NCATS Division of Clinical Innovation
Innovating Clinical and Translational Science

Plans, conducts, and supports research to develop new methods that enhance clinical processes

Plans, conducts, and supports research to evaluate existing approaches and technologies in the clinical spectrum

Allocates resources to clinical and translational infrastructure and investigators

Supports training programs relevant to clinical phases of translational science
NCATS Clinical and Translational Science Awards (CTSA) Program

- National network of medical research institutions and their partners/collaborators
- In fiscal year 2023, NCATS invested $629M in the CTSA Program to speed translation of research discoveries into improved patient care
CTSA Program Focus

- Develop, demonstrate, and disseminate innovations that turn science into health faster
- Promote impactful partnerships and collaborations
- Address health disparities
- Provide a national resource for the rapid response to urgent public health needs
- Promote training and career support
- Nurture emerging field of translational science
Suite of CTSA NOFOs

REQUIRED

- CTSA Hub Grants to Medical Research Institution(s) (UM1)
- Institutional Mentored Career Dev Program (K12)

OPTIONAL

- Post-doc (T32)
- Pre-doc (T32)
- Short-term (R25)
- High Impact Specialized Innovation (RC2)

IDENTIFICATION of processes & innovations that feed CTS

DEVELOPMENT of new approaches, technologies, resources and models

DEMONSTRATION of their utility

DISSEMINATION of the data, analysis and methodologies to the community
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Limited Competition: High Impact Specialized Innovation Programs in Clinical and Translational Science for UM1 CTSA Hub Awards (RC2 Clinical Trials Optional)

PAR-24-054

Reissue of PAR-21-340

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Jing Chen, Ph.D., Scientific Review

Victor Henriquez, Ph.D., Scientific Review

December 7, 2023

During this presentation, please send your questions to: RC2NOFO@nih.gov
What's new?

• Clinical Trials Optional
• Impact Statement
• New Attachments
• NOFO specific review criteria

Please send your questions to: RC2NOFO@nih.gov
Overview

- Purpose, Description, Scope and Examples
- Application Types Allowed & Instructions
- Eligibility Information
- Research Strategy
- Award Budget and Project Period
- Other Attachments
- Review & selection process
- Important Dates
- Contacts and Resources
- FAQs and Live Questions

Please send your questions to: RC2NOFO@nih.gov
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**DISSEMINATION**

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Purpose

The purpose of the High Impact Specialized Innovation Programs (SIPs) is to support unique activities, resources, capabilities and/or expertise at awarded CTSA UM1 (PAR-21-293) hubs to help advance one or more of the NCATS CTSA Program goals. The SIPs initiative is 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). Specifically, this NOFO seeks to support novel approaches in areas that address specific knowledge gaps, scientific opportunities, new technologies/platforms, data generation and/or analysis, or novel research methods that will advance clinical and translational science (CTS) and research (CTR) at CTSA UM1 hubs.

Funding Opportunity Description

• SIPs are expected to have a **significant impact** on Clinical and Translational Science (CTS).

• Address specific knowledge gaps that will advance clinical and translational science (CTS) and research (CTR) at CTSA UM1 hubs.

• Resources, activities, and expertise supported through the RC2 mechanism are expected to enhance the **development and demonstration** activities or projects within a CTSA hub.

• Highly **useful and transformative** to the broader clinical and translational science community.
Examples of SIPs

- Digital Health
- Decentralized trials
- Telehealth
- Pragmatic trials
- AI/ML algorithms in medicine
- Decision support systems
- Data science and novel statistical methods
- RWD/RWE
- Innovative CT designs
- Genetics and genomics
- Other areas of need for specialized programs
Scope and Specific Requirements:

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.

• Creation of unique resources and/or development of transformative technologies and/or platforms that can benefit a wide range of projects and/or activities at CTSA UM1 hubs.

• High-impact discovery-based projects or hypothesis-generating science.

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

Potential applicants are highly encouraged to contact NCATS Scientific/Research Contacts listed in this NOFO to discuss the scope of the project, required materials, responsiveness, and clinical trials status designation prior to submission of an application.

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 and UL1 hubs and with non-CTSA organizations are encouraged.
Application Types Allowed and Instructions

- New
- Resubmission
- **Clinical Trial?** Optional. Need help determining whether you are doing a clinical trial?

- **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 NOFO or in a Notice from NIH Guide for Grants and Contracts).

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.
PAR-24-054 (RC2 Clinical Trial Optional)

- A wide-range of clinical research can fit NIH’s definition of a clinical trial.
- See NIH’s definition of a clinical trial.
- Leverage NIH’s decision tool.
- Misclassified clinical trial applications may be withdrawn.

Note: NIH Clinical Trial-Specific Review Criteria Policy: The goal of this policy is to ensure that key pieces of clinical trial-specific information are submitted with each application and that reviewers appropriately consider this clinical trial-related information.

Sources:
https://grants.nih.gov/policy/clinical-trials/definition.htm
https://grants.nih.gov/policy/clinical-trials/review-criteria.htm
Eligibility

• All applicant organizations and/or active award recipients for PAR-21-293 Clinical and Translational Science Award (UM1 Clinical Trial Optional) are eligible to apply under this NOFO.

• Only the primary UM1 CTSA program hub organization is eligible to apply (not partner or collaborator institutions).

