

## NC TraCS Clinical & Translational Science (CTS) Pilot Awards Request for Applications (RFA)- Deadline: August 13, 2024

### I. Key Dates for Cycle 4

- |  |                                  |
|--|----------------------------------|
| • FOA Release Date                           | April 22, 2024                   |
| • FAQ Sessions                               | <b>TBD</b> – May/June 2024       |
| • *Applicants meet w/CTS Pilot Program staff | April 22 – July 31, 2024         |
| • **Meetings held with TraCS service reps    | April 22 – July 31, 2024         |
| • Application Due Date                       | August 13, 2024                  |
| • Review meeting                             | ~October 1, 2024                 |
| • Anticipated Funding Announcement           | ~Mid-October, 2024               |
| • Regulatory/NCATS Prior Approval Deadline   | February 1 – March 1, 2025       |
| • Anticipated Funding Start                  | November 1, 2024 - April 1, 2025 |
- \* To ensure optimal responsiveness to the FOA, all applicants are **required** to consult with TraCS pilot program staff prior to submitting a proposal (see “IV.A. Consultation with NC TraCS Pilot Program Staff” below).
- \*\* Applicants proposing to use TraCS services are **required** to meet with and obtain approval from service representatives prior to submitting a proposal (see “IV.B. Use of NC TraCS Research Services” below).

### II. Purpose of RFA/Examples of appropriate projects

The North Carolina Translational and Clinical Sciences Institute (NC TraCS) is the academic home of the National Institutes of Health Clinical and Translational Science Award (CTSA) at UNC Chapel Hill.

The CTS award program is intended to support Clinical and Translational Science (CTS), the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational *process*. Whereas translational research focuses on the specific case of a target or disease, **translational science focuses on the general case that can be applied to research on any target or disease.**

Submitted pilot projects must be focused on translational science, i.e., focused on (i) understanding a scientific or operational principle underlying a step of the translational process with the goal of developing generalizable principles to accelerate translational research, or (ii) addressing a broadly encountered roadblock in the process of translational research. Translational **research** projects, i.e., projects focused on crossing a particular step of the translational process for a particular target or disease, are generally not allowed. However, the proposed research may use a specific translational research use case to test a CTS hypothesis, *as long as the CTS relevance of the work is clearly described.*

Types of CTS Pilot activities that may be supported include:

- Development of new research methodologies and/or new technologies/tools/resources that will advance the efficiency and effectiveness of research
- Development of strategies to increase inclusion of understudied populations
- Early-stage development of new therapies/technologies with *generalizable* application to an identified translational roadblock
- Demonstration, in a particular use case(s), that the new methodology or technology advances

translational science by successfully making one or more steps of the translational process more effective or efficient

- Dissemination of effective tools, methods, processes, and training paradigms

### III. Funding & Eligibility

#### A. PI Eligibility

- UNC-CH Principal Investigator applicants should hold a faculty appointment or a non-faculty appointment like “research scientist” or other position typically held by investigators from research institutes and centers who are eligible to apply for investigator-initiated awards and NIH “R” funding. For questions regarding eligibility, contact [mbcassely@med.unc.edu](mailto:mbcassely@med.unc.edu).
- Any eligible investigator from one of the NC TraCS academic partner institutions (UNC-CH, NC A&T or NC State) can serve as the project PI.
- Teams of multiple PIs are encouraged, with the understanding that (i) all PIs will share equal responsibility for the conduct and direction of the project, and (ii) all co-PIs individually fulfill the PI eligibility requirement described above. However, one PI - designated as the “Contact PI” - will serve as the primary contact between the research team and CTS Pilot Program administration.

#### B. PI/Co-I Support

PIs must include between 1-5% salary effort (up to the NIH salary cap). Other faculty (eg, Co-Is) who are significant contributors to the project must also budget effort commensurate with their role in the project, with a minimum of 1% salary effort per contributor. Budget guidelines are detailed in Section VII below.

#### C. Award size, Cost Sharing

TraCS CTS Pilot awards offer \$25,000 - \$50,000 in direct costs. However, please note that:

1. *There is no requirement for matching funds from the investigator and it is not allowable to include matching funds in your budget.*
2. Cost sharing is not allowed. Pilot projects must be supported with CTS Pilot Award funds only, and no other funding sources may be budgeted for these projects.
3. Pilot grant awardees may avail themselves of TraCS services if such assistance will strengthen their projects, although the level of TraCS assistance to be provided *must* be discussed and agreed upon before grant submission (see Section IV.B “Use of NC TraCS Research Services” below). To maximize the value of the pilot award, these TraCS services are available to Pilot grant awardees at significantly reduced rates.

