SCHOOL OF MEDICINE
North Carolina Translational and Clinical Sciences Institute

NC TraCS Clinical & Translational Science (CTS) Innovation to Impact Awards
Request for Applications (RFA)
Concept Proposal Deadline: October 17, 2024
Full Proposal Deadline: February 27, 2025
Updated October 10, 2024 (updates in yellow highlight)

Key Dates	
• FOA Release	August 2024
• FAQ Session	September 13, 2024
• **Concept Proposal Due Date**	**October 17, 2024**
• Invitations for Full Proposals	November 2024
• **Full Proposal Due Date**	**February 27, 2025**
• Review of Full Proposals	Spring 2025
• Anticipated Negotiations & Revisions	Summer-Fall 2025
• Anticipated Project Initiation Activities	Fall 2025 – Spring 2026
• Anticipated Funding/Project Start	Fall 2025 – Spring 2026

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 NC TraCS CTS Research Program is soliciting applications for the CTS Innovation to Impact Awards. These awards are intended to support and advance **Clinical and Translational Science (CTS) projects focused on developing innovative solutions that accelerate the discovery and implementation of effective treatments to improve the health of all people.**

While translational *research (TR)* aims to move discoveries in specific diseases from the lab to the patient, translational *science (TS)* seeks to find broadly applicable innovations and methods that speed up the research process and can be relevant across multiple diseases or research questions. Effective translational science follows the NCATS Translational Science Principles.

Example Project that Addresses a CTS Roadblock
Broadly encountered CTS Roadblock: Poor engagement of underrepresented or minority populations in clinical research.
Project (TS): Design a new recruitment/retention strategy that addresses poor engagement in these populations.
Use-Case (TR): Incorporate the new recruitment/retention strategy in a TR study (e.g., trial of a new drug) that targets these populations. By using the drug trial as a TR "use case" to evaluate and demonstrate the effectiveness of the new recruitment strategy, the research team addresses both the TR question (drug effectiveness) and the TS question (recruitment strategy effectiveness).
Translational Impact: This trial design can then be adapted and used by other researchers for different diseases to increase study diversity.

Applications should propose a research project that includes a **translational science (TS)** aim applied to a **translational research (TR)** question (*see box for example*). 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 must aim to address a truly significant roadblock in CTS science (*see list of common roadblocks*). Projects focused *only* on **translational research** (i.e., projects focused on crossing a particular step of the translational process for a particular target or disease) are not responsive to this RFA.

Awards through the CTS Research Program may range from $125,000-$250,000 per year in direct costs for an award period of 2-3 years (3 year maximum). 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 Section III)*. Applying is a multi-step process *(see Section III*), and these awards will function as Cooperative Agreements, wherein NC TraCS will have significant involvement and oversight.

Examples of ongoing CTS Research Program projects***:***

Characterization and Assessment of Sources of Social Determinants of Health
Project: This project involves a collaboration with the U.S. Census Bureau and compares social determinants of health (SDoH) variables across a variety of sources. The investigators are working to understand the reliability of and any biases within the data *(TS)*. The use of these variables is also being studied to investigate the association between SDoH responses and diabetes outcomes (*TR use-case*). In a separate cohort of participants, investigators will use semi-structured interviews and focus groups to better understand the experiences and perspectives of health care providers, medical assistants, and patients or their caregivers in asking, following up on, and answering questions related to SDoH during routine clinical practice *(TR)*. ***Deliverables:*** Develop a set of guidelines to inform researchers of the features and caveats of the sources of SDoH data *(TS)*, an analytical toolkit to assist researchers in using these data appropriately in their research *(TS)*, and recommendations to healthcare systems about revisions to SDoH questions to decrease burden on patients and/or providers *(TS)*. ***Collaboration with TraCS resources and services:*** Informatics and Data Science (IDSci), Patient and Community Engagement in Research (PACeR), Qualitative Research, Inclusive Science Program (ISP), Recruitment and Retention, Team Science, and the Research and Coordination Management Unit (RCMU).

