

Overview of the UM1 FOA

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During the presentation send your questions to: CTSAFOAQuestions@mail.nih.gov

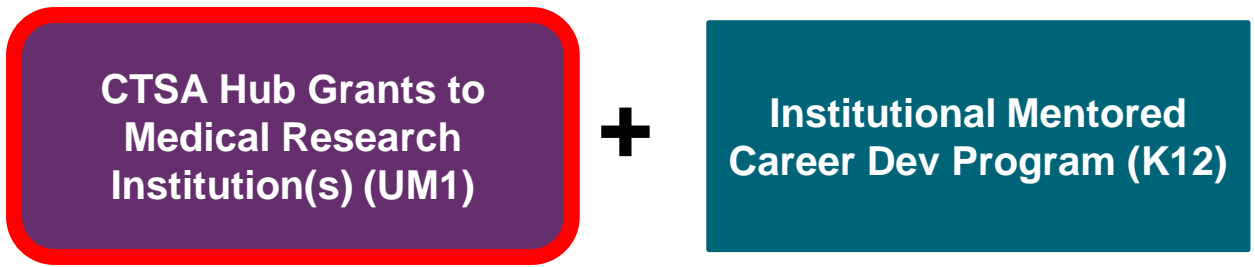
Questions and Answers are posted here and will be updated periodically:

<https://ncats.nih.gov/ctsa/funding/application-information-par-21-293>

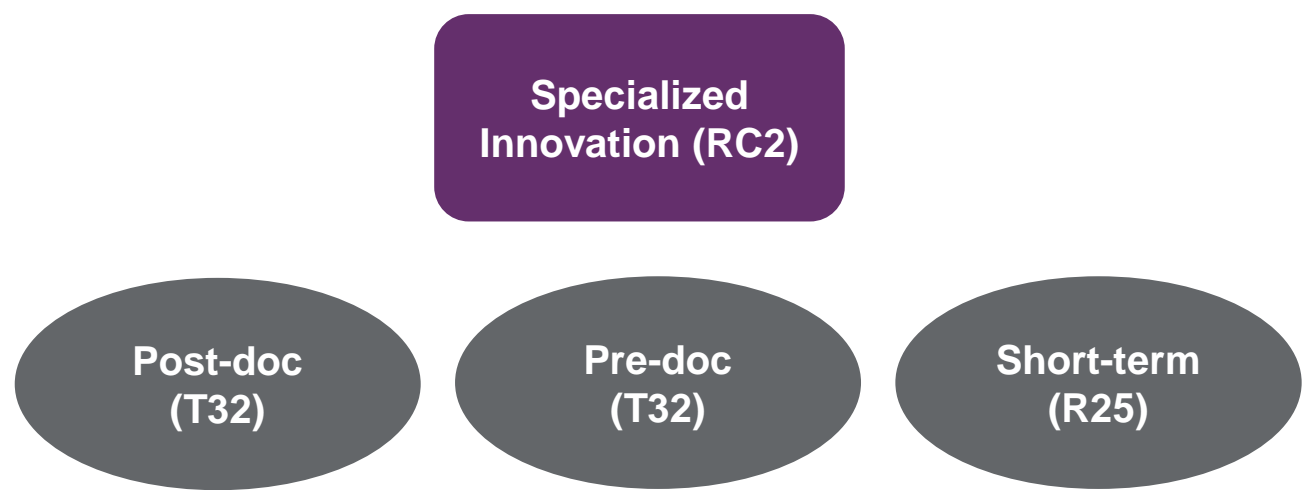


Suite of CTSA FOAs

REQUIRED



OPTIONAL



Overview

- Purpose
- Application Types Allowed & Instructions
- Non-responsive applications
- Required & Optional Career, Training, and Research Education Opportunities
- UM1 FOA Diagram
- Award Budget
- Other Attachments: CTSA Program Summary Data Guide
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- Review criteria
- Important Dates
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Reminder to Applicants

- **Please Note:**

- The primary source of all information regarding ANY funding opportunity announcement is the funding opportunity itself and any notices linked therein.

