



Colorado Clinical and Translational Sciences Institute (CCTSI)

UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

CCTSI COVID-19-Related Research Pilot Grant Program (C2R2-Pilot) Request for Applications (RFA)

I. Funding Opportunity Summary

The Colorado Clinical and Translational Sciences Institute (CCTSI) is announcing **rapid review and funding** of CCTSI COVID-19-Related Research Pilot (C2R2-Pilot) grant applications. The C2R2-Pilot Program will support the development of novel diagnostic and treatment methods and innovative technologies related to the COVID-19 outbreak. This will include, but not be limited to, proposals focused on diagnosis of COVID-19 and its complications; evaluation and management of COVID-19, including early phase treatment trials; protection of healthcare workers and rapid development and deployment of PPE; and approaches to protect the public after the initial extreme quarantine period. Proposals for screening and testing approaches for COVID-19 will only be considered if novel. **This RFA is clinically oriented and very time-sensitive. It is meant for an immediate translation or implementation into clinical management of COVID-19 crisis, protection, or recurrence.**

II. Key Information

Award Amount: \$25,000, Direct Costs Only

Award Duration: 1 year

Award Period: April 2020 –April 2021

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CCTSI Pilot Grant Program Coordinator
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III. Important Dates

3/31/2020	RFA Release
4/3/2020	Application Submission Deadline 5:00 PM MDT
4/9/2020	Notification of Selection for awards
4/10/2020	Earliest start of one-year active funding period

IV. Purpose

The CCTSI COVID-19-Related Research Pilot Program (C2R2-Pilot) will provide one-year awards to promote development of novel diagnostic and treatment methods and innovative technologies related to the COVID-19 outbreak. This will include, but not be limited to, proposals focused on diagnosis of COVID-19 and its complications; evaluation and management of COVID-19, including early phase treatment trials; protection of healthcare workers and rapid development and deployment of PPE; and approaches to protection of the public after the initial extreme quarantine period. The COVID-Pilot Program supports the development of novel diagnostic and treatment methods and innovative technologies related to the COVID outbreak. **This RFA is clinically oriented and very time-sensitive. It is meant for an immediate translation or implementation into clinical management of COVID-19 crisis, protection, or recurrence.**

We hope that in the near future we will be able to offer additional support for all important basic science application, but they are not a focus of the present C2R2-Pilot program.

V. Funding Priorities

- Proposed projects must represent the rapid development, deployment, and/or testing of assays, treatments, devices, software, standard operating procedures, or technology to address the COVID-19 outbreak in its various phases.
- The use of institutional state-of-the-art technology available from [CCTSI Resources](#) and [CU Cancer Center Shared Resources](#) and [AMC Research Core Facilities](#) and [Biostatistical Epidemiology and Research Design \(BERD\)](#) for C2R2-Pilot projects are highly encouraged, but they are not required to do so if not applicable to the project OR if they can justify use of alternate resources.
- Cross-disciplinary, cross-campus, and collaborative projects are encouraged.

VI. Available Funding

Each award is for up to \$25,000 (direct costs) for one year. All C2R2-Pilot funds are distributed to CCTSI Affiliated Institutions only, so there are no cost-share budget reviews required.

VII. Definitions

CCTSI Affiliated Institutions: University of Colorado Anschutz Medical Campus, University of Colorado Boulder, Children's Hospital Colorado, Colorado State University, Denver Health, Kaiser Permanente of Colorado, National Jewish Health, University of Colorado Denver, University of Colorado Hospital, VA Eastern Colorado Health Care System (see the CCTSI website for information about [CCTSI Affiliated Institutions](#)).

Clinical Trials: The NIH defines clinical trials as clinical research studies involving human participants assigned to an intervention in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related biomedical or behavioral outcome.

Key Roles: Principal Investigator, co-Principal Investigator, co-Investigator (all must be CCTSI Affiliated Faculty)

Non-Key Roles: Consultants, Advisory Committee, etc. (Professional Research Assistants, Graduate Students, Undergraduate Students, Fellows, Postdoctoral students are encouraged)

Translational research: Translational research is intentionally broadly construed and includes any basic (animal or laboratory), pre-clinical, clinical, behavioral, community-based, and population based translational research with promise to improve human health.

Underrepresented, minority, and female researchers: Groups that have historically been underrepresented in biomedical research include, but are not limited to: women, African Americans, Hispanic Americans, Native Americans (including Alaska Natives), natives of the U.S. Pacific Islands, individuals with disabilities and individuals from socially, culturally, economically or educationally disadvantaged backgrounds that have inhibited their ability to pursue research careers.

