NC TraCS Clinical & Translational Science (CTS) Pilot Awards
Request for Applications (RFA)
Deadline: July 14, 2026

Key Dates	
• FOA Release	March 2, 2026
• FAQ Session	April 7, April 13
• *Applicants meet w/ CTS Pilot Program Staff	March - June 2026
• **Meetings w/ TraCS service reps	March - June 2026
• **Application Due Date**	**July 14, 2026**
• Notification of Proposal Selection	October 2026
• Regulatory/NCATS Prior Approval Deadline	February 2027
• ***Anticipated Funding/Project Start	April 1, 2027 (earliest)

* To ensure optimal responsiveness to the RFA, all applicants are ***required*** to consult with TraCS Pilot Program Staff prior to submitting a proposal (see ***III.A. Mandatory 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 ***III.B. Use of NC TraCS Research Services*** below).

*** The earliest anticipated project start date is April 1, 2027.

I. Purpose of RFA and Examples of 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 Pilot 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 generalizable principles that can be applied to research on any target or disease.***

Submitted pilot projects must be focused on translational science; that is, they must be focused on either (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 translational research process. Proposals that focus primarily on advancing a single target-, disease-, or intervention-specific translational research project ***without clear generalizable CTS lessons*** are not responsive. However, the proposed research may use a specific translational research use case to test a CTS hypothesis, provided the application clearly articulates (a) the broader CTS problem and (b) how the lessons learned will generalize beyond the use case.

Types of CTS Pilot activities that may be supported include (this list is not exhaustive):

- Development of new research methodologies and/or new technologies, tools, or resources that advance the efficiency and effectiveness of research

- Strategies to improve recruitment of patients into clinical trials

- Early-stage development of new therapies or technologies with *generalizable* application to an identified translational roadblock

- Demonstration, within a particular use case(s), that a new methodology or technology advances translational science by making one or more steps of the translational process more effective or efficient

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

Projects should address broadly encountered barriers (e.g., translational roadblocks), such as inefficient recruitment and retention workflows, lack of scalable engagement approaches, bottlenecks in data harmonization and reuse, limited generalizable methods to improve trial feasibility, tools and processes that shorten time-to-study start while maintaining rigor and compliance, and technological advances with applicability beyond a specific use case.

Past funded projects: Applicants may find it helpful to review brief descriptions of past CTS Pilot Program Awardees.

II. Funding & Eligibility

A. PI/Co-I Eligibility

- ***Principal Investigator (PI) applicants*** must hold a faculty appointment or an independent, permanent research appointment (e.g., research scientist) at one of the NC TraCS academic partner institutions (UNC-CH, ***N.C. A&T***, or ***NC State***) and be eligible to apply for investigator-initiated NIH "R" funding. Individuals in non-faculty roles may require institutional eligibility confirmation or waiver documentation prior to application submission.

- ***Multiple-PI (MPI) teams are permitted.*** In MPI applications, all PIs share equal responsibility for the conduct and direction of the project, and each co-PI must independently meet the PI eligibility requirements described above. One PI must be designated as the ***Contact PI***, who will serve as the primary administrative contact between the research team and the CTS Pilot Program.

- ***Co-Investigators (Co-Is)*** must (i) hold an appointment at one of the NC TraCS partner institutions and (ii) be at the postdoctoral level or higher (e.g., research associate, permanent research staff, or faculty).

- All other project team members must be employed by an NC TraCS academic partner institution (UNC-CH, ***N.C. A&T***, or ***NC State***). Collaborators outside of the partner institutions are not allowed, except for commercial entities and consultants (see ***VI. Budget Guidelines***).

For questions regarding eligibility, contact Kaitlin Zalcikova at kaitlin_zalcikova@med.unc.edu.

B. PI/Co-I Support

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

C. Award Size and Cost Sharing

NC TraCS CTS Pilot Awards provide $25,000–$50,000 in direct costs. Applicants are strongly encouraged to develop project budgets in consultation with the CTS Pilot Program and to budget up to the $50,000 direct cost cap where project needs justify it.

Please also note:

- **Cost sharing is *not* allowed.** Pilot projects must be supported **solely** with CTS Pilot Award funds. No other funding sources may be included in the project budget (see **VI. Budget Guidelines** for additional details).