PLEASE READ THE FOA, APPLICATION INSTRUCTIONS AND ALL NOTICES

- **Resources:**

- Application Information for PAR-21-293: Clinical and Translational Science Award (UM1 Clinical Trial Optional) <https://ncats.nih.gov/ctsa/funding/application-information-par-21-293>
- CTSA Program UM1 Budget Request Tables <https://ncats.nih.gov/ctsa/funding/CPUBRT>
- CTSA Program Summary Data Guide <https://ncats.nih.gov/ctsa/funding/CPSDG>

- **Questions?**

- UM1: CTSAFOAQuestions@mail.nih.gov



UM1 Notices (through June 2022)

Applicants are responsible for being aware of any notices related to FOAs. These may be released throughout the life of a FOA. Text may be changed in the FOA to reflect the Notice.

Mechanism	Release Date	Notice	Notice Title	Short Description
UM1/K12/T32/R25/RC2	January 31, 2022	NOT-TR-22-008	Notice of Change to Expansion of Eligibility of Optional Companion Applications for CTSA Program Funding Opportunities: PAR-21-293 (UM1), PAR-21-340 (RC2), PAR-21-339 (R25), PAR-21-338 (T32), and PAR-21-337 (T32).	Clarification that optional companion applications can be submitted under the following scenarios: concurrently with the UM1, while the UM1 application is under review consideration, after the UM1 application is funded, while the UM1 is under consideration for funding.
UM1/K12	February 25, 2022	NOT-TR-22-022	Notice of Change to Expansion of Eligibility of PAR-21-336 (K12) Required Companion Application for CTSA Program Funding Opportunity PAR-21-293 (UM1).	Clarification that required companion K12 application can be resubmitted under the following scenarios: concurrently with the UM1, while the UM1 application is under review consideration, after the UM1 application is funded, while the UM1 is under consideration for funding.
UM1	March 23, 2022	NOT-TR-22-024	Notice of Change in Eligibility to PAR-21-293 Clinical and Translational Science Award (UM1 Clinical Trial Optional)	CTSA UM1 applications from organizations named as a Partner Institution in a funded CTSA UM1 or CTSA UL1 award are not allowed, except under rare circumstances with compelling justification.
UM1	June 22, 2022	NOT-TR-22-032	Notice of Change to PAR-21-293 Clinical and Translational Science Award (UM1 Clinical Trial Optional) in Eligibility	For the purposes of this FOA, NIH funding to the Partner/Partnering Institution MUST BE included for determination of maximum direct cost budget requests. Partner/Partnering Institution(s) must be effectively integrated into the proposed activities of the CTSA UM1 hub and are necessary for attaining its strategic goals and research priorities. For the purposes of this FOA, NIH funding to the Collaborating Institution is NOT included for determination of maximum direct cost budget requests.



Purpose

This funding opportunity announcement (FOA) invites applications for the Clinical and Translational Science Award (CTSA) Program hubs that will be part of a national, collaborative consortium focused on bringing more treatments to more patients more quickly through advancing clinical and translational science (CTS) by:

1. developing, demonstrating, and disseminating scientific and operational innovations that improve the efficiency and effectiveness of clinical translation from identification to first-in-human studies to medical practice implementation to community health dissemination;
2. promoting partnerships and collaborations to facilitate and accelerate translational research projects locally, regionally, and nationally;
3. creating, providing, and disseminating innovative research programs and partnerships across institutions and communities to address health disparities and deliver the benefits of translational science to all;
4. creating and implementing scientific and operational innovations that increase the quality, safety, efficiency, effectiveness, and informativeness of clinical research;
5. providing a national resource for the rapid response to urgent public health needs; and
6. creating, providing, and disseminating CTS training for clinical research professionals of all disciplines on the research team.

<https://grants.nih.gov/grants/guide/pa-files/PAR-21-293.html>



Application Types Allowed and Instructions

- New
- Renewal (as allowed)
- Resubmission (as allowed)

- **Notes:**
 - All previously funded CTSA's (U54 → UL1) must submit as a NEW application
 - Organizations with active grants funded under FOAs [PAR-15-304](#), [PAR-18-464](#) & [PAR-18-940](#) that have more than 16 months of support remaining on the day of the submission deadline are not eligible to apply.