Wayfinding for Prognostic Modeling
Project: Using factors routinely available in medical records, combined with clinician judgement, statistical analyses, model verification, and risk-targeted care plan development in a *wayfinding process*, this team is developing an *oncology (TR use-case) risk-stratified intervention system (OR-SIS) (TS)*. They aim to demonstrate that *OR-SIS* is acceptable to both clinician and patient users, feasible to implement, results in fewer Acute Care Events (ACEs) and prolonged therapy use and facilitates equity among historically marginalized patients *(TS)*. In addition, it will serve as a *translational science process prototype* for prognostic modeling in other clinical contexts *(TS)*. ***Deliverables:*** Develop a *generalizable* process that will serve as a translational science prototype for prognostic modeling in other clinical contexts, validate this new process, and demonstrate its acceptability and feasibility for implementation *(TS)*. ***Collaboration with TraCS resources and services:*** IDSci and Biostatistics.

Other examples of translational science that may be supported include:

- Development of new research methodologies and/or new technologies/tools/resources that will increase the efficiency and effectiveness of translation
- Development of strategies to increase inclusion of understudied populations
- 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. Applicant Eligibility

Eligibility

UNC-Chapel Hill Principal Investigator applicants should hold either a faculty appointment, a non-faculty appointment like "research scientist", or another independent research position typically held by investigators from research institutes and centers who are eligible to apply for investigator-initiated awards and NIH "R" funding. Post-doctoral research associates may not apply as PI. For specific questions regarding eligibility, contact Kaitlin Zalcikova.

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 Research Program administration.

III. Multi-Step Application Procedure

Applying is a multi-step process (*see figure above, additional details for steps A-F below*). These awards will function as Cooperative Agreements, where the CTS Research Program will have significant involvement and oversight. Applicants are **(A)** required to meet with TraCS CTS Research Program staff to discuss their project while preparing their concept proposal. Applicants should also **(B)** identify TraCS resources and services that may be relevant to their proposal, prior to **(C)** submitting their Concept Proposal. Once Concept Proposals are reviewed, applicants may be invited to prepare a Full Proposal. During this time, they will be required to **(D)** meet with the identified TraCS resources and services to define the collaboration and obtain estimates of support *(TraCS Service Agreement, see section III.D.7)*. Applicants will then **(E)** submit their Full Proposal. After review of Full Proposals, selected teams may move forward into **(F)** Negotiations and Revisions with CTS Research Program staff and TraCS program staff, and will be requested to revise their application as needed. Once negotiations are complete, and the scope and milestones for the projects are agreed upon, applicants will move into the Project Initiation phase, at which point TraCS will assign a Project Manager to provide support for 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, and developing a Project Management Plan for the project. Additional Planning Activities will also take place. Once NCATS approves the project submission, applicants will receive the official project Notice of Start (projects are anticipated to begin in 2025 or 2026).

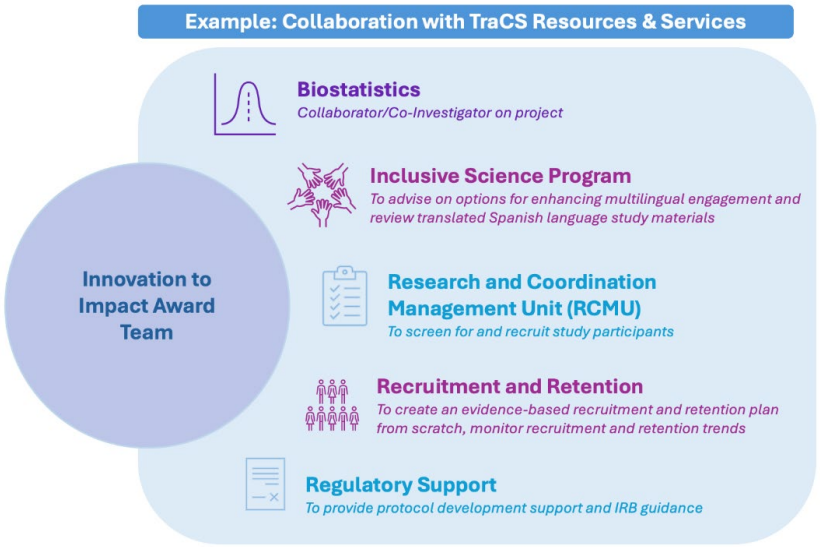
A. Consultation with NC TraCS CTS Research Program Staff Prior to Concept Proposal Submission