VIII. Eligibility

- The Principal Investigator, the co-Principal Investigator, and all co-Investigator(s) all must hold Instructor level or above faculty appointments within a CCTSI Affiliated Institution. (See the CCTSI website for list of [CCTSI Affiliated Institutions](#)).
- All individuals in Key Roles must be CCTSI Members at the time of application. Verify membership status and/or sign up for free membership via the [CCTSI Membership](#) webpage.
- Investigators from non-CCTSI Affiliate Institutions may participate in Non-Key Roles only. They must collaborate with a faculty (Instructor level and above) from a CCTSI Affiliated Institution who would be eligible to serve as PI on an application.
- Underrepresented in medicine, female, and minority researchers are particularly urged to apply, as the CCTSI intends to contribute to the creation of a research workforce that is representative of the U.S. population.
- Graduate, undergraduate, postdoctoral students, fellows and PRAs are encouraged to participate in Non-Key Roles.

IX. Exclusions/Restrictions

- Award funds can only be used to support research at CCTSI Affiliate Institutions. Support of research at non-CCTSI Affiliate Institutions or outside the United States is not allowed.
- Any clinical trials proposed in CCTSI Pilot applications are restricted to Phase I or Phase IIA. Clinical trials in Phase IIB, Phase III or Phase IV will not be supported.

X. Pre-Application Policies

Affiliate home organizations may require applicants to complete an internal review process prior to submission. Applicants should check with their institutional grants or sponsored projects office to ascertain if their institution has pre-submission requirements for programs related to non-federal internally funded seed grant programs. Any awarded projects that have not met these requirements prior to submission will not be activated until all such affiliate institutional requirements are met.

- **CU Anschutz and CU Denver Investigators:** Applications do not require official pre-award review (routing) through the CU Denver Office of Grants and Contracts (OGC) prior to submission.
- **CSU Investigators:** Applications do not require official pre-award review (routing) through the CSU Office of Sponsored Programs (OSP) prior to submission, but will require post-submission review if the expedited review committee move the proposal forward based on scientific merit. Please contact Aimee Oke (aimee.oke@colostate.edu) for details.
- **CU-Boulder applicants:** You are required to complete an internal review process prior to receiving an award, but no prior approval for applying is required.

XI. Required Application Documentation

Applicants may use standard PHS 398 forms, although this is not required. Format must be Arial 11 pt. font, single-spaced, with ½ inch margins. PDF format is preferred, but Word is also accepted. File naming convention: PILastName_DocumentName

1. Abstract (limit 250 words)

- Provide a concise summary of the project for application review and announcement of awards.
- Include overall goal, anticipated outcomes, and how the research meets RFA objectives.

2. Research Plan (4-page limit)

- Incorporate information on background and preliminary studies, where appropriate, and information on use of CCTSI resources (or rationale for using alternative resources). Applicants are highly encouraged to use institutional state-of-the-art technology available from [CCTSI Resources](#) and [CU Cancer Center Shared Resources](#) and [AMC Research Core Facilities](#) and [Biostatistical Epidemiology and Research Design \(BERD\)](#) for C2R2-Pilot projects, but they are not required to do so if not applicable to the project OR if they can justify use of alternate resources.

2.1 Specific Aims (limit ½ page)

- Provide a clear, concise summary of objectives and specific aims.

2.2 Background and Significance (limit 1 page)

- Explain the importance of the problem or barrier to progress in addressing the COVID-19 outbreak.
- Describe how management of the current or subsequent phases of the COVID-19 outbreak will be changed if the proposed aims are achieved.
- Preliminary data that show PI expertise in the proposed area of the pilot is encouraged, but not required.

2.3 Approach (suggested 1-2 pages)

- Describe the overall strategy, methodology, and analysis to be used to accomplish the specific aims of the project within the one-year timeline.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- Describe proposed tests, procedures, participant population and ages in enough detail to allow an adequate evaluation of your approach. If appropriate, please indicate if the protocol has already been IRB approved but do not include the IRB protocol with the submission.

3. References (no page limit)

4. Budget and Justification (2-page limit)

- Award funds can only be used to support research at CCTSI Affiliate Institutions. Support of research at non-CCTSI Affiliate Institutions or outside the United States is not allowed.
- All applications must provide a one-year budget (including other project support) and budget justification consistent with NIH requirements.
- Each award is for up to \$25,000 (direct costs) for one year.
- All C2R2-Pilot funds are distributed to CCTSI Affiliated Institutions only, so there are no cost-share budget reviews required.
- Clearly define the project expenses with cost categories relevant to the project, such as Personnel, Supplies, Lab Testing, Animals, Human Subjects, etc.
- While salary support commensurate with percent effort is allowed for PI and personnel from CCTSI Affiliated Institutions, this is subject to NIH salary cap restrictions.
- Salary support for individuals in Non-Key roles, who are also employed by CCTSI Affiliated Institutions, may be included in the budget. Salary support for individuals in Non-Key Roles who are not at CCTSI affiliates is not permitted.
- Proposals that utilize institutional state-of-the-art technology available from [CCTSI Resources](#) and [CU Cancer Center Shared Resources](#) and [AMC Research Core Facilities](#) and [Biostatistical Epidemiology and Research Design \(BERD\)](#) for C2R2-Pilot projects are highly encouraged. If you are using other facilities for your research, include your rationale in your Budget Justification.
- Describe any other sources of funding that are involved in this project and any other sources of funding that may have been sought in the Budget Justification.