- **Application Instructions:** It is critical that applicants follow the instructions in the **Research (R) Instructions** in the [SF424 \(R&R\) Application Guide](#), except where instructed to do otherwise (in this FOA or in a Notice from [NIH Guide for Grants and Contracts](#)).



Non-responsive Applications

- The following will be considered non-responsive. Non-responsive applications **will not be reviewed**.
 - Applications that do not answer Yes to the involvement of Human Subjects.
 - Applications in which the PDs/PIs do not commit at least two months effort each.
 - Applications that lack the required K12 Clinical Scientist Institutional Career Development Program Award companion application (upon initial submission [NOT-TR-22-022](#)).
 - Applications that lack a specific plan describing the partnership between the UM1, the required K12, and any optional components.



Required and Optional Career, Training, and Research Education Opportunities

- This FOA only accepts applications that are part of a collaborative set of multiple applications.
 - Upon **initial submission**, a set **must** contain 1 application to this UM1 FOA and 1 application to K12 FOA;
 - A UM1 hub application without the required companion K12 application will not be reviewed.
 - The required K12 application will only be awarded if the UM1 application is awarded.
 - However, if the UM1 application is funded and the companion K12 application is not funded, a resubmitted K12 application will be accepted (without the UM1 application).
 - One UM1 hub application may also submit concurrently, while the UM1 is under review consideration, while the UM1 is under consideration for funding, or after award:
 - 1 application to the T32 predoc FOA, and/or
 - 1 application to the T32 postdoc FOA, and/or
 - 1 application to the R25, and/or
 - 2 applications to the RC2 FOA.
 - Optional companion applications will only be awarded if the UM1 application is awarded.
 - Optional companion applications (initial and resubmission) will be accepted concurrently or if the UM1 application is awarded.
- The application must provide a specific plan describing the partnership between the UM1, the required K12 and any optional components.

[NOT-TR-22-008](#) and [NOT-TR-22-022](#)



UM1 FOA Diagram

**Section I
FOA Description**

Key Terms, Definitions and Uses in this FOA

Background

CTSA Program

CTSA Program UM1 Hub Application Structure

Required and Optional Career, Training and Research Education Opportunities

Resources Provided by NCATS

**Section II
Award Info**

**Section III
Eligibility Info**

**Section V
Review Information**

Section IV: Application and Submission Information
[includes Page Limitations, Facilities & Other Resources, Data Tables, Partner Institutions, Budget, Research Plan (Specific Aims + Research Strategy)]

**Element A:
Overview**

6 pgs

Essential Characteristics of Successful CTSA Hubs

Vision, Strategic Goals, & Impact

Track Record in CTS

**Element B:
Strategic Management**

12 pgs

Strategic Management Module
(Module Leader & Application PI)

**Element C:
Training & Outreach**

12 pgs

Workforce Development for Clinical Research Staff Professionals Module
(Module Leader)

Community & Stakeholder Engagement Research Module
(Module Leader)

**Element D:
CTS Resources & Pilots**

18 pgs

Resources & Services Module
(Module Leader)

CTS Pilot Module
(Module Leader)

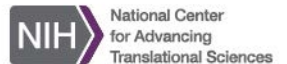
Health Informatics Module
(Module Leader)

**Element E:
CTS Research Program**

6 pgs

CTS Research Program
(Program Leader)

NOTES:
 >PER APPLICATION:
 -One budget with budget justifications broken down by Element & Module
 -One set of criterion scores and one overall impact score