- Pilot awardees may utilize NC TraCS research services if such support will strengthen the proposed project. The scope and level of TraCS service support **must** be discussed and agreed upon prior to application submission (see **III.B Use of NC TraCS Research Services**). To maximize the value of the pilot award, these services are available to awardees at significantly reduced rates.

III. Pre-Application Consultations with TraCS

A. Mandatory Consultation with NC TraCS Pilot Program Staff

To ensure that proposed projects are responsive to the goals of the CTS Pilot Program, prospective applicants are **required** to meet with Pilot Program staff prior to application submission. During this consultation, staff can advise on how best to frame the translational science problem to be addressed, the general methodological approach, and whether NC TraCS research services may strengthen the project.

Applicants may request a Pilot Program consultation through the "Start a Request" link on the TraCS home page. Select "CTS Pilot Program" from the "TraCS Programs" dropdown menu.

B. Use of NC TraCS Research Services

If the applicant proposes to use NC TraCS research services (e.g., Biostatistics, Recruitment & Retention), *the applicant **must** meet with the relevant service representative(s) ideally following the initial Pilot Program consultation and obtain: (1) a written cost estimate and (2) confirmation of service availability and approval. Both are required prior to application submission*.

- *Applicants are **strongly encouraged** to consult with TraCS service representatives **as early as possible** (at least three weeks prior to submission) to allow sufficient time for review, approval, and completion of the required TraCS Service Agreement Form. Because TraCS services are capacity-dependent, the scope and level of support must be agreed upon in advance and documented in the application (see **Section IV.10** below).*

- To maximize the value of the pilot award, TraCS will provide a *1:1 cost match* to offset approved TraCS service expenses. **This match applies only to TraCS services and to no other budget item**, and results in an effective 50% reduction in the hourly service rate. All requested TraCS service costs must be itemized in the Budget and Budget Justification.

- *Applications that do not include the required, approved TraCS Service Agreement(s), describing the TraCS assistance to be provided will be considered incomplete and will **not** be reviewed.*

Applicants may request a service consultation through the "Start a Request" link on the TraCS home page by selecting the relevant TraCS program from the program dropdown menu in the request form.

IV. Proposal Submission

Applications are submitted using the NC TraCS online pilot submission system. Applications are due by **5:00 p.m. on Tuesday July 14, 2026**. Applicants will be notified by email in **October 2026** whether their application has been selected for funding.

Proposal sections (except the Abstract and Impact Statement) must be uploaded as individual PDF files.

The required application components are:

1) **Scientific Abstract:** Summary of the proposal (online entry; 1,200-character limit, including spaces).

2) **Impact Statement:** Briefly describe the likelihood for your project to exert a sustained, powerful influence on the research field(s) involved (online entry; 250-character limit, including spaces).

3) **Discussion of the CTS problem to be addressed:**

   - Outline the CTS problem the work will address and the overarching hypothesis underlying the proposed CTS project

   - Explain how addressing this problem will have broad applicability

   - Explain the relevance of any proposed Clinical and Translational Research (CTR) use case to the broader CTS problem (**if applicable**)

   - Detail how, if the project is successful, the results or lessons learned will impact other areas of translational research (**provide specific examples where possible**)

   (PDF; **2-page limit**, 1.5 line spacing, Arial ≥11 pt, 0.5-inch margins)

4) **Research Team:** Briefly describe the research team, highlighting the skills and experience that supports feasibility and the specific role each member will play (PDF; **1-page limit**, 1.5 line spacing, Arial ≥11 pt, 0.5-inch margins).

5) **Response to Previous Review (if applicable):** If previously submitted to the TraCS CTS Pilot Program, describe how the revised application addresses prior reviewer critiques (PDF; **2-page limit**, 1.5 line spacing, Arial ≥11 pt, 0.5-inch margins).

6) **Research Plan:** The Research Plan **must** include **Specific Aims**, **Innovation**, and **Approach**. Where applicable, provide clear evidence of how the proposal meets review criteria and how the work will produce generalizable translational science knowledge (PDF; **5-page limit** including tables/figures, references excluded, 1.5 line spacing, Arial ≥11 pt, 0.5-inch margins).

