeks prior to the proposal deadline.

For cancer-related research, please contact the Lineberger Comprehensive Cancer Center for biostatistical support (email LCCC_BIOS@med.unc.edu).

Full applications are submitted using the NC TraCS <u>online pilot submission system</u>. Applications are due by 5:00 p.m. on the posted due date. Proposal sections (except the Scientific Abstract and Impact statement) are uploaded as individual PDF files. The application sections are:

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- 1. **Scientific Abstract:** A summary of the application. (1,500-character limit, ~250 words)
- 2. **Impact:** Summarize the likelihood for your project to exert a sustained, powerful influence on human health (*350-character limit*, ~50 words)
- 3. **Phase 1 Activities Report** (applicable only to Phase 1 awardees): The Phase 1 Activities Report should detail all productive activities undertaken during Phase 1 of ACTeR (e.g., early team building activities, attendance at regularly scheduled meetings, collaborations, workshops specific to team priorities, etc.) (*PDF*, 2-page maximum, including tables and figures. References do not count towards the page limit.)

- 4. **Proposal Narrative:** For all PDFs, use 1.5 line spacing, font no smaller than Arial 11, and 1-inch margins. Suggested page limits for each section of the Proposal Narrative are denoted in parentheses.
 - a. Phase 2 Project Plan: Define the Specific Aims (1-page), Significance/Innovation (1-page), the Approach for the proposed project (4 pages), which includes a plan for proposed preliminary data studies (2 pages). Within these documents, be sure to describe i) the human health issue to be addressed, ii) the project's relevance to translational research, iii) the proposed solution to the human health issue, iv) the overall objectives of your project, v) how the aims require a multidisciplinary approach, and vi) how the research area is new or complementary (but not overlapping or competing) with existing institutes, units, programs or centers on campus. (PDF, 6-page limit, excluding references)
 - b. **Team Overview and Structure:** Describe the team's composition at time of application, identifying all team members, their affiliations, and their roles (e.g., specific expertise, how they will contribute to the project and multidisciplinary mission of the project). Describe how the team has evolved prior to this application or since initiating Phase 1 (*if applicable*). If applying for Direct-to-Phase 2 ACTeR, please provide details on early team building activities, attendance at meetings or workshops specific to the team priorities, prior collaborations, etc. Describe why your assembled team is unique and required for this project, how the project benefits from a multidisciplinary approach, how the diverse expertise of the team will contribute to its success, and outline any plans for identifying future team members (*if applicable*) (*PDF*, 2-page limit).
 - c. **Timeline of Activities:** Outline the proposed activities for the funding period, including timeline and milestones for the Phase 2 support (up to 12 months). Strong timelines will include specific plans for team meetings, application-related milestones, detailed plans for research interactions (e.g., to discuss preliminary data, etc.) and communications with internal and/or external team members, as well as any plans to identify/recruit additional team members, if applicable. (*PDF*, 1-page limit)
 - d. Plans for Future Funding: Provide evidence of topic alignment with *large-scale* extramural support that indicates the project would lead to future funding (e.g., aligns with institute's mission, with cleared concepts, or is aligned with work that has been previously supported), a description of the specific sources of extramural funding that could be targeted, and a timeline for soliciting external support. Describe the overarching plans for future multidisciplinary grant applications that could be pursued in Phase 2 (i.e., not just an R01). In addition, provide a clear plan for long-term team sustainability and/or continued funding beyond the first external grant submitted (e.g., how will the team continue to exist beyond the grant application, plans for programmatic growth), including a timeline and milestones. Describe the potential for the team's research area to turn into a new program or center on campus. (*PDF*, 1-page limit)
- 5. Cited References: (PDF, no page limit)
- 6. **Budget:** Use PHS 398 Form Page 4 (see also Section VII "Budget Guidelines"). The total budget should not exceed \$50,000. (PDF, no page limit)
- 7. **Budget Justification:** Include sufficient detail for reviewers to assess whether appropriate resources have been requested (see section VII "Budget Guidelines" below). (PDF, no page limit)
- 8. **Human and/or Animal Subjects:** This section may be applicable to teams proposing preliminary studies. 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 are 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 are to 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. This section should only be used to describe safety and recruitment issues as described above, and should not include operational details of the study, as these should be addressed in the "Approach" section of the project plan.

NC TraCS ACTeR awards with investigators from multiple institutions will receive assistance from the NC TraCS Regulatory Service in navigating the IRB and IACUC approval process, including making use of reliance agreements where possible. Further, because NC TraCS is funded through a CTSA grant from NIH's National Center for Advancing Translational Sciences (NCATS), all TraCS-funded grants involving human subjects and/or vertebrate animals research are subject to NCATS review and approval prior to TraCS funds being released Therefore, if your proposal is funded and involves human subjects research, TraCS will require additional documentation to send to NCATS. NCATS expects to complete their review in less than 30 days.

