



## NC TraCS Clinical & Translational Science Innovation to Impact Awards Request for Applications (RFA)

**Concept Proposal Deadline: May 26, 2026**

**Full Proposal Deadline: October 1, 2026**

Key Dates	
• FOA release	March 9, 2026
• FAQ session	March 25, 2026
• <b>Concept Proposal Due Date</b>	<b>May 26, 2026</b>
• Invitations for Full Proposals	June 2026
• <b>Full Proposal Due Date</b>	<b>October 1, 2026</b>
• Review of Full Proposals	Fall 2026
• Provisional proposal selection	December 2026
• Anticipated negotiations & revisions	Winter 2027
• Anticipated project initiation activities	Spring 2027
• Anticipated funding/project start	Earliest start April 1, 2027

### Note the following:

- To ensure optimal responsiveness to the RFA, all applicants are **required** to consult with NC TraCS Clinical and Translational Science (CTS) Research Program staff prior to submitting a **Concept Proposal** (see section **IV.A Requirements for Concept Proposals**).
- Applicants proposing to use TraCS resources and services are **required** to meet with and obtain approval from service representatives prior to submitting a **Full Proposal** (see section **IV.B Requirements for Full Proposals**).

## 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 (NIH) Clinical and Translational Science Award (CTSA) at UNC Chapel Hill.

The CTS Innovation to Impact (i2i) Awards 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 i2i proposals must focus on a research project that includes a **translational science (TS)** aim applied to a **translational research (TR)** question. This means your project should focus on developing innovative methods or approaches that enhance the research process while also addressing a specific disease or condition. Projects focused primarily on advancing a single target-, disease-, or intervention-specific TR project **without clear generalizable insights that address a truly significant CTS roadblock** are not responsive.

**This NC TraCS i2i Award will provide up to \$125,000 per year in direct costs in years 1 and 2, and up to \$250,000 in year 3.** Awardees are encouraged to utilize any of the numerous [resources and](#)

[services offered by TraCS](#), although this is not mandatory. To maximize the value of the award, these resources and services will be available to awardees at a reduced rate (see **IV.B**). Applying is a multi-step process (see **III. Multi-Step Application Process**), and these awards will function as Cooperative Agreements, wherein NC TraCS will have significant involvement and oversight.

**Examples of past and upcoming i2i projects:**

- **Wayfinding for Prognostic Modeling: A Translational Science (TS) Process for Developing an Oncology Risk-Stratified Intervention System (OR-SIS):** While the use of prognostic models has grown tremendously in biomedical research, including to support practice-based risk stratification, **a persistent TS challenge is the disconnect between model development and the delivery of actionable, patient-centered clinical interventions.**

This project aimed to address this gap by developing a “wayfinding” process that combined clinician judgement, statistical analyses, model verification, and risk-targeted care plan development. The wayfinding process was used to design and implement an oncology risk-stratified intervention system (OR-SIS) within UNC Health’s Epic environment to predict who may be at elevated risk for Acute Care Events (ACEs), which may enable clinicians to intervene earlier and prevent avoidable complications. The resulting generalizable TS prototype for prognostic modeling is one that can be adapted across clinical contexts to enhance patient care. It also offers a repeatable pathway for accelerating the translation of predictive analytics into clinical workflows across diverse care settings, ultimately increasing the efficiency, timeliness, and impact of care delivery (see also [TraCS Feature Story](#)).

**Collaboration with TraCS resources and services:** Informatics & Data Science (IDSci) and Biostatistics.

- **CAR-T Beyond Cancer: Expanding Perceptions and Participation in Clinical Trials for Cell-Based Therapies in Lupus and Autoimmunity:** Although CAR-T cell therapy shows significant promise for autoimmune diseases like lupus, its translation beyond oncology remains limited. **Key barriers including cost, low patient and clinician awareness, and its strong association as a cancer treatment, have constrained clinical trial participation in non-oncology settings.**

This project seeks to overcome these TS barriers by developing engagement strategies and educational resources grounded in the perspectives of both patients and clinicians. This project aims to enhance understanding of and participation in CAR-T lupus clinical trials as a TR use-case, ultimately enabling the broader adoption of cell-based therapy trials across diverse disease areas. The resulting strategies will form a generalizable TS framework for improving recruitment, communication, and stakeholder engagement in emerging therapeutic trials.