7) **Data Analysis Plan (required):** All applications must include a Data Analysis Plan describing the proposed analytical approach, key assumptions, feasibility, and interpretation framework appropriate to the project's design and data types. Plans should address, as applicable, quantitative analyses, hypothesis testing, sample size justification, power calculations, qualitative analyses, or complex data modeling. If NC TraCS Biostatistics and/or Qualitative Research Service (QRS) will be used, the Data Analysis Plan must align with the approved TraCS Service Agreement(s). Applications that do not include a Data Analysis Plan will be considered incomplete and will not be reviewed (PDF; **1-page limit**; 1.5 line spacing; Arial ≥11 pt; 0.5-inch margins).

8) **Cited References:** (PDF; **no page limit**).

9) **Plans for Future Funding:** Describe in as much specific detail as possible how the data generated during the pilot project will support subsequent external funding applications (PDF; *1-page limit*, 1.5 line spacing, Arial ≥11 pt, 0.5-inch margins).

10) **Use of NC TraCS Services (if applicable):** A TraCS Service Agreement Form must be completed for each TraCS service utilized. (All forms combined into a single PDF).

11) **Timeline:** Outline proposed activities for the funding period (up to 12 months), including milestones. Applicants should describe readiness to initiate the project as early as April 1, 2027, and plans to complete the scope within the allowable funding period. Because *no-cost extensions are not permitted*, applicants must (i) address plans for obtaining institutional (IACUC/IRB) and NCATS approvals in preparation for an April 1, 2027 project start and (ii) spending grant funds within the one-year funding period. Include specific factors (e.g., 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 April 1, 2027 and completing the work within one year (PDF; *2-page limit* including graphics, 1.5 line spacing, Arial ≥11 pt, 0.5-inch margins).

12) **Budget:** Use PHS 398 Form Page 4 (see also *VI. Budget Guidelines*). Total direct costs may not exceed $50,000. The project budget period is April 1, 2027 to March 31, 2028. Ensure there is a 50% cost reduction applied to the standard TraCS service rates when preparing your budget.

13) **Budget Justification:** Provide sufficient detail for reviewers to assess whether appropriate resources, including TraCS services, have been requested. Multi-institution projects must include institution-specific budgets and justifications combined into a single PDF (PDF; *no page limit*, 1.5 line spacing, Arial ≥11 pt, 0.5-inch margins).

14) **Protection of Human and/or Animal Subjects:** Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) approval *is not required prior to submission*; however, applicants must briefly describe any human or animal subject involvement. If human subjects, samples, or data are involved, describe: (i) subject involvement and characteristics, (ii) specific risks to participants, (iii) protections against those risks, and (iv) sources of materials that will be obtained from human subjects as part of their study participation. *Do not use this section for experimental detail better suited to the Research Plan*. No funds will be released until required NCATS, IRB, and/or IACUC approvals are obtained (see *VII. Regulatory and Reporting Information*) (PDF; *no page limit*, 1.5 line spacing, Arial ≥11 pt, 0.5-inch margins).

15) **Biosketches:** Applicants must use the New NIH Biosketch Common Form. Provide biosketches for anticipated key personnel. (Combined into a single PDF, *no page limit*). Note that PDFs need to be flattened to be merged (see eRA Commons Instructions).

16) **Letters (if applicable):** Letters may be included if they: (i) describe work to be performed by a consultant (*do not* include letters from co-PIs, co-Is, or NC TraCS collaborators), or (ii) confirm a commitment of resources required for project success.

17) **External Funding Agency Review (If applicable):** If referencing prior review by an external sponsor (e.g., NIH), include reviewer comments. If the pilot project is intended to address specific critiques, highlight the relevant sections (PDF; *no page limit*).

V. Review Criteria

It is the applicant's responsibility to present the proposal in a clear and logical manner, to make a compelling case for the significance of the proposed work, and to describe the methods in sufficient

detail to allow for a thorough evaluation. All applicants – whether funded or not – will receive written feedback from reviewers.

The following criteria will be considered:

1) **CTS Significance:** The extent to which the proposed work is likely to ***advance clinical and translational science methods, processes, or principles.***

2) **Novelty and Innovation:** The degree to which the project introduces new or improved concepts, approaches, tools, or frameworks relevant to translational science.

3) **Multidisciplinary Team:** The extent to which the investigative team is appropriately multidisciplinary and integral to the successful conduct of the proposed research.