Award Budget

- **CTSA UM1 hub applications** submitted in response to this FOA must be submitted by a single applicant institution, plus the option of one or more partnering institutions and/or one or more collaborating institutions.
- **Partner/Partnering Institution(s)** must be effectively integrated into the proposed activities of the CTSA UM1 hub and are necessary for attaining its strategic goals and research priorities.
 - A Partnering Institution may be included as a partner **in only one** CTSA UM1 hub application.
 - A “**Partner’s**” NIH funding is used for determination of maximum direct cost budget requests for the UM1
- **Collaborator/Collaborating Institution(s)** have a significant role in one or more aspects of the CTSA UM1 hub and may be included in more than one CTSA UM1 hub application.
 - NIH funding to the collaborating institution **may NOT** be included for determination of maximum direct cost budget requests.
- An organization named as Partner/Partnering Institution in a CTSA UM1 application (and subsequent UM1 award), or a CTSA UL1 award funded previously under [PAR-18-940](#), [PAR-18-464](#) or [PAR-15-304](#) may be listed as a Partner with only one UM1 or UL1 unless the UM1 and UL1 are from the same organization.
- **List of Institutions that are partners of CTSA Program hubs in FY22:** [CTSA Partner List - FY22 \(updated 9.1.2022\)](#)

Notice: [NOT-TR-22-032](#) (released June 22, 2022)

More info: <https://ncats.nih.gov/ctsa/funding/CPUBRT>



Award Budget

FY24 Awards: [NOT-TR-22-033](#) (released July 20, 2022)

Table A: Institutional NIH Direct Cost (DC) Funding Table [FY17-21 FY17-FY21 NIH DC Funding-all Orgs-FINAL.xlsx](#)

Table B: Maximum Direct Cost (DC) Budget Requests for CTSA UM1 hubs

	Size Eligibility Budget Tiers for FOA Applicants (FOA receipt dates January 13, 2023 , May 12, 2023 , September 15, 2023)	Maximum Direct Cost Budget Requests for UM1
Hub Tier	<i>5-year average of the most current NIH Direct Cost (DC) Funding of the applicant institution, <u>PLUS</u> 5-year average of the most current NIH Direct Cost (DC) funding of any partner(s)*</i> <i>(based on FY2017-FY2021 NIH Fund data)</i>	UM1
A	>\$320,000,000	\$6,500,000
C	\$235,000,000 - \$320,000,000	\$5,000,000
T	\$145,000,000 - \$234,999,999	\$3,600,000
G	<\$145,000,000	\$2,600,000

CTSA Program UM1 Budget Request Tables: <https://ncats.nih.gov/ctsa/funding/CPUBRT>



Verification of Funding Tier Calculations

- Applications for the following due dates must use the following tables:

Table A: Institutional NIH Direct Cost (DC) Funding Table
FY17-21 [FY17-FY21_NIH_DC_Funding-all_Orgs-FINAL.xlsx](#)

**Table B: Maximum Direct Cost (DC) Budget Requests
for CTSA UM1 hubs**

- Applicants are strongly encouraged to verify their funding tier calculation with NCATS in advance of application submission through the CTSA FOA Questions mailbox (send to: CTSAFOAQuestions@mail.nih.gov). Once NCATS verification is received and recorded, the applicant should include a note in the R&R Budget Section of the application that NCATS has reviewed and accepted the funding calculation prior to submission.



Other Attachments: CTSA Program Summary Data Guide

- "Other Attachments" must be included to aid in the review of applications (are required components of the application or will not be reviewed).
- Information provided in the required attachments should not be repeated in the narrative. However, it is encouraged to cross-reference the tables in the narrative so reviewers can more easily find this information.
- Use of the Template Data Tables is optional but all fields must be addressed if another table format is used.



Other Attachments: CTSA Program Summary Data Guide

Required attachments should be uploaded only once. Information provided in the required attachments should not be repeated in the narrative. Applications that lack any of the attachments specified below will be considered incomplete and will not be reviewed.