**Collaboration with TraCS resources and services:** Qualitative Research Service, Recruitment and Retention, Patient and Community Engagement in Research (PaCER), and Biostatistics.

**Other examples of TS projects that may be supported include but are not limited to:**

- Development of new research methodologies and/or new technologies/tools/resources that will increase the efficiency and effectiveness of translation
- Early-stage development of new therapies/technologies with **generalizable** application to an identified translational roadblock
- Dissemination of effective tools, methods, processes, and training paradigms
- Development and testing of a new method for drug discovery that will accelerate discovery of new drugs in several different disease areas
- Development of a more effective and efficient method for getting evidence into practice that can be applied to several different types of practices and evidence

## II. Eligibility & Funding

### 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. Post-doctoral research associates may not apply as PI.
- **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 Research 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 **VIII. Budget Guidelines**).

For specific questions regarding eligibility, contact [Kaitlin Zalcikova](#).

### B. Award Size and Cost Sharing

***This NC TraCS i2i Award will provide up to \$125,000 in direct costs per year for years 1 and 2, and up to \$250,000 in year 3.***

Please also note:

- **Project timelines should be developed based on the yearly budget periods and funding:**

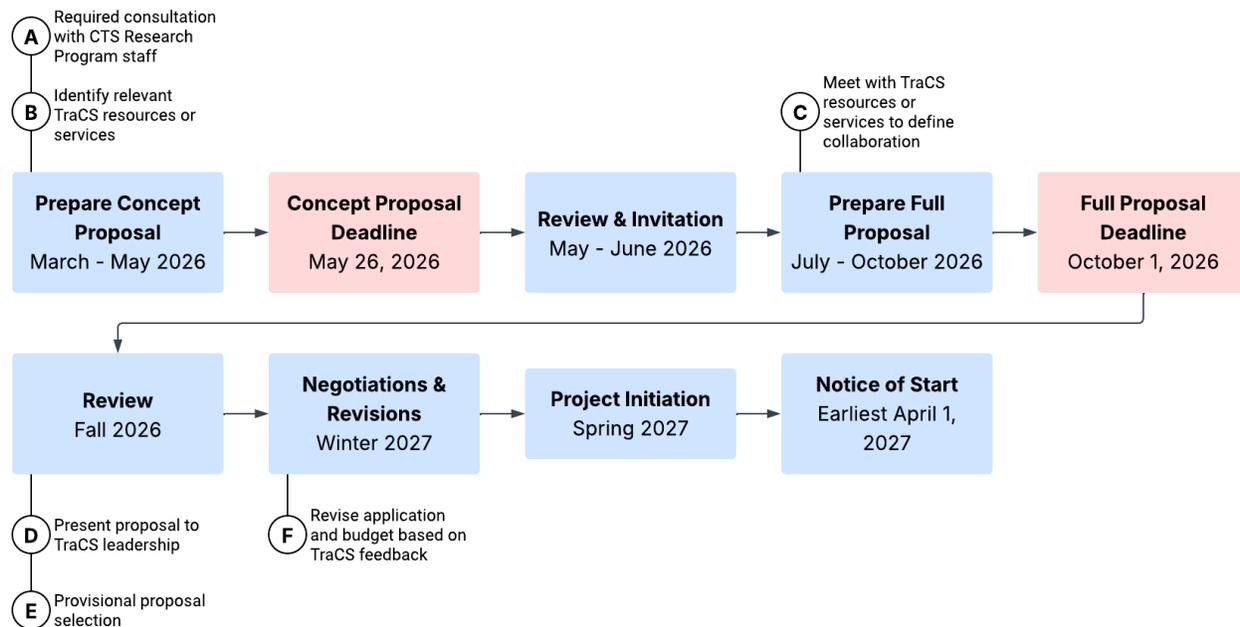
i2i Award Year	Budget	Project Period
Year 1	\$125,000	4/1/27-3/31/28
Year 2	\$125,000	4/1/28-3/31/29
Year 3	Up to \$250,000	4/1/29-3/31/30