### IV. Pre-Application Consultations with TraCS

#### A. Mandatory consultation with NC TraCS Pilot Program Staff

To ensure that the proposed work is as responsive as possible to the goals of the CTS Pilot Program, prospective applicants are required to meet with Pilot Program staff to discuss their project prior to submission. Staff can advise on how to best present the translational science problem to be addressed, the general methodological approach, and whether any TraCS services might be useful. Applicants can request a Pilot Program consult through the “Submit a Request” link on the [TraCS home page](#).

#### B. Use of NC TraCS Research Services

If the applicant proposes to use [TraCS services](#), for example, Biostatistics or Recruitment & Retention, **the applicant must meet with service representatives and obtain a written estimate and approval**

**from each relevant service prior to submission.** This should be done after the initial meeting with the Pilot Program staff.

While TraCS services are available to pilot awardees at reduced cost, this assistance is not unlimited and is dependent on service capacity. The extent of assistance available to the applicant must be determined and agreed upon prior to submission, and this must be described in the grant application (see Section V.9 below) using a [TraCS Service Agreement form](#), and itemized in the grant Budget and Budget Justification. Please consult with service representatives sufficiently early so that the extent of TraCS assistance can be discussed and agreed upon before the submission deadline. Complete a form for each TraCS service you need, save the document(s) as PDFs and combine them into a single PDF to be uploaded with the application.

We strongly recommend that applicants initiate discussions with TraCS services **at least 3 weeks** before the submission deadline, to ensure that the TraCS service requested can be reviewed and agreed upon, and the requisite Service Agreement completed, before grant submission.

*Applications that do not include the requisite TraCS Service Agreement(s), describing the TraCS assistance to be provided, and approved by appropriate service representatives, will be considered incomplete and will not be reviewed.*

Applicants can request a service consult through the “Submit a Request” link on the [TraCS home page](#).

## V. Proposal Submission

Applications are submitted using the NC TraCS [online pilot submission system](#). Applications are due by 5:00 p.m. on Tuesday **August 13, 2024**. Applicants will be notified by email around **mid-October 2024** whether or not their application has been selected for funding. Proposal sections (except the Abstract and Impact Statement) are uploaded as individual PDF files. The application sections are:

- 1) **Scientific Abstract:** Summary of the proposal (*online 1500 character limit, ~250 words*).
- 2) **Impact Statement:** Briefly describe the likelihood for your project to exert a sustained, powerful influence on the research field(s) involved (*online 300 character limit, ~50 words*).
- 3) **Discussion of the CTS problem to be addressed:** This section of the application should clearly:
  - Outline the CTS problem the work will address and the overarching hypothesis that underlies the proposed CTS project
  - Explain how addressing this problem will have broad applicability
  - Explain the CTS relevance of any Clinical and Translational Research (CTR) use case proposed (*if applicable*)
  - Detail how if the project is successful the results or lessons learned will impact other realms of translational research – please provide specific examples if possible (*PDF, 2-page limit, 1.5 line spacing, font no smaller than Arial 11, and 0.5-inch margins all round*).
- 4) **Research Team:** Briefly describe the research team, highlighting the skills and experience that speak to the feasibility of the proposed work and what specific role each will play in the project (*PDF, 1-page limit, 1.5 line spacing, font no smaller than Arial 11, and 0.5-inch margins all round*).
- 5) **Response to Previous Review:** If you previously submitted the application to the TraCS CTS Pilot Program, outline how the revised application addresses reviewer critiques. (*PDF, 2-page limit, 1.5 line spacing, font no smaller than Arial 11 and 0.5-inch margins all round*).
- 6) **Research Plan:** The Research Plan should include Specific Aims, Innovation, and Approach. Include, where applicable, clear evidence of how the proposal meets the review criteria and how the project will be generalizable. (*PDF, 5-page limit, including tables and figures. 1.5 line spacing, font no*

*smaller than Arial 11, and 0.5-inch margins all round. Cited references do not count towards the 5-page limit.)*