- 1. *Institution* (use filename *Hub Institution Organization*):** Provide 1) a chart/diagram indicating the hub's organizational status within the institution and how the hub leadership is integrated within the institution and 2) a chart/diagram indicating the working relationships between the hub and included partnering institution(s).
- 2. *Hub's Senior Leadership* (use filename *Hub Senior Leadership*):** Information and role of each Contact PD/PI, Other PDs/Pis, Module, and Program Leaders and Co-Leaders. **Limited to ONE page.**
- 3. *Information on Hub Partners and Collaborators* (use filename *Hub Partners and Collaborators*):** A table listing of all partnering and collaborating institutions with contributions and justifications for the participation of each; justifications must be commensurate with the specified role. Partnering institutions must be effectively integrated into the proposed activities of the CTSA UM1 hub and are necessary for attaining its strategic goals and research priorities. Collaborating institutions have a significant role in one or more aspects of the CTSA UM1 hub. **Limited to THREE pages.**

Suggested templates here: <https://ncats.nih.gov/ctsa/funding/CPSDG>



Other Attachments: CTSA Program Summary Data Guide

4. ***Resources and Facilities*** (use file name *Resources and Facilities*): A table listing of SPECIFIC resources that are anticipated to be used during the performance period of the UM1. **Limited to FIVE pages.**
5. ***Clinical Trial Experience*** (use filename *Clinical Trial Experience*): A brief description of all NIH-funded single and multi-site clinical trials with site activation during the 6 months up to and prior to the application from the hub and participating partners and collaborators. **Limited to FIVE pages.**
6. ***Clinical and Translational Science Track Record*** (use filename *CTS Track Record*): Institution, partners, and collaborators' accomplishments and progress in CTS research efforts and high impact achievements that are generalizable to the advancement of CTS over the past 5 years; emphasize those that have advanced better methods and/or improved health. **Limited to FIVE pages.**
7. ***Coordination and Integration Plan*** (use filename *Coordination and Integration Plan*). The application must include a specific plan describing the partnership between the UM1, the required K12 and any optional components, such as the research education (R25), and/or pre-and post-doctoral training (T32) awards. The UM1 application must describe the overarching goals of each component and the coordination, integration, synergy, and mutual reinforcement of resources between the components. Include a description of the roles of any shared partners and/or collaborators. **Limited to THREE pages.**

Suggested templates here: <https://ncats.nih.gov/ctsa/funding/CPSDG>



Element C: Training & Outreach

- Personnel support for the required and optional companion training and education activities to ensure activities are conducted as an integrated endeavor **may be included if costs are not duplicative.**
- Applicant institutions should include a statement providing assurance that the activities and costs are not duplicative with the UM1 activities.
- Failure to provide an assurance statement may result in the removal of potential duplicative costs prior to award.



Element D: Clinical and Translational Resources and Pilots

- Clinical and Translational Science Pilot Module:
 - Include costs for the review, tracking, management, and overall administration of the Module as well as the Pilot projects:
 - Number of Pilot Projects: A minimum of four and a maximum of eight Pilot projects, per year.
 - Budgets: Must be between \$25,000 and \$50,000, direct costs.
 - Project Period: Cannot exceed 12 months.
 - Cost sharing is not allowed. Pilot projects must be fully supported with NIH funds awarded through this funding announcement (no other funding sources may be used to support these projects). The review process, resources, and expertise developed through this Module may be utilized for the review of other projects not funded through this application; however, NIH assumes no responsibility for those projects and should not receive any reports related to those projects.



Element D: Clinical and Translational Resources and Pilots (continued)

- Clinical and Translational Science Pilot Module:
 - Individual projects should not be included in the application submission. Pilots are submitted to NCATS for prior approval after the award if they are conducting research with Human Subjects or Vertebrate Animals or have a foreign component.
 - More information: Post-Award Grant Actions: Prior Approval and Reporting of Research with Human Subjects and/or Vertebrate Animals <https://ncats.nih.gov/ctsa/funding/prior-approval-paga>



Element E: CTS Research Program

- Clinical and Translational Science (CTS) Research Program
 - Include funds for personnel, research, and other expenses, as appropriate.
 - Direct costs for the CTS Research Program must not exceed \$500,000 per year in direct costs.
 - Each CTS Research Project may not be less than \$125,000 **per year in direct costs** for a suggested period of 2-3 years.
 - Multiple projects may be undertaken concurrently.
 - Each hub must request at least one project in this application.
 - Subsequent projects will require prior approval if the project includes research with human subjects, vertebrate animals, and/or foreign components.