- **No-cost extensions are *not* permitted across years**, so applicants must plan for obtaining institutional and NCATS approvals in advance of project start (provisional project selection December 2026; earliest project start April 1, 2027).
- **Cost sharing is *not* allowed.** Projects must be supported **solely** with i2i Award funds. No other funding sources may be included in the project budget (see **VIII. Budget Guidelines** for additional details).
- Awardees may utilize NC TraCS resources and services if such support strengthens the proposed project. The scope and level of TraCS service support **must** be discussed and agreed upon prior to application submission. To maximize the value of the i2i award, these services are available to awardees at significantly reduced rates.

### III. Multi-Step Application Process

Applying is a multi-step process (*summarized in figure below*). These awards will function as **Cooperative Agreements**, where the CTS Research Program will have significant involvement and oversight.

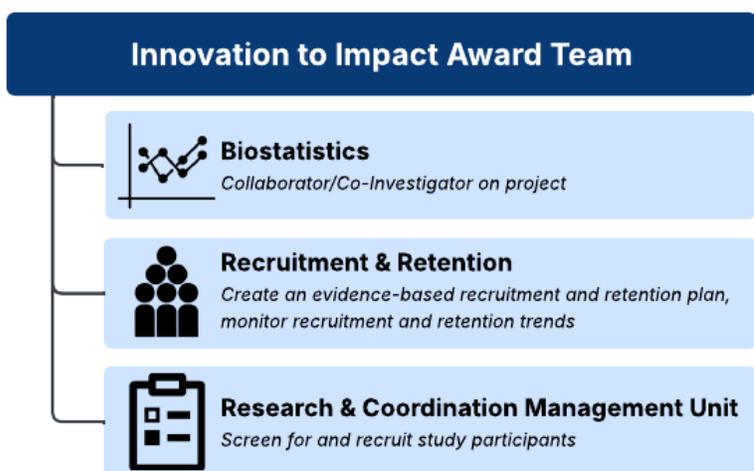
- During the **Concept Proposal** development phase, applicants must **(A)** attend a consultation with TraCS CTS Research Program staff to discuss their project and **(B)** identify the TraCS resources and services that may be relevant to their proposal. Once Concept Proposals are reviewed, select applicants may be invited to prepare a Full Proposal.
- During the **Full Proposal** development phase, applicants must **(C)** meet with the identified TraCS resources and services to define the collaboration and obtain estimates of support (**TraCS Service Agreement**, see [Section VI.8](#)). Applicants will then submit their Full Proposal for review. Select teams may be asked to **(D)** present their ideas to TraCS leadership. Top applicants will then be **(E)** provisionally selected to move forward into Negotiations and Revisions.
- During the **Negotiations and Revisions** phase, teams may be requested to **(F)** revise their application (and budget) as needed (i.e., in response to reviewer and leadership feedback). Once negotiations are complete and the scope and milestones for the projects are agreed upon, applicants will move into the Project Initiation phase.
- During the **Project Initiation** phase, TraCS will assign a Project Manager to provide support for project start-up including coordinating and finalizing Memorandums of Understanding (MOUs) with TraCS programs and services, ensuring institutional and NIH regulatory documents (e.g., IRB) are prepared as needed, assisting with NCATS prior approval documents, developing a Project Management Plan for the project, etc. Once NCATS approves the project, TraCS will issue an official project Notice of Start (earliest start of April 1, 2027).