4) **Future Funding or Commercialization Potential:** The likelihood that the project will lead to subsequent external funding and/or commercialization opportunities.

5) **Scientific and Methodological Rigor:** The soundness, appropriateness, and rigor of the proposed methods and analytical approach.

6) **Feasibility:** The likelihood that the project can (i) begin on or around ***April 1, 2027***, and (ii) achieve its stated objectives within the one-year project period.

7) **Community Engagement (if applicable):** The appropriateness and quality of community engagement strategies relevant to the proposed work.

VI. Budget Guidelines

- NC TraCS CTS Pilot Award budgets support expenditures over a 12-month project period. For this funding cycle, the project period will begin no earlier than ***April 1, 2027***. Accordingly, all required regulatory documentation (NCATS, IRB, and/or IACUC, as applicable) must be received by NC TraCS prior to fund release, and the PI must confirm readiness to initiate the project by that date. All funds are expected to be expended within the approved project period. ***No-cost extensions are not permitted***.

- In accordance with NCATS policy for CTS Pilot Awards, ***voluntary cost sharing is not permitted***. The proposed work much be supported ***solely*** by CTS Pilot Award funds. Pilot Program staff will work with awardees to ensure that project budgets conform to NCATS guidelines.

- For projects involving investigators across multiple partner institutions, separate institution-specific budgets and budget justifications must be prepared and combined into a single submission. While equitable distribution of funds across institutions is encouraged, the proposed scope of work should drive budget allocation. Unequal distribution is allowable if well justified. Indirect costs (F&A) will be provided on funds expended at ***N.C. A&T*** or ***NC State*** in accordance with institutional agreements. These indirect costs will be provided ***in addition*** to the pilot award and should ***not*** be itemized in the project budget.

- The following table summarizes mandatory, allowable, and non-allowable budget items:

Mandatory Costs
- ***All*** personnel effort ***must*** be budgeted. No personnel effort, including faculty, may be listed as "in-kind." This includes: o PIs, Co-PIs, and other significant contributors (e.g., Co-Is) should include between 1-5% salary effort (at the NIH salary cap). These effort guidelines apply to project leadership (PIs and Co-Is) only and do *not* apply to non-faculty research personnel (e.g.,

technicians, RAs, GRAs), whose effort should reflect the level required to complete the work.

    o   Research support personnel (e.g., research assistants, technicians, research staff)

- Equipment, research supplies, and core laboratory costs
- Other project expenses necessary for successful completion of the proposed work
- Approved NC TraCS research services, at 50% the standard hourly rate (see **Section III.B**)

Allowable Costs
• CTS Pilot funds may be expended **only**: (i) at participating partner institutions (UNC-CH, N.C. A&T, NC State), or (ii) with external commercial entities providing services otherwise unavailable within partner institutions. This may include **Consultants** providing specialized services (e.g., media production). Private individuals serving as consultants must be registered as a UNC-approved vendor or "Independent Contractor." Researchers from outside institutions may _not_ serve as consultants. Applications proposing consultant costs must include adequate justification in the Budget Justification.   • Travel **_directly related to data collection for the CTS project_**   • Manuscript preparation, submission, or publication costs **_directly related to the CTS project_**

Non-Allowable Costs
• Salary support or other expenses for personnel at non-TraCS partner institutions   • Office supplies or general communication costs   • Meals or food **_even if related to focus groups or data collection_**   • Travel **_unrelated to data collection_**   • Conference travel, registration, or attendance (in-person or virtual)   • Professional training or educational coursework   • Costs incurred outside the United States (e.g., foreign individuals or foreign entities)

VII. Regulatory and Reporting Information

1) Please note that NC TraCS Pilot Awards are funded through a Clinical and Translational Science Award (CTSA) from the National Center for Advancing Translational Sciences (NCATS) and therefore carry the same regulatory and reporting requirements as other NIH-funded awards.

2) We anticipate completing application review and notifying successful applicants by **October 2026.** The project funding period will begin no earlier than **April 1, 2027,** and is strictly limited to one year. It is therefore critical that funded teams are prepared to initiate project activities by this date.