All applicants are ***required*** to consult with CTS Research Program staff prior to submitting a Concept Proposal, to ensure optimal responsiveness. During the consult, staff can advise the applicant on how best

to approach their application and whether any TraCS services might be useful. Applicants can request a **CTS Innovation to Impact Research Award** consult through the "Submit a Request" link on the TraCS home page. 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. Identify TraCS Resources and Services Relevant to the Proposal

All applicants are *strongly encouraged* to utilize, and collaborate with, TraCS resources and services (*see graphic to the right and a list of programs*). Applicants should review TraCS resources and services and identify which services they think may be relevant to their project.



C. 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** ***(1-page limit****, single line spacing, Arial 11, and 0.5-inch margins all round):* 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** ***(1-page limit****, single line spacing, Arial 11, and 0.5-inch margins all round):* 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:** When prompted in the **application system**, 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. 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 **October 17, 2024**. 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.

D. Full Proposal 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 **February 27, 2025**. 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 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 300 character limit, **~50 words**)*.
3) **Generalizable Insights:** Describe the generalizable CTS innovations or insights this project seeks to generate *(online 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. *(**1-page limit**, single line spacing, Arial 11, and 0.5-inch margins all round). You may submit a revised version from your Concept Proposal.*
5) **Research Plan:** The Research Plan should include Specific Aims, Significance, Innovation, and Approach. Include, where applicable, clear evidence of how the proposal meets the review criteria. *(PDF, **6-page limit**, including tables and figures. Single line spacing, Arial 11, and 0.5-inch margins all round. Cited references do not count towards the 6-page limit.)*
    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) **Cited References:** *(PDF, **no page limit**)*
7) **Collaboration with TraCS services:** *The applicant is **required** to consult with representatives of each of the relevant services they plan to engage with **prior to** submission*.
    a. **Service Consult:** To request a consult from any of the services for the Full Proposal, please do so through the "Submit a Request" link on the TraCS home page. Please include "Innovation to Impact Award – Services Consult" in the title of the Request. CTS Research Program staff can also

offer advice on which services to use and can assist in putting applicants in contact with service representatives. *We strongly encourage applicants to consult with TraCS services as early as possible (at least 3 weeks prior to submission), so that the details of the collaboration and TraCS Service Agreement can be finalized before the Full Proposal submission deadline.*

b. **TraCS Service Agreement(s):** The agreed-upon nature and extent of services available to the applicant team, and the name of the TraCS service representative with whom the applicant met, *must* be described in the **TraCS Service Agreement Form**, as well as itemized in the grant Budget and Budget Justification for ***each*** service the applicant plans to engage. *Applications that propose to use a TraCS service, but do not include a completed TraCS Service Agreement Form for each relevant service, will be considered incomplete and will not be reviewed.*

c. **Preliminary Project Readiness Questions:** When prompted in the application system, applicants are required to answer a few additional readiness questions related to their project (*see the "Application Instructions and FAQ" section on the webpage for additional details on readiness questions).*

8) **Timeline:** Outline the proposed project activities for the funding period, including the timeline, milestones, and deliverables (up to 3 years). It is important that the proposed work can be completed within the proposed funding period, *as no-cost extensions are **not** permitted across years.* Include specific items that must be completed prior to the start of the project at the beginning of the timeline (e.g., obtaining institutional (IACUC/IRB) and NCATS approvals, established study cohort, other regulatory documents, etc.) that speak to the feasibility of commencing the study and completing the work within the budget period. *(PDF, **2-page limit**, including graphics, single line spacing, Arial 11, and 0.5-inch margins all round.)*

9) **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 stakeholders 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, and 0.5-inch margins all round.)*