- 7) **Cited References:** (PDF, **no page limit**)
- 8) **Plan for Future Funding:** Describe in as much specific detail as possible how the data generated during the pilot project will support subsequent application(s) for external grant support (PDF, **1-page limit**, 1.5 line spacing, font no smaller than Arial 11, and 0.5-inch margins all round).
- 9) **Use of TraCS services (if applicable).** A [TraCS Service Agreement form](#) be filled out for each TraCS service to be utilized. Those forms should then be converted to PDF, combined and uploaded into the application.
- 10) **Timeline:** Outline the proposed activities for the funding period, including timeline and milestones (up to 12 months). It is important that the proposed work (i) must be ready to start by April 1<sup>st</sup>, 2025, and (ii) must be completed within the 1-year funding period, as no-cost extensions are not permitted. Therefore, the timeline should address plans for (i) obtaining institutional (IACUC/IRB) and NCATS approvals, and (ii) spending grant funds within the funding period. Include specific factors (eg, submitted/approved IACUC/IRB protocols, including protocol ID numbers if available, availability of an established study cohort, etc) that speak to the feasibility of commencing the study by April 1<sup>st</sup>, 2025 and completing the work within 1 year (PDF, **2-page limit**, including graphics, 1.5 line spacing, font no smaller than Arial 11, and 0.5-inch margins all round).
- 11) **Discussion of the health equity ramifications of the proposed work.** One of the goals of the CTSA Program is to “Create, provide, and disseminate innovative research programs and partnerships across institutions and communities to address health disparities and deliver the benefits of translational science to all.” **If applicable**, describe how the proposed project will ensure that a broader population of patients will be served by the health care system, and/or benefit the health of patients that are underserved currently. (PDF, **1-page limit**, 1.5 line spacing, font no smaller than Arial 11, and 0.5-inch margins all round).

**Note:** Two publications discussing diversity, equity, and inclusion (DEI) in clinical and translational research are useful references when preparing this section:

Boulware *et al* (2022) Diversity, equity and inclusion actions from the NCATS Clinical and Translational Science awarded programs. *Nature Medicine*. DOI: <https://doi.org/10.1038/s41591-022-01863-7>

Castillo and Harris (2021) Directing Research Toward Health Equity: a Health Equity Research Impact Assessment. *J Gen Intern Med*. DOI: <https://doi.org/10.1007/s11606-021-06789-3>

- 12) **Budget:** Use [PHS 398 Form Page 4](#) (see also Section VII “Budget Guidelines” below). The total direct project budget should not exceed \$50,000.
- 13) **Budget Justification:** Include sufficient detail for reviewers to assess whether appropriate resources, including TraCS services, have been requested. For projects involving more than one institution, institution-specific budgets and budget justifications must be included, combined into a single PDF (PDF, **no page limit**, 1.5 line spacing, font no smaller than Arial 11, and 0.5-inch margins all round).
- 14) **Protection of Human and/or Animal Subjects:** Although Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) approval is not required prior to submission; briefly describe any human or animal subject issues. However, for the purposes of project review, please describe any human- or animal subject issues. If human subjects will be involved in the research, provide a description of their involvement and characteristics, specific risks to subjects who participate, and protection against those risks. Describe the sources of materials that will be

obtained from human subjects as part of their study participation. *Do not use this space to include experimental detail that should be described in the research plan.* Note that no funds will be disbursed until required NCATS, IRB or IACUC approval is received (*See Section VIII below*) (*PDF, No page limit, 1.5 line spacing, font no smaller than Arial 11, and 0.5-inch margins all round*).

- 15) **Biosketches:** [NIH-format](#). Provide for team members at the PI or Co-I level only. (*Combined into a single PDF, no page limit*).
- 16) **Letter(s) if applicable:** Letters may be included if (i) they outline work that will be done for the project by a Consultant (**do not** include letters from co-PIs, co-investigators or NC TraCS collaborators) or (ii) clearly state a commitment of resources required for the project's success.
- 17) **External Funding Agency Review (if applicable):** If the proposal references a prior review from an external funding agency (eg., NIH), include the agency reviewer comments (*PDF, no page limit*). If the purpose of the pilot project is to respond to specific reviewer concerns, the relevant section of the review should be indicated by highlighting or other means.

## VI. Review Criteria

It is the applicant's responsibility to present the proposal in a clear and logical fashion, to make a convincing case for the significance of the work and to present the proposed methods in sufficient detail so that an adequate evaluation of the proposal can be made. All applicants – funded or not – will receive written feedback from the reviewers.