## IV. Mandatory Consultations with TraCS

### A. Requirements for Concept Proposals

- All applicants are **required** to consult with CTS Research Program staff prior to submitting a Concept Proposal, to ensure optimal responsiveness. During the consultation, CTS Research Program staff can advise the applicant on how best to approach their application and whether any [TraCS services](#) may be useful. Applicants may request a CTS Research Program consultation through the “Start a Request” link on the [TraCS homepage](#). When completing this request form, select “CTS Innovation to Impact Awards” from the “TraCS Programs” dropdown menu and provide a brief description of the TS challenge and TR use-case your potential proposal aims to address.
- Applicants should review TraCS resources and services and identify which services they think may be relevant to their project (see graphic for examples).
- All applicants are also **strongly encouraged** to attend CTS Innovation to Impact Award informational session. Please check the [webpage](#) for more information on session dates and times.



### B. Requirements for Invited Full Proposals

Applicants may collaborate with [TraCS resources and services](#) if such support will strengthen the proposed project.

For the **Full Proposal**, 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) prior to submission to obtain: (1) a written cost estimate and (2) confirmation of service availability and approval.**

- *Applicants are **strongly encouraged** to consult with TraCS service representatives at least three weeks prior to **Full Proposal** 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 **VI.8** below).*
- To maximize the value of the i2i 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.

## V. Concept Proposal Structure and Submission

The Concept Proposal comprises two single-page PDFs that are uploaded through the appropriate link on the submission page. Note that the online submission system occasionally refers to the Concept Proposal as an “LOI” (Letter of Intent). For the purposes of this application process, “LOI” = “Concept Proposal.”

- 1) **Proposed Work** (PDF; **1-page limit**, single line spacing, Arial ≥11 pt, 0.5-inch margins): Outline the proposed work in the form of a standard NIH-style Specific Aims page, **indicating which aims are translational research contributions and which are translational science contributions**. Within this Aims page, make sure to:
  - a. Define the translational science problem(s) this project seeks to understand/solve: Outline and clearly indicate the TS challenge/barrier that the work will address and how addressing this challenge will have broad applicability.
  - b. Define the translational research question(s) or use-case this project seeks to understand: Outline and clearly indicate the TR question(s) the project seeks to address.
  - c. Project Impact: Detail how, if the project is successful, the results or lessons learned will impact other realms of translational research, providing specific examples if possible. Be sure to comment on avenues the project team will take to ensure successful new discoveries are put into practice.
  - d. Deliverables: Highlight the project deliverables (e.g., toolbox, guidelines, TS technique or process, etc.).
- 2) **Research Team** (PDF; **1-page limit**, single line spacing, Arial ≥11 pt, 0.5-inch margins): Describe the research team, highlighting the skills and experience that speak to the feasibility of the proposed work and what specific role each team member will play on the project.
- 3) **Collaboration with TraCS resources and services:** (online entry; multi-select choices with option to add text). Applicants are required to identify which services they think may be relevant to their project and briefly describe the role(s) they envisage the services(s) playing in the proposed work. At this stage, we are seeking to understand potential collaborations and how collaboration with the TraCS service may enhance the project. **Responses do not commit the investigator or TraCS to the collaboration.**

Concept Proposals are submitted using the NC TraCS [online submission system located under “Clinical and Translational Science Innovation to Impact Awards.”](#) Applications are due by **5:00 p.m. on May 26, 2026**. After evaluation by CTS Research Program leadership, applicants will be notified by email within ~6 weeks whether their Concept Proposal has been selected to move forward as a Full Proposal.

## VI. Invited Full Proposal Structure and Submission

Applicants invited to submit a Full Proposal will use the NC TraCS [online submission system](#). Applications are due by **5:00 p.m. on October 1, 2026**. All applicants, successful or not, will be notified by email within ~12 weeks of the deadline regarding the outcome of their application, and those selected for funding will move into the Negotiations and Revisions stage.

