

# Overview of the High Impact Specialized Innovation Programs (SIPs) RC2 FOA [PAR-21-340](#)

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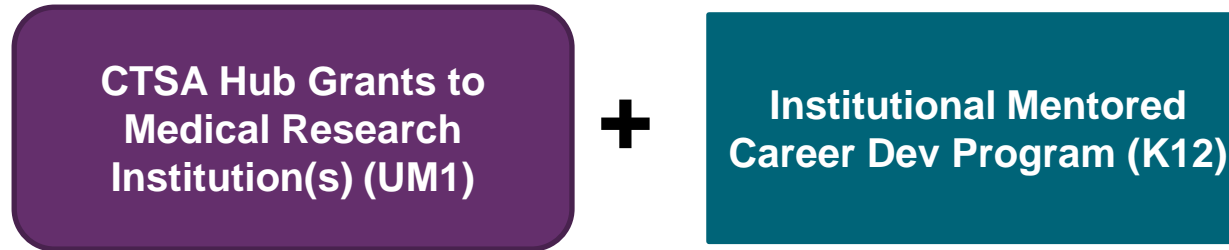
**During this presentation, please send your questions to:**

[CTSAFOAQuestions@mail.nih.gov](mailto:CTSAFOAQuestions@mail.nih.gov)

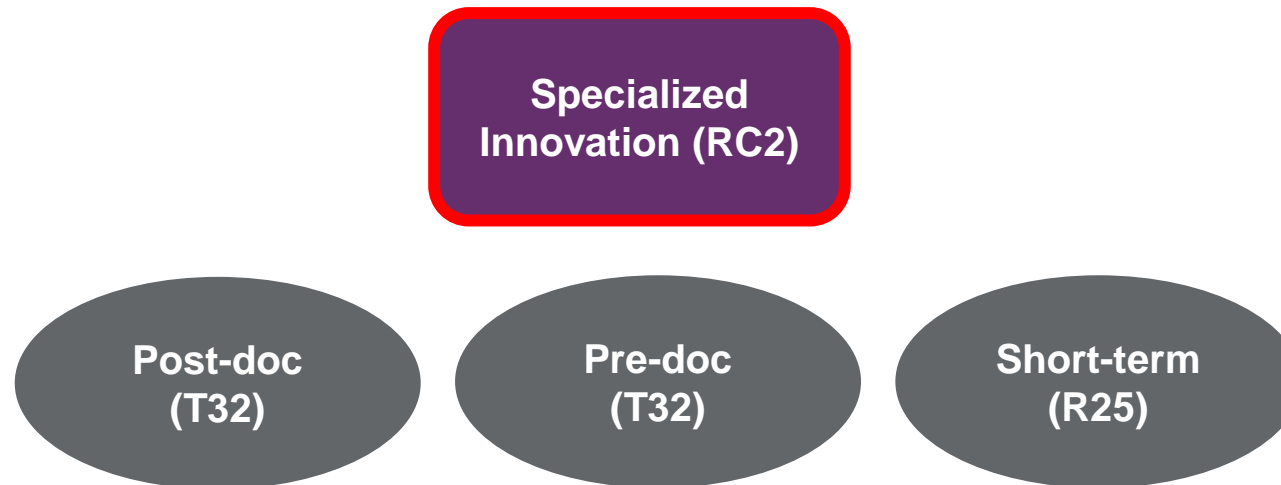


# Suite of CTSA FOAs

## REQUIRED



## OPTIONAL



# Overview

- Purpose, Description and Examples
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- Scope & Specific Requirements
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- Eligibility
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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**

- **Additional 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> (includes RC2 FAQs)

- **Questions?**

- UM1/RC2: [CTSAFOAQuestions@mail.nih.gov](mailto:CTSAFOAQuestions@mail.nih.gov)



# RC2 Relevant 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	<a href="#">NOT-TR-22-008</a>	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.
RC2	May 10, 2022	<a href="#">NOT-TR-22-023</a>	Notice of Special Interest (NOSI): Research through NCATS' Clinical and Translational Science Award (CTSA) Program: High Impact Specialized Innovation Programs (RC2)	Highlight interest in receiving grant applications focused in Digital Health Technologies



# Limited Competition: High Impact Specialized Innovation Programs in Clinical and Translational Science for UM1 CTSA Hub Awards (RC2 Clinical Trials Not Allowed)

## Purpose

The purpose of the High Impact Specialized Innovation Programs (SIPs) is to support the development and demonstration of unique hub capabilities, research platforms and/or resources to address in a timely manner critical gap areas and/or roadblocks in clinical and translational science at awarded UM1 Clinical and Translational Science Awards (CTSA) Program hubs ([PAR-21-293](#)). Successful programs supported through this funding opportunity are expected to lay a strong foundation for future adoption and/or dissemination of capabilities to additional CTSA Program hubs.