**The following criteria will be considered during review of the proposal:**

- 1) CTS Significance of the translational work – its likelihood to **advance clinical & translational science methods and processes**.
- 2) Novelty/Innovation
- 3) Multidisciplinary team in place that is integral to the conduct of the research
- 4) Diversity, equity and inclusiveness (DEI) relevance of proposed work
- 5) Potential for the project to lead to future external funding or to a commercialization opportunity
- 6) Soundness of the proposed methods
- 7) Feasibility of (i) starting the project April 1<sup>st</sup>, 2025, and (ii) accomplishing the stated project goals within the one-year project period
- 8) Level of community engagement (if applicable)
- 9) Utilization of services and resources of NC TraCS

## VII. Budget Guidelines

- 1) NC TraCS CTS pilot grant budgets cover expenditures for a 12-month period. The funding period for this cycle will commence as soon after funding notification (~mid-October) as possible, but **no later than April 1, 2025**, so it is important that applicable regulatory (NCATS/IRB/ IACUC) documentation is received by NC TraCS and that the PI indicates that everything is in place for the project to begin by that date. The expectation is that all funds will be expended by the end of the grant period, as no-cost extensions are not permitted.
- 2) Per NCATS rules for CTS Pilot Awards, voluntary cost share is not permitted. The proposed work must be supported *solely* by the CTS pilot award. Pilot Program will work with awardees to ensure that their project budget is in accordance with NCATS guidelines.

- 3) Pilot grant funds **must** be budgeted for **(i)** PI, co-PI(s), other significant contributor salary support, **(ii)** research support personnel, including RAs/GRAs, technicians and other research staff, **(iii)** travel necessary to perform the research, **(iv)** equipment, research supplies and core lab costs, or **(v)** other purposes deemed necessary for the successful execution of the proposed project.
- 4) **All** personnel effort **must** be included in the budget, and no personnel effort, including faculty, may be listed as “in kind”. Include at least 1% per PI, with no more than a total of 5% salary effort across multiple PIs (at the NIH salary cap). Other faculty (eg, Co-Is) who are significant contributors to the project may also budget effort of up to 5% each (at the NIH salary cap). These % FTE guidelines apply only to members of the project leadership (PIs and co-Is), but do *not* apply to non-faculty technical staff or RAs or GRAs, who should be budgeted according with their actual % FTE.
- 5) Where the proposed work involves investigators from more than one institution, separate institution-specific budgets and budget justifications should be included. While an equitable distribution of funds between institutions is encouraged, the proposed work will determine the optimal distribution of effort and funds between team members and institutions, and unequal distribution of funds between institutions is acceptable if adequately justified. Indirect costs will be paid based on grant funds spent at NC A&T or NC State, but these are additional to the award and should **not** be itemized in the Budget.
- 6) The following items may **not** be budgeted for in a Pilot grant application: **(i)** office supplies or communication costs, **(ii)** meals (except for focus groups), **(iii)** travel, including to conferences, except as required to collect data, **(iv)** conference registration or attendance, **(v)** professional education or training, **(vi)** manuscript preparation and submission, or **(vii)** costs outside of the U.S. (e.g., foreign individuals, foreign entities).

## VIII. Other Guidelines

- 1) We anticipate completing review and notifying successful applicants by **Mid-October, 2024**. The grant funding period will commence as soon as possible after notification and no later than **April 1, 2025**, and is strictly limited to 1 year. It is very important, therefore, that teams be ready to start their work on April 1, 2025. Prior to receiving funds, research involving human subjects and/or vertebrate animals must have appropriate approvals from the UNC-CH IRB. *Applicants are strongly encouraged to start preparing IRB paperwork as soon as possible.* 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 prior to funds being released. Human subjects 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 the requisite certification of training in the protection of human subjects prior to the start of the grant period.
- 2) NC TraCS is funded through a CTSA grant from the National Center for Advancing Translational Sciences (NCATS). NCATS reviews and approves all NC TraCS pilot grants involving human and animal subjects research prior to funds being released. If a funded application involves human or animal subjects research, NC TraCS will require additional documentation to send to NCATS. *NCATS review can only commence after institutional approvals (IRB/IACUC) have been received.* NCATS expects to complete their review in less than 30 days, and grants determined to be “minimal risk” are usually approved within a few days.
- 3) NC TraCS staff will work closely with funded projects throughout the grant period to monitor progress and provide assistance. In the period between notification of application success and commencement of the funding period, Pilot Program staff will work with awardees to assist with regulatory documentation and to liaise with other TraCS services to ensure that required services

will be available to the research team. We envisage an arrangement closer to a cooperative agreement than a standard research grant, so that Pilot Program staff and Navigators will work closely with investigators, meeting regularly to discuss progress, troubleshoot unforeseen obstacles and plan future research- and funding directions. A 6-month interim progress report and a final progress report will be required. NC TraCS expects the project PI to report over the lifetime of the work the outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations and patents.

If an awardee leaves their position, they should contact NC TraCS **prior** to departure to discuss next steps.