• RC2 companion optional applications may 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 applications will only be awarded if there is an awarded UM1 application from the RC2 applicant organization.
Additional Information on Eligibility

• UM1 hub institution can submit up to two RC2 applications for SIPs per cycle as the primary institution.
• A UM1 hub may have up to two RC2 SIPs awards as the primary recipient.

• A RC2 in extension period counts towards the maximum of two RC2s that may be awarded.
• A UM1 hub that is in an extension period is not allowed to submit RC2s as the primary recipient unless a pending UM1 application has been submitted or is under review or under funding consideration.

• Resubmission of a RC2 application without the required UM1 application is only allowed if the UM1 application is awarded.
Eligible Individuals (PD/PI)

- The PD/PI or contact PD/PI must be employed by and/or a recipient of funding and/or have an academic appointment from a CTSA Program UM1 hub prime institution as defined above in Eligible Organizations.

- Investigators from UM1 hub partners or collaborators who wish to co-lead a SIP, can co-direct in partnership with a contact PD/PI who is employed by and/or a recipient of funding and/or has an academic appointment at a CTSA Program UM1 prime hub institution using the multiple PD/PI option.
Research Strategy key points

*Critical Need/Gap Area Addressed:*

Describe how the proposed project is unique and how it is expected to solve a real gap or overcome a key roadblock in clinical and translational science. It is expected that the capability or resource will be in an area of need where there are currently no clearly available solutions/tools/resources or where the existing solutions are suboptimal.

*Impact:*

How the proposed RC2 could impact health and medicine?

If successful, how the proposed RC2 could be more broadly disseminated?

How does it change the landscape in CTS?
Programs are expected to demonstrate the following:

- Work cannot be reasonably expected to be carried out successfully without support provided by this NOFO.
- Promote and advance the [NCATS Strategic Plan](#) and, specifically addresses one or more of the [CTSA Program Goals](#).
- Accelerate the development of innovative resources, approaches, tools, solutions, therapies, diagnostics, devices and/or apps.
- Catalyze clinical and translational science locally at UM1 hubs
- Generated results and resources are expected to become integrated into the broader clinical and translational science community locally, regionally and/or nationally.
- Plan for sustainability of applicable research efforts and resources beyond the RC2 funding.
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 their 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.
SF424(R&R) Other Project Information

• Attachment 1 (Up to 2 pages) “UM1 and RC2 Coordination and Integration Plan”
• Attachment 2 (Up to 1 page) “RC2 Program Milestones”
• Attachment 3 (Up to 2 pages) “Program Evaluation and Sustainability Plan”

Applications that do not include one or more of these attachments will be considered incomplete and will not be reviewed.
Attachment 1: UM1 and RC2 Coordination and Integration Plan

• Applicants must provide a specific plan describing the collaboration, support, equipment, coordination, synergy and integration between the UM1 hub and any of its elements and modules and other UM1 companion NOFOs and the proposed RC2 Program.
Attachment 2: Program Milestones

• Applicants must include a table with **key milestones to be achieved throughout the RC2 program period**. Both short-term/interim (monthly or quarterly) and long-term (yearly) milestones should be clearly outlined in word table format. Each milestone should be constructed to succinctly include: (a) the goals and timeline for completion, (b) the criteria for success, including quantitative and/or qualitative metrics that will be used to assess success.
Attachment 3: Program Evaluation and Sustainability Plan

- Applicants must provide a clear plan to evaluate the success and impact of the proposed program based on the predetermined milestones and SIP utilization.

- List key metrics and measures of success to be utilized to evaluate the overall impact of the program and how success will be measured in an objective and tangible manner on a regular basis.

- In addition, outline plans for sustainability of the SIP beyond the RC2 grant period (once grant funding ends) and how do applicants envision their Specialized Innovation Program to continue through partnerships, collaborations, support, etc. after the RC2 ends.
Applications Not Responsive

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

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

Applications that do not include:
• UM1 and RC2 Coordination and Integration Plan
• Program Milestones
• Program Evaluation and Sustainability Plan
• Letter of Support from UM1 PD/PI

Will not be reviewed.
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

<table>
<thead>
<tr>
<th>Application Due Dates</th>
<th>Review and Award Cycles</th>
<th>Earliest Start Date</th>
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<tr>
<td><strong>New</strong></td>
<td><strong>AIDS - New/Renewal/Resubmission/Revision, as allowed</strong></td>
<td><strong>Scientific Merit Review</strong></td>
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<td>January 12, 2024</td>
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<td>June 2024</td>
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<td>May 17, 2024</td>
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<tr>
<td>September 14, 2026</td>
<td>Not Applicable</td>
<td>March 2027</td>
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All applications are due by 5:00 PM local time of applicant organization.
Contacts

Scientific/Research Contact(s)
Pablo Cure, M.D., M.P.H., Program
National Center for Advancing Translational Sciences (NCATS)
Telephone: 301-827-2014
Email: RC2NOFO@nih.gov

Peer Review Contact(s)
Victor Henriquez, Ph.D., Scientific Review Branch
National Center for Advancing Translational Sciences (NCATS)
Telephone: 301-435-0814
Email: RC2NOFO@nih.gov

Financial/Grants Management Contact(s)
Nichol Cleveland, M.Ed., Grants Management Branch (NCATS)
National Center for Advancing Translational Sciences (NCATS)
Telephone: 301-451-6331
Email: RC2NOFO@nih.gov
Resources

• Clinical and Translational Science Award (UM1 Clinical Trial Optional): https://grants.nih.gov/grants/guide/pa-files/PAR-21-293.html
Questions?