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# Funding Opportunity Description

- The SIPs are envisioned as part of the current innovation ecosystem to support the generation of a research resource and/or foster discovery-based or hypothesis-generating science that can have a **significant impact** in Clinical and Translational Science (CTS).
- Support novel approaches in areas that address specific knowledge gaps, scientific opportunities, new technologies/platforms, data generation, or novel research methods that will advance clinical and translational science (CTS) and research (CTR) **at CTSA UM1 hubs and possibly beyond.**
- Resources, activities, and expertise supported through the RC2 mechanism are expected to be available to enhance the **development and demonstration** activities or projects within a CTSA hub.



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# Examples of SIPs areas of interest

- Telehealth
- Regulatory science
- Clinical informatics
- Genetics and genomics
- Pragmatic trials resource support
- Dissemination and implementation
- Rural health
- Health disparities
- Community outreach and engagement
- Digital Health Technologies (see NOSI: [NOT-TR-22-023](#))
- Other areas of need for specialized programs



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# Notice of Special Interest (NOSI): Research through NCATS' Clinical and Translational Science Award (CTSA) Program: High Impact Specialized Innovation Program

**Digital Health Technologies (DHT)** that can be adopted and implemented for clinical and translational research. These technologies and approaches enable generation of novel data types that can give a more robust assessment of human health as well as subsequent perturbations due to disease and/or therapeutic intervention. DHTs include: wearables, mobile health (mHealth apps), ambient sensors, health information technology (IT), and other software as a medical device (SaMD) solutions. Digital health approaches incorporate any combination of computing platforms, connectivity, software, and/or sensors to generate digital biomarkers.

More information: [NOT-TR-22-023](#) (Released March 18, 2022)



# Scope and Specific Requirements

Through the RC2 mechanism, SIPs should address one or more of the following objectives:

- Groundbreaking, innovative, high impact and cross-cutting research, resources and/or activities that address one or more of the [CTSA Program Goals](#) and have the highest potential to improve and accelerate biomedical research.
- Programs in Clinical and Translational Science that could fundamentally enhance the research enterprise and that require the participation, interaction, coordination, and integration of activities within a CTSA UM1 hub and possibly beyond.
- Creation of large-scale unique resources and/or development of transformative technologies and/or platforms that can benefit a wide range of projects and/or activities related to CTS locally at CTSA UM1 hubs.
- High-impact discovery-based and hypothesis-generating science.

Inclusion of preliminary data in the applications is allowed, but not required.



# Application Types Allowed and Instructions

- **New**
- **Resubmission**
- **Clinical Trial?** Not Allowed: RC2s proposing a [NIH defined clinical trial](#) would be considered non-responsive and will not be reviewed. [Need help determining whether you are doing a clinical trial?](#)

**Applicants are encouraged to consult with Program Officials at NCATS on whether their study meets the definition of a clinical trial or not before submission.**

- **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](#)).



# Eligibility key points

- Only primary UM1 hub institution is eligible to apply as a prime (not partner or collaborator institutions).
- No more than two RC2 applications may be submitted.
- No more than two RC2 applications may be awarded to an active (not in an extension period) CTSA UM1 hub as a primary recipient, at a given time.
- Collaborations with other components of the CTSA UM1 hub and/or with institutions listed as partners and/or collaborators are encouraged. Also, collaborations with other CTSA UM1 hubs, UL1 hubs and with non-CTSA institutions are encouraged.



## Eligible Individuals (PD/PI)

- The PD/PI or contact PD/PI **must be employed** by and/or a recipient of funding from a currently funded CTSA Program UM1 hub prime institution as defined above in Eligible Organizations.
- Investigators who are not employed by and/or a recipient of funding from a CTSA Program UM1 hub institution but who wish to co-lead a SIP, can co-direct in partnership with a contact PD/PI who is employed by a currently funded CTSA Program UM1 hub institution using the multiple PD/PI option.



# Research Strategy key points

## ***Critical Need/Gap Area Addressed:***

Program uniqueness, gap areas in CTS to be solved, address one or more of the [CTSA Program Goals](#).