## CTS Pilot Frequently Asked Questions (FAQs)

### **1. I submitted an application to the CTS Pilot program, but I wasn't funded. Can I resubmit?**

Yes, you can resubmit one time (two applications total). We recommend that you meet with Program staff to discuss how best to address the reviewers' critiques and include a 2-page "Response to Previous Review" document in your application, outlining how you have updated your project and grant application in response to reviewer input. We *strongly* suggest that you don't simply respond in the "Response" doc and leave the Research Plan unchanged – update the entire application as appropriate. Applicants can request a Pilot Program consult through the "Submit a Request" link on the [TraCS home page](#).

### **2. Are investigators/institutions from outside the TraCS partnership allowed?**

Yes. Team members from outside institutions are allowed. If these investigators are at the PI/Co-I level, their biosketch(es) should be included in the application packet. *However*, no subcontract will be issued to institutions other than TraCS partners (UNC-CH, NC A&T, NC State).

### **3. Do I have to include TraCS services in my budget?**

Awardees may incorporate TraCS service assistance into their projects. The cost of these services should be included in the grant budget. Remember that the nature and extent of assistance to be provided *must* be discussed with the appropriate TraCS service rep(s) and agreed upon prior to grant submission. This agreement must be documented in one or more [TraCS Service Agreement forms](#) included in the grant application. Pilot Program staff can assist applicants in navigating this process.

### **4. What about international partners or research?**

Pilot funds cannot be used to support research outside of the US. However, data previously generated through international research can be used in pilot projects, as long as data analysis etc is conducted domestically.

### **5. What can awardees expect in terms of TraCS input and assistance post-award?**

TraCS envisages these awards as more like cooperative agreements than simple grants, so that TraCS will provide ongoing input into the conduct and direction of the work. This will involve the convening of a TraCS support team, comprising a TraCS Navigator, faculty content experts and potentially TraCS service reps, who will meet regularly with the research team to evaluate progress, identify roadblocks and discuss workarounds, and discuss next steps, such as research directions and potential funding opportunities.

### **6. Can any funds be spent outside the TraCS partnership institutions?**

Yes, with adequate justification. While we encourage awardees to spend grant funds on "in-house" university services such as sequencing cores, if a specific service is unavailable, an appropriate outside service can be paid for using grant funds, as long as this is addressed in the Budget Justification.

### **7. Does the number of institutions involved in the project affect the total award amount?**

No. Pilot award budgets will be between \$25k and \$50k, regardless of the number of institutions involved, and the total grant amount will be distributed between institutions, based on the scope of work proposed at each institution. While multi-institution applications must include individual institution-specific budgets and budget justifications, the sum of these budgets will not exceed the \$50k grant limit.

### **8. Can CTS pilot grant funds be used to pay consultants?**

Yes, as long as the necessity of using a consultant and a description of the skills/services they provide are described in the Budget Justification and detailed in a Consultant's Letter. Since PIs and Co-Is can



only receive limited salary support (see 9 below), a consultant cannot also serve as a PI/Co-I, and *vice versa*.

**9. Can CTS pilot grant funds be used to support PI or Co-I salary?**

PI and co-PI efforts **must** be budgeted at between 1-5% effort each (at NIH salary cap). No personnel, including faculty, may be listed as “in kind”. Other faculty who are significant contributors (eg, Co-Is) to the project must also budget effort (at least 1% effort each, at the NIH salary cap). Salary support can also be budgeted for research support personnel, including GRAs, technicians and other research staff.

**10. Are there any limitations to equipment purchases?**

Equipment can be budgeted if its necessity for the proposed work is justified in the Budget Justification. Plans to purchase a large piece of equipment or to spend a significant portion of the budget on equipment should be discussed with Pilot Program staff prior to submission.

**11. Should I budget for indirect costs?**

Indirect costs will be paid based on grant funds spent at NC A&T or NC State, but these are additional to the award and should **not** be itemized in the Budget.

**12. When should I start preparing my IACUC/IRB paperwork?**

We recommend that you start preparing your regulatory paperwork as early as possible – preferably as soon as you receive a funding notification. Because these grants use NIH funds, they require NCATS regulatory approval, which can only be applied for *after* institutional (IRB/IACUC) approval has been received. This extra step can add up to 4-5 weeks to the regulatory approval process. We recommend that applicants endeavor to have their institutional approvals in place as soon as possible after award notification and no later than mid- to late February.

**13. Two pages are allowed to discuss the CTS problem that my proposed work will address and to describe how my work fits into this CTS context. Can I use this space for other purposes (eg, my Research Plan)?**

No – your Research Plan must be described within the five-page Research Plan doc. Even if you don’t use all of the available two pages to discuss the CTS relevance of your proposed work, this space should **not** be used for any other purpose. Reviewers will not be obliged to consider any extraneous research detail included in this doc.