Proposal sections (except the Abstract, Impact Statement, and Generalizable Insights) are uploaded as individual PDF files. The application sections are:

- 1) **Scientific Abstract:** Summary of the proposal (online entry; 1500-character limit, **~250 words**).
- 2) **Impact Statement:** Briefly describe how your project will exert a sustained, powerful influence on the research field(s) involved (online entry; 300-character limit, **~50 words**).
- 3) **Generalizable Insights:** Describe the generalizable CTS innovations or insights this project seeks to generate (online entry; 1500-character limit, **~250 words**).
- 4) **Research Team:** Describe the research team, highlighting the skills and experience that speak to the feasibility of the proposed work and what specific role each team member will play on the project. (PDF; **1-page limit**; single line spacing, Arial ≥11 pt, 0.5-inch margins).
- 5) **Research Plan:** The Research Plan must include **Specific Aims, Significance, Innovation, and Approach**. Where applicable, provide clear evidence of how the proposal meets the review criteria. (PDF; **6-page limit, including 1-page Specific Aims**, all tables and figures, excluding references, single line spacing, Arial ≥11 pt, 0.5-inch margins.)
  - a. **Specific Aims:** You may submit a revised version of your Concept Proposal Aims page here, ensuring you address the following:
    - i. Define the translational science problem(s) this project seeks to understand/solve: Outline and clearly indicate the TS challenge/barrier that the work will address and how addressing this challenge will have broad applicability.
    - ii. Define the translational research question(s) or use-case this project seeks to understand: Outline and clearly indicate the TR question(s) the project seeks to address.
    - iii. Project Impact: Detail how, if the project is successful, the results or lessons learned will impact other realms of translational research, providing specific examples if possible.
    - iv. Deliverables: Highlight the project deliverables (e.g., toolbox, guidelines, etc.).
- 6) **Data Analysis Plan (required):** All applications must include a separate 1-page 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).
- 7) **Cited References:** (PDF; **no page limit**)
- 8) **Collaboration with TraCS services:** Applicants **must** consult with all TraCS services they plan to engage with **prior to** submission.
  - a. **Service Consult:** Submit a consult request for **each service** through the “Start a Request” link on the [TraCS homepage](#) and title it “Innovation to Impact Award – Services Consult.” Early consultation (≥3 weeks before submission) is strongly encouraged to allow time to finalize the TraCS Service Agreement(s).
  - b. **TraCS Service Agreement(s):** For each service, applicants must submit a completed [TraCS Service Agreement Form](#). Corresponding costs must be itemized in the Budget and Budget Justification. **Applications lacking required agreements will be considered incomplete and not reviewed.**

- c. **Preliminary Project Readiness Questions:** Applicants must also answer brief project readiness as prompted in the application system. These questions will help identify whether support from additional TraCS services may be needed.
- 9) **Timeline:** Outline proposed activities for the project (up to three years), including milestones and deliverables. Because **no-cost extensions are not permitted across years**, applicants must (i) address plans for obtaining institutional (IACUC/IRB) and NCATS approvals in preparation for project start (**provisional proposal selection December 2026; earliest possible start date April 1, 2027, with all approvals**) and (ii) spending grant funds within each budget year. Include specific factors (e.g., submitted/approved IACUC/IRB protocols, protocol ID numbers if available, availability of an established study cohort, any potential agreements that need to be completed, etc.) **that speak to the feasibility of commencing the study and completing the work** (PDF; **2-page limit** including graphics, single line spacing, Arial ≥11 pt, 0.5-inch margins).
- 10) **Plan for Dissemination and Implementation:** Provide detailed plans that demonstrate how the results and findings from this project will be effectively disseminated and implemented, to ensure that the impact of the project is maximized, and the results are translated into practical applications. Consider the dissemination strategy (target audiences, methods and channels, timeline, partnerships and collaborations), implementation plan (application of findings, integration into practice, stakeholder engagement), and sustainability (long-term impact, additional support at the end of the project). Applications should discuss the commitment of key collaborators to implement and sustain strategies proven successful in the research. For example, projects that collaborate with a health system should have a clear path to the health system sustaining and/or using the findings. (PDF; **1-page limit**, single line spacing, Arial ≥11 pt, 0.5-inch margins).
- 11) **Budget:** Use [PHS 398 Form Page 4](#) for **each** budget year. Use PHS 398 Form Page 5 to summarize the budget for the entire **award period** (up to 3 years). Total direct costs may not exceed (i) \$125,000 in years 1 and 2 or (ii) \$250,000 in year 3. For multi-institutional projects, distinct institution-specific budgets must be prepared. Ensure there is a 50% cost reduction applied to the [standard TraCS service rates](#) when preparing your budget. See also **Section VIII. Budget Guidelines**.
- 12) **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 justifications (PDF; **no page limit**, single line spacing, Arial ≥11 pt, 0.5-inch margins).
- 1) **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 **IX. Regulatory and Reporting Information**) (PDF; **no page limit**, single line spacing, Arial ≥11 pt, 0.5-inch margins).