Prior to the release of funds, research involving human subjects and/or vertebrate animals must receive appropriate institutional approvals. Regulatory approvals must be obtained through the UNC-Chapel Hill, NC State, or N.C. A&T Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC), respective of the Contact PIs primary appointment. **_Applicants are strongly encouraged to begin preparing IRB submissions as early as possible, as a new pilot project specific IRB/IACUC will be required for the pilot project even_**

if there is an existing IRB/IACUC in place. Either: (i) an IRB/IACUC approval letter, or (ii) an IRB determination letter (e.g., " Determination that Research or Research-Like Activity does not require IRB Approval") must be submitted to NC TraCS before funds can be released.

All human subjects research must be conducted in accordance with the University's Federalwide Assurance and HIPAA requirements. In addition, all personnel listed on the project budget who are engaged in human subjects research must complete required training in the protection of human subjects prior to the start of the award period.

3) NCATS reviews and approves all NC TraCS pilot projects involving human subjects and/or vertebrate animal research prior to the release of funds. If a funded project includes such research, NC TraCS will request additional regulatory documentation for submission to NCATS.

   NCATS review can only begin after institutional approvals (IRB and/or IACUC) have been obtained. NCATS review may be subject to a 30-day prior approval period; however, projects determined to be "minimal risk" are often approved more quickly.

   NC TraCS staff will work closely with funded teams throughout the award period to monitor progress and provide support. Between notice of award and the start of the funding period, Pilot Program staff will assist awardees with regulatory documentation and coordinate with TraCS research service units to ensure service availability.

   The Pilot Program operates in a manner more closely aligned with a ***cooperative agreement*** than a traditional research grant. Program staff and Navigators will engage regularly with investigators to review progress, troubleshoot challenges, and plan future research and funding trajectories.

   A 6-month interim and final progress report will be required. NC TraCS also expects the PI/Contact PI to report long-term outcomes resulting from pilot support, including subsequent external funding, publications, presentations, and intellectual property.

4) If the project involves human subjects, samples, or data, inclusion enrollment reporting is required. Unless the study is determined to qualify for IRB Exempt Category 4, investigators must report participant race, ethnicity, sex, and age at regular intervals in accordance with NIH policy. This is required on a per participant level under the TraCS grant. Here are the specific instructions for the participant level data collection requirement and accepted values.

5) If an awardee anticipates leaving their institutional position prior to the end of the award period, they must contact NC TraCS in advance to discuss project transition, relinquishment, or closeout procedures.

VIII. Tips for Writing an Effective Proposal

1) Remember that reviewers, while scientifically literate, are unlikely to be experts in your specific field. When describing the technical details of your proposed work, avoid jargon and "inside" references. It is critical that reviewers understand what you propose to do, but it is your responsibility to present the narrative at a level accessible to a non-expert audience.

2) This grant mechanism focuses on ***Clinical and Translational Science (CTS)*** – specifically, identifying broadly encountered roadblocks and barriers to the conduct of translational research so that addressing these barriers will accelerate a range of translational research endeavors. Therefore, it is essential to clearly define the broader translational barrier your project addresses. This distinction is central to the review process. If you propose to use a more focused translational research use case to address a translational science question, ensure that these

two components – the broader translational science problem and the narrower translational research application – are clearly distinguished, while also explaining how the use case will inform or resolve the broader question.

3) Consider what will happen to your research after the CTS Pilot funding period ends. What are your plans for future research directions and external funding?

4) When describing your research team, ensure that the specific roles of team members are clearly defined and that the collective expertise is appropriate and sufficient to support the proposed work.

IX. CTS Pilot Frequently Asked Questions (FAQs)

1. I submitted an application to the CTS Pilot Program but was not funded. Can I resubmit?

Yes. Applicants may resubmit one time (two submissions total). We recommend meeting with Pilot Program staff to discuss how best to address reviewer critiques. Resubmissions must include a 2-page "Response to Previous Review" document outlining how the application has been revised in response to feedback. Importantly, responses should not be confined to the response document alone. The entire application (particularly the Research Plan) should be updated as appropriate.

Applicants may request a consultation through the "Start a Request" link on the TraCS home page by selecting "CTS Pilot Program."

2. Are investigators or institutions from outside the NC TraCS partnership allowed?

No. Award funds may not be issued (via subcontract or any other mechanism) to institutions outside the NC TraCS partnership. Because NIH regulations require that *all* personnel effort be budgeted, and no effort may be listed as "in-kind," outside research personnel cannot be included as team members.