## ***Program Milestones:***

Table with key short and long-term milestones to be achieved throughout the RC2 program period. *Applications that do not include Program Milestones will not be reviewed.*

## ***Program Evaluation and Sustainability Plan:***

Clear plan to evaluate the success and impact of the proposed program based on pre-determined milestones and SIP utilization at participating institutions. *Applications that do not include the Program Evaluation and Sustainability Plan will not be reviewed.*



# Award Budget and Project Period

- Application budgets are limited to no more than \$500,000/year in direct costs excluding consortium/contractual F&A costs.
- It is recommended that the contact PD/PI devote at least one to two person months of his/her efforts to the project. No overlap of time or effort between this award and separately funded projects is permitted.
- Consultants and any associated costs (consultant fees, per diem, travel) may be included when their services are required and justified within the award.
- RC2 budget should include travel expenses for appropriate personnel (up to three people) to attend a yearly in-person meeting to present RC2 progress, lessons learned and impact.

**Requested project period may be up to 5 years.**



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## Section IV. Application and Submission Information

*If this attachment is not included, the application will be considered **incomplete and will not be reviewed.***

### The UM1 and RC2 Coordination and Integration Plan

- One attachment of **no more than 2 pages** in length called "UM1 and RC2 Coordination and Integration Plan" must be uploaded under Other Attachments.

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# Applications Not Responsive to PAR-21-340

The following types of applications will be deemed **nonresponsive and will not be reviewed:**

- Applications that propose:
  - Clinical Trial(s) according to the NIH definition of a Clinical Trial.
  - Feasibility/Pilot projects.
  - Dissemination and implementation of novel resources/activities at other hubs.
  - Ancillary studies or research that is a logical extension of ongoing work.
  - Core (or related) services to supplement the budgets of existing UM1 efforts.
  - Applications with Studies with a major emphasis outside of the NCATS Strategic Plan and the goals of the CTSA Program.



# Resource Sharing Plans

Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

The CTSA Program encourages sharing of resources with broad availability of policies, practices, materials, and tools to facilitate collaboration, reuse, and replication.

The Resource Sharing Plan must include the following:

- Software sharing
- Data sharing
- Model organisms
- Genomic data sharing



# Incomplete applications

Applications that do not include:

- Program Milestones
- Program Evaluation and Sustainability Plan
- Letter of Support from UM1 PD/PI
- Other Attachment: UM1 and RC2 Coordination and Integration Plan

**Will not be reviewed.**



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# Review and Selection Process

- Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by NCATS, in accordance with [NIH peer review policy and procedures](#), using the stated [review criteria](#). Assignment to a Scientific Review Group will be shown in the eRA Commons.
- As part of the scientific peer review, all applications will receive a written critique.
- Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- **The following will be considered in making funding decisions:**
  - UM1 parent application funding determination.
  - Scientific and technical merit of the proposed project as determined by scientific peer review.
  - Availability of funds.
  - Relevance of the proposed project to CTSA program priorities.



# Important Dates

Application Due Dates		Review and Award Cycles	
New	Scientific Merit Review	Advisory Council Review	Earliest Start Date
<b>May 13, 2022</b>	October 2022	January 2023	April 2023
<b>September 16, 2022</b>	March 2023	May 2023	July 2023
<b>January 13, 2023</b>	June 2023	October 2023	December 2023
<b>May 12, 2023</b>	October 2023	January 2024	April 2024
<b>September 15, 2023</b>	March 2024	May 2024	July 2024
<b>January 12, 2024</b>	June 2024	October 2024	December 2024
<b>May 17, 2024</b>	October 2024	January 2025	April 2025
<b>September 13, 2024</b>	March 2025	May 2025	July 2025

**PAR-21-340**

AIDS Receipt Dates: Not Applicable



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# Contacts

## Scientific/Research Contact(s)

Pablo Cure, M.D., M.P.H.

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## Peer Review Contact(s)

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## Financial/Grants Management Contact(s)

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National Center for Advancing Translational Sciences (NCATS)

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Email: [CTSAFOAQuestions@mail.nih.gov](mailto:CTSAFOAQuestions@mail.nih.gov)

**FAQs can be found under RC2 Companion Application tab:**

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



# Resources

- High Impact Specialized Innovation Programs FOA:  
<https://grants.nih.gov/grants/guide/pa-files/PAR-21-340.html>
- Notice of Special Interest (NOSI): Research through NCATS' Clinical and Translational Science Award (CTSA) Program: High Impact Specialized Innovation Programs (RC2).  
<https://grants.nih.gov/grants/guide/notice-files/NOT-TR-22-023.html>
- 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): <https://grants.nih.gov/grants/guide/notice-files/NOT-TR-22-008.html>
- FAQs Regarding UM1 and RC2 FOAs:  
<https://ncats.nih.gov/ctsa/funding/application-information-par-21-293>



## Next Up: Technical Assistance for the K12, R25 and T32 FOAs

*During the presentation send your questions to:*  
[CTSATrainingFOAQuestions@mail.nih.gov](mailto:CTSATrainingFOAQuestions@mail.nih.gov)