- 13) **Biosketches:** Applicants must use the New [NIH Biosketch Common Form](#). Provide biosketches for team members at the PI or co-I level only. (Combined into a single PDF, **no page limit**). Note that PDFs need to be flattened to be merged (see [eRA Commons Instructions](#)).
- 14) **Letter(s) if applicable:** Letters may be included if they (i) outline work that will be done for the project by a consultant (**not** necessary for co-PIs, co-investigators or NC TraCS service collaborators) or (ii) clearly state a commitment of resources required for the project's success.

## VII. 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.

The following criteria will be considered:

- 1) **Significance:** The extent to which the proposed work is likely to advance CTS methods and processes, the significance of the translational roadblock it addresses, and its impact on the CTR use-case
- 2) **Novelty/Innovation:** The degree to which the project introduces new or improved concepts, approaches, tools, or frameworks relevant to translational science.
- 3) **Impact/Implementation Potential:** The extent to which the proposed project (i) demonstrates clear potential for meaningful clinical, research, and/or community impact, and (ii) the likelihood that it will generate a tangible discovery, intervention, tool, or deliverable with strong potential for implementation at UNC and/or beyond.
- 4) **Multidisciplinary Team:** The extent to which the investigative team is appropriately multidisciplinary and integral to the successful conduct of the proposed research.
- 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 achieve its stated objectives within the project period.
- 7) **Community Engagement (if applicable):** The appropriateness and quality of community engagement strategies relevant to the proposed work.

## VIII. Budget Guidelines

- NC TraCS i2i award budgets cover expenditures in 12-month periods. 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 these i2i awards, **voluntary cost sharing is not permitted**. The proposed work must be supported **solely** by i2i award funds. CTS-RP 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 i2i award and should **not** be itemized in the project budget.

- CTS i2i 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.
- The following table summarizes mandatory, allowable, and non-allowable budget items:

Mandatory Costs
<ul style="list-style-type: none"> <li>• <b>All</b> personnel effort <b>must</b> be budgeted. No personnel effort, including faculty, may be listed as “in-kind.” This includes:               <ul style="list-style-type: none"> <li>○ PI, co-PI, other significant contributor salary support</li> <li>○ Research support personnel (e.g., research assistants, technicians, research staff)</li> </ul> </li> <li>• Equipment, research supplies, and core laboratory costs</li> <li>• Other project expenses necessary for successful completion of the proposed work</li> <li>• Approved NC TraCS research services, at 50% the standard hourly rate (see <b>Section IV.B</b>)</li> </ul>
Allowable Costs
<ul style="list-style-type: none"> <li>• Travel <b>directly related to data collection for the i2i project</b></li> <li>• Manuscript preparation, submission, or publication costs <b>directly related to the i2i project</b></li> </ul>
Non-Allowable Costs
<ul style="list-style-type: none"> <li>• Salary support or other expenses for personnel at non-TraCS partner institutions</li> <li>• Office supplies or general communication costs</li> <li>• Meals or food <b>even if related to focus groups or data collection</b></li> <li>• Travel unrelated to data collection</li> <li>• Conference travel, registration, or attendance (in-person or virtual)</li> <li>• Professional training or educational coursework</li> <li>• Costs incurred outside the United States (e.g., foreign individuals or foreign entities)</li> <li>• Indirect costs</li> </ul>