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

No. Use of NC TraCS services is optional.

However, awardees may incorporate TraCS services if such support strengthens the project. Service scope and cost *must* be discussed with the relevant TraCS program representative(s) prior to submission and documented in one or more TraCS Service Agreement Forms included in the application.

TraCS supplements approved service costs through a *1:1 cost match*, resulting in an effective 50% reduction in service expenses. Pilot Program staff are available to help applicants navigate this process.

4. What about international partners or research?

Pilot funds may not be used to support research conducted outside the United States. However, previously generated international data may be used in pilot projects, if analysis and project activities are conducted domestically.

5. What level of TraCS involvement should awardees expect post-award?

TraCS administers Pilot Awards in a manner more akin to a cooperative agreement than a traditional grant. Awardees will receive ongoing programmatic support, including a TraCS Navigator, faculty content experts, and TraCS service representatives (where relevant).

This support team will meet regularly with investigators to review progress, identify barriers, discuss solutions, and plan future research directions and funding opportunities.

6. Can any funds be spent outside NC TraCS partner institutions?

Yes, but **only** under limited circumstances, such as engaging a consultant or vendor to provide a service unavailable within partner institutions.

While awardees are encouraged to use on-campus university resources (e.g., core facilities), external services may be allowable if justified in the Budget Justification (see **VI. Budget Guidelines**).

7. Does the number of institutions involved affect the total award amount?

No. Pilot Awards range from $25,000 to $50,000 regardless of the number of partner institutions involved. For multi-institution projects, institution-specific budgets and budget justifications are required; however, the combined total may not exceed the $50,000 direct cost cap.

8. Can CTS Pilot funds be used to pay consultants?

Yes, provided the consultant's role and necessity are clearly justified in the Budget Justification and supported by a Consultant Letter describing services to be provided.

Because PI and Co-I salary support is limited, an individual may not serve simultaneously as a consultant and project investigator. Additionally, because funds cannot be transferred to outside institutions, external researchers may not serve as consultants (see **VI. Budget Guidelines**).

9. Can CTS Pilot funds support PI or Co-I salary?

Yes. PI and co-PI effort **must** be budgeted between 1–5% effort each (at the NIH salary cap). No personnel effort may be listed as "in-kind." Significant faculty contributors (e.g., Co-Is) must also budget effort, with a minimum of 1% effort each (at the NIH salary cap). Salary support may also be requested for research personnel such as GRAs, technicians, and research staff.

10. Are there limitations on equipment purchases?

Equipment costs are allowable if well justified in the Budget Justification.

Proposals seeking to purchase major equipment or allocate a substantial portion of the budget to equipment should consult Pilot Program staff prior to submission.

11. Should I budget for indirect costs?

Indirect costs will be provided on funds expended at **N.C. A&T** or **NC State** in accordance with institutional agreements. These costs are provided in addition to the Pilot Award and should **not** be included in the project budget.

12. When should I begin preparing IACUC/IRB paperwork?

As early as possible – ideally immediately following funding notification.

Because Pilot Awards are supported by NIH funds, projects involving human or animal research require NCATS regulatory approval, which can only be initiated **after** institutional (IRB/IACUC) approvals are secured. This additional step may add 4–5 weeks to the regulatory timeline. Awardees are encouraged to obtain institutional approvals as soon as possible after notification and no later than mid- to late February.

13. The RFA allows two pages to discuss the CTS problem. Can I use this space for other content (e.g., Research Plan material)?

No. The Research Plan must be presented within the designated 5-page Research Plan document. Even if applicants do not use the full two pages to describe CTS relevance, this section may **not** be

used for other purposes. Reviewers are not obligated to consider extraneous material placed outside its designated section.

14. The Funding Announcement lists a start date of April 1, 2027. If approvals are in place earlier, can I begin my project sooner?

No. Pilot funding periods are aligned with NIH/CTSA funding cycles. Projects may begin **no earlier than April 1, 2027 (or another officially communicated start date)**, regardless of regulatory readiness.

Pre-award time may be used for preparatory activities (e.g., finalize protocols, complete training, establish agreements, and prepare study materials), but pilot-funded project work and expenditures may not occur before the approved start date.

Please note that the award period is strictly time-limited, and no-cost extensions are not permitted. Projects that initiate later may have less time to complete the proposed work.