Cost Sharing

- This FOA does not require cost sharing as defined in the [NIH Grants Policy Statement](#).
- Applicants should describe the institutional environment and available resources in the resources section of the application. Any applicant identifying voluntary committed cost share in the budget sections of the application will be bound to the cost share commitment for the entire approved project period. Personnel effort requested without salary support will be considered voluntary committed cost share and the applicant institution will be bound to the relevant salary, fringe and associated F&A costs for the entire approved project period.
- Voluntary committed cost share **will not be accepted and will not be considered in the review score for the following categories:**
 - key personnel (PD/PIs, Module and Program Leaders/Co-Leaders),
 - the Resource and Services Module (Module D1),
 - the CTS Pilot Module (Module D2), or the
 - CTS Research Program Element (Element E).
- Voluntary committed cost share for other items identified after peer review will be considered; however, any alteration in cost share commitments for the specified categories prior to award will deem the application ineligible for award. Future award consideration would require submission of a revised application.



Note the following definitions:

- **Direct Funding:** Full and/or partial funding allocated directly to the project from the federal funds awarded.
- **Voluntary Committed Cost Share:** In accordance with **Uniform Guidance 2 CFR 200.306**, voluntary committed cost share is cost sharing pledged by the grantee institution on a voluntary basis that is quantified in either the proposal budget or narrative and becomes a binding requirement of the award.
- **Voluntary Uncommitted Cost Share:** Any effort or resource contributed to a sponsored award that was not included in either the proposal budget or narrative or committed to the sponsor prior to award.



QUESTION: *Why is cost share not considered in the review score for the following categories: key personnel (Program Directors/Principal Investigators [PD/PI], Module and Program Leaders/Co-Leaders), the Resource and Services Module, the Clinical and Translational Science (CTS) Pilot Module, or the CTS Research Program Element?*

- Per Uniform Guidance Section 75.306, *“Under federal research proposals, voluntary committed cost sharing is not expected. It cannot be used as a factor during the merit review of applications or proposals but may be considered if it is both in accordance with HHS award agency regulations and specified in the Notice of Award. Criteria for considering voluntary committed cost sharing and other program policy factors that may be used to determine who may receive a federal award must be explicitly described in the notice of funding opportunity.”* There has been a rise in voluntary committed cost share proposed in applications submitted in response to the Clinical and Translational Science Award (CTSA) Hub program. NCATS has an obligation to ensure that voluntary committed cost share is not considered as a factor of merit review because cost share is neither expected nor required for this program. Therefore, NCATS has provided explicit guidance in the notice of funding opportunity as to how voluntary committed cost share will be considered. Applicants considering proposing voluntary committed cost share in a grant application should work directly with their Office of Sponsored Programs and/or Authorized Organization Representative to understand their institutional policies and procedures for voluntary committed cost share prior to submitting their applications.



UM1 Review Criteria

- The CTSA hub UM1 application will be evaluated as an integrated effort consistent with the goals and objectives outlined in the Description.
- Reviewers will provide an overall impact score for the entire UM1 application to reflect their assessment of the likelihood for the CTSA hub to exert a sustained, powerful influence on CTS, in consideration of the following standard review criteria and review criteria specific to this FOA.
- In addition to standard review criteria, review criteria “Specific to this FOA” is provided.



Important Dates

Application Due Dates		Review and Award Cycles	
New	Scientific Merit Review	Advisory Council Review	Earliest Start Date
January 13, 2023	June 2023	October 2023	December 2023
May 12, 2023	October 2023	January 2024	April 2024
September 15, 2023	March 2024	May 2024	July 2024
January 12, 2024	June 2024	October 2024	December 2024
May 17, 2024	October 2024	January 2025	April 2025
September 13, 2024	March 2025	May 2025	July 2025



Contacts

Scientific/Research Contact(s)

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Next Up: Technical Assistance for the RC2 FOA

During the presentation send your questions to: CTSAFOAQuestions@mail.nih.gov