In summary, while the ACTeR program requires applicants to outline procedures and protections relevant to human subjects and vertebrate animals in the appropriate attached documents, these outlines do not replace formal NCATS, IRB or IACUC approvals, which must be in place before any ACTeR funds can be released. (PDF, No page limit)

- 9. **Biosketches:** NIH-format. Provide for all team members. (*Combine all biosketches into a single PDF, no page limit*).
- 10. 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. (PDF, No page limit)
- 11. **Resubmission Summary** (if applicable): Resubmission applications should include a summary that details any changes to the original application. Include the names of any NC TraCS advisors consulted for the resubmission. *Applicants are limited to two submissions* (an original submission and one resubmission) per application.

VII. Budget Guidelines

- 1. Phase 2 ACTeR program financial support component provides up to \$50,000 in research funds, to be expended over a funding period not exceeding 12 months. The funding period will not commence until all regulatory approvals (NCATS, IRB, IACUC) have been obtained. If the team is not ready to start within 4 months of notification of support, NC TraCS reserves the right to withdraw the award. The expectation is that all funds will be expended by the end of the project period, at which point any unexpended funds will revert back to NC TraCS.
- 2. One budget for the project should be submitted. In the event that the proposed project involves the need for work done by a non-UNC affiliate, this need should be discussed in advance with the ACTeR Program Staff.
- 3. ACTeR Phase 2 funds may be budgeted for: 1) workshop/symposium costs, 2) associated travel and meals, 3) the use of NC TraCS services, if needed, 4) for the generation of

- preliminary data, and 5) research support (including salary support for research staff) necessary for the successful execution of the proposed project.
- 4. Funds may <u>not</u> be budgeted for 1) salary support for PI, faculty collaborators or faculty consultants, 2) professional education or training, 3) manuscript preparation and submission, 4) registration for or attendance of conferences, 5) costs outside of the U.S. (e.g., foreign individuals, foreign entities) or 6) indirect costs.

VIII. Other Guidelines

- 1. NC TraCS staff, and particularly the Team Science PM, will work closely with funded projects throughout the support period to monitor progress and provide assistance where necessary.
- 2. In addition to regular meetings with the TS PM, teams will meet with ACTeR program staff and provide updates on their activities and progress every 6 months, outlining the progress over the previous reporting period, and plans for the following period. TS Program Staff will review these reports in the context of the Phase 2 plan submitted with the application and any significant deviation, will prompt a meeting between ACTeR and Team Leadership to reevaluate the Phase 2 plan. At the end of the Phase 2 funding period, the Contact PI and Project Manager will prepare a final report, which will enable ACTeR Leadership to evaluate Team progress and future plans.
- 3. Awardee support will culminate in the final submission of a competitive grant application by or around the 12-month deadline.
- 4. NC TraCS expects the PI to report the outcomes achieved due to the award over the lifetime of the work (e.g., subsequent external funding, publications, presentations and patents, and to acknowledge NC TraCS research support where appropriate).
- 5. In the event of a major personnel change, the contact PI should notify NC TraCS TS staff.

IX. Submission Instructions and Review

To ensure that the proposed work is as responsive as possible to the goals of the ACTeR program, applicants are <u>strongly encouraged</u> to first <u>consult with NC TraCS Team Science</u> to discuss their project and application. Staff can advise the applicant on how to best present their proposed plan prior to submission. <u>For "Direct-to-Phase 2" applicants, this consult is mandatory, and applications will not be accepted for Direct-to-Phase 2 support without prior approval.</u>

Applications will be accepted only through the NC TraCS online submission system. Applications are due by 5:00PM (ET) on Tuesday, September 6th, 2022. See the NC TraCS website for ACTeR application due dates. After submitting the application, applicants will receive email confirmation that the application was received. Applications will be reviewed based on their responsiveness to review criteria by a committee comprising TS program staff and content experts drawn from the TraCS Pilot Program study section. Applicants will be notified by email whether their application has been selected to receive support within 2 months of the submission date. Partner institutions may have internal submission approval processes that should be completed prior to the NC TraCS submission deadline.

X. Expected Phase 2 Deliverables

At the end of the Phase 2 support period, <u>all teams are required</u> to submit a detailed report of their Phase 2 activities and expenditures (*2-page maximum for narrative*). This should also include any grant, manuscript, or patent submissions. If the team goals for Phase 2 were not met, the report should also describe why.

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