10) **Discussion of the health equity ramifications of the proposed work (*if applicable*):** 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*." Discuss the proposed work's potential to contribute to health equity solutions. *(*PDF, ***1 page limit,** single line spacing, Arial 11, and 0.5-inch margins all round.)*

a. Full Proposals may address health disparities in several ways, from assessing community needs to including diverse perspectives in manuscripts. Examples of ways in which health equity can be integrated into proposals include (but are not limited to):

i. Mechanistic studies of biological factors associated with disparities

ii. Development and testing of new methods and models that aim to mitigate disparities

iii. Use of health equity conceptual frameworks to guide study design

iv. Data analysis stratified by key risk factors

v. Partnerships with community members with lived experience

b. ***Note:*** The following publications discussing health equity in clinical and translational research are useful references when preparing this section:

i. 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

ii. Breathett, K., Spatz, E. S., Kramer, D. B., Essien, U. R., Wadhera, R. K., Peterson, P. N., Ho, P. M., & Nallamothu, B. K. (2021). The Groundwater of Racial and Ethnic Disparities Research: A Statement From *Circulation: Cardiovascular Quality and Outcomes*. *Circulation. Cardiovascular quality and outcomes*, *14*(2), e007868. https://doi.org/10.1161/CIRCOUTCOMES.121.007868

iii. National Institute on Minority Health and Health Disparities (2017). NIMHD Research Framework. Retrieved from https://nimhd.nih.gov/researchFramework. Accessed on October 9, 2024.

11) **Budget:** Use PHS 398 Form Page 4 *(see also Section V. "Budget Guidelines" below)*. The total project budget, across all participating institutions, should not exceed $250,000 per year. Collaborations with TraCS programs and services should be included in this budget. Programs and services collaborators will offer a 50% cost reduction on standard hourly rates for projects funded with this mechanism. For multi-institutional projects, distinct institution-specific budgets must be prepared and submitted as a single PDF.

12) **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 budget justifications must be included, combined into a single PDF *(PDF, **no page limit**, single line spacing, Arial 11, and 0.5-inch margins all round.)*

13) **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. 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 (Note this this description does *not* obviate the need for protocol submission to, and approval by, the IRB). 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 IRB, IACUC, and NCATS approvals are received (*See Section VI. below*) *(PDF, **No page limit**, single line spacing, Arial 11, and 0.5-inch margins all round.)*

14) **Biosketches:** NIH-format. Provide for team members at the PI or Co-I level only. (*Combined into a single PDF, **no page limit**).*

15) **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.

IV. 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.

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

1) CTS significance of the work, the translational roadblock it addresses, and its likelihood to advance CTS methods and processes

2) Relevance of the CTR use-case to the identified broader translational roadblock
3) Novelty/Innovation
4) Multidisciplinary team in place that is integral to the conduct of the research
5) Soundness of the proposed methods
6) Feasibility of accomplishing the stated project goals within the award period
7) Plan for implementation of the discoveries in systems at UNC and beyond
8) Utilization/Collaboration with NC TraCS resources and services
9) Contribution to health equity
10) Level of community engagement *(if applicable)*

V. Budget Guidelines

1) NC TraCS CTS Research Program award budgets cover expenditures for 12-month periods. From this round of applications, we anticipate one project starting Fall 2025 and a second project starting Spring 2026. 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 the agreed-upon date. The expectation is that all yearly funds will be expended, *as no-cost extensions are not permitted*.
2) CTS Research funds may be budgeted for **(i)** PI, co-PI, 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.
3) 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 N.C. A&T or NC State, but these are additional to the award and should ***not*** be itemized in the Budget.
4) The following items may ***not*** be budgeted for in a CTS Research Program 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, **(vii)** costs outside of the U.S. (e.g., foreign individuals, foreign entities), or **(viii)** indirect costs.

VI. Other Guidelines

1) Prior to receiving funds, research involving human subjects must have appropriate approvals from the UNC-CHAPEL HILL IRB. 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 award 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 CTS Research Program awards 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 awards determined to be "minimal risk" are usually approved within a few days.

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

CTS Research Program 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, faculty content experts if needed, and TraCS resources and services representatives, 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. **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, as long as data analysis, etc., is conducted domestically.

3. **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.

4. **Do I have to include TraCS resources and services in my budget?** All applicants are *strongly encouraged* to collaborate with TraCS resources and services. 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.

5. **Can CTS Research award 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.

6. **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.

7. **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.

8. **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.

9. **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 into the Negotiations and Revisions stage. 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.