## IX. Regulatory and Reporting Information

- 1) Please note that NC TraCS i2i 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 **Fall 2026**. The project funding period will begin no earlier than **April 1, 2027**, and has strict yearly budget periods.

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 i2i project specific IRB/IACUC will be required 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 i2i 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. 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.

- 4) 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.

## **X. CTS Research Program (i2i Awards) Frequently Asked Questions (FAQs)**

- 1) **What is meant by the award being a cooperative agreement?** These awards will function as cooperative agreements, where 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 CTS Research Program Project Manager, TraCS resources and services representatives, faculty content experts if needed, and TraCS leadership, who will meet regularly with the research team to evaluate progress, identify roadblocks and discuss workarounds, and advise on next steps. NC TraCS expects the project PI to report over the lifetime of the work the outcomes achieved due to the award (e.g., subsequent external funding, publications, presentations and patents).
- 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) **What about international partners or research?** Funds cannot be used to support research outside of the US. However, data previously generated through international research can be used in projects, if data analysis, etc., is conducted domestically.
- 4) **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 **VIII. Budget Guidelines**).
- 5) **Can CTS Research award funds be used to support PI or Co-I salary?** Yes, this award can cover PI and co-I salary up to the NIH salary cap.
- 6) **Can CTS Research award funds be used to pay consultants?** Yes, if 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 of Support.
- 7) **Can the Innovation to Impact Award fund a clinical trial?** The NIH will not allow the Innovation to Impact award to fund Phase III or later clinical trials. It may fund Phase I and II. [Please refer to this decision aid to determine if your study is a Phase III clinical trial.](#)
- 8) **Do I have to include TraCS resources and services in my budget?** No. Use of NC TraCS services is optional. However, awardees may incorporate TraCS services if such support strengthens the project. 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, agreed upon, and documented in the [TraCS Service Agreement Form](#) with the appropriate TraCS Service rep(s) prior to Full Proposal submission. CTS Research Program staff can assist applicants in navigating this process, if needed.
- 9) **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 Program staff prior to submission.
- 10) **Should I budget for indirect costs?** No indirect costs may be budgeted for UNC. Indirect costs will be paid based on award funds spent at N.C. A&T or NC State, but these are additional to the award and should **not** be itemized in the Budget.
- 11) **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 enter the Negotiations and Revisions phase. Because these awards 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.
- 12) **April 1, 2027, is listed as the earliest anticipated funding/project start date. If approvals are in place earlier, can I begin my project sooner?** No. The i2i 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.

- 13) **What if I anticipate that the approvals or agreements needed for the project may take longer? Can I begin my project later than April 1, 2027?** Yes. However, the i2i funding periods are aligned with NIH/CTSA funding cycles, so the budget for each year must be spent down within each project period. If you expect institutional and/or NCATS approvals will take longer for study start-up, you must incorporate this in your project timeline (i.e., if you expect you will need until 6/1/27 to complete approvals, you should plan for a 10-month project period for the first year).

<b>i2i Award Year</b>	<b>Budget</b>	<b>Project Period</b>
<b>Year 1</b>	\$125,000	4/1/27-3/31/28
<b>Year 2</b>	\$125,000	4/1/28-3/31/29
<b>Year 3</b>	Up to \$250,000	4/1/29-3/31/30