- Unallowable expenses include but may not be limited to: non-CCTSI Affiliate Institutions budgets, international entities, computers, telecommunications, food, furniture, administrative support, non-project specific office expenses, and professional dues/fees.

5. Biosketches (current NIH format and page limit)

- A Biosketch in current NIH format and page limit is required for all individuals in Key Roles (Principal Investigator, co-Principal Investigator, co-Investigator).

6. Letters of Support (no page limit)

- There is no limit to the number of Letters of Support you include in your application.

6.1 Institutional Prior Approval LOS: For CSU Investigators

- Applications do not require official pre-award review (routing) through the CSU Office of Sponsored Programs (OSP) prior to submission, but will require post-submission review if the expedited review committee move the proposal forward based on scientific merit. Please contact Aimee Oke (aimee.oke@colostate.edu) for details.

6.2 Institutional Prior Approval LOS: For Investigators Outside CU Denver and AMC

- CCTSI Affiliate home organizations may require applicants to complete an internal review process prior to submission. Applicants should check with their institutional grants or sponsored projects office to ascertain if their institution has pre-submission requirements for programs related to non-federal internally funded seed grant programs. If so, documentation of compliance must be submitted with the application.

6.3 Other Financial Commitments LOS (if applicable)

- Letter(s) of support from the authorized official(s) from external organizations, departments, or non-CCTSI Affiliated Institution collaborators with cost-share requirements who have agreed to honor their financial commitment must be submitted with the application.

6.4 Other Letters of Support (optional)

- Letters of Support may be included from department chairs, consultants, foundations, commercial sources, manufacturers, etc.

XII. Application Process

Submission Method: The mandatory Intent-to-Submit Form (LOI) and Application Form may only be submitted online via the CCTSI [C2R2-Pilot Program](#) website or by clicking the link below:

[**CLICK TO APPLY**](#)

If an applicant intends to apply for funding for multiple projects, then each project must be submitted separately online. All submissions will be time-stamped. Submissions received after the 5pm MDT deadline will not be accepted. The online system will allow you to save, exit, return, review, and revise your submission as often as you wish using the “Save and Return Later” function up until the 5pm MDT submission deadline.

XIII. Review Process

The CCTSI Executive Committee, supplemented with Peer reviewers with appropriate expertise, will evaluate applications with a specific emphasis on research that rapidly addresses the COVID-19 outbreak. The Review Panel will be chaired by CCTSI C2R2-Pilot Program Director. All Executive Committee decisions are final.

XIV. Review Criteria

Innovation: Will the proposal enhance diagnosis and/or management of COVID-19 or protect healthcare workers and the public as outlined in the RFA? Is the proposal innovative and novel?

Approach/Scientific Merit: Will the proposed study design achieve the proposed aims? What is the likelihood of success given the proposal as outlined? How feasible is the proposed one-year time frame?

Significance (especially to the management of COVID-19): Can the new method or technology be generalized and translated rapidly?

Investigators: Do the investigators have the necessary expertise and capacity to complete the proposed research? Is all necessary expertise present?

Environment: Does the research environment improve the likelihood that the proposed research can be completed and have an impact? Does the proposal consider use of CCTSI resources, including Study Design, Biostatistics, CTRCs, Core laboratories, and/or Bionutrition core?

XV. Post-award Requirements

Regulatory Requirements: All approvals/exemptions from appropriate review bodies or regulatory groups must be provided by the successful PI prior to the release of funds. This includes, but is not limited to: COMIRB, IACUC, Biosafety, IBC, Children's Hospital Research Institute (CHRI), CSU IRB, and/or other regulatory groups relevant to the proposal and applicant's institution.

- **Human Subject Research (HSR) and/or Vertebrate Animal Research (VAR) Studies:** Official institutional documentation of approval/exemption must be submitted to CCTSI by the PI prior to the release of funds (e.g., COMIRB and/or IACUC or equivalent).
- **CTRC projects:** PIs are required to obtain Scientific Advisory and Review Committee (SARC) approval for all projects using CTRC resources (inpatient/outpatient research facilities, clinical research nursing support, nutrition research support, exercise research laboratory, and CTRC Core Lab support).
- **Applicants should consider whether consultation with CU Innovations would be appropriate for novel or patentable methods or technology.**

Monthly Reporting: If funded, PIs must report monthly during the pre-award period to the CCTSI Pilot Program Coordinator, Debra Szuster (debra.szuster@cuanschutz.edu) regarding progress toward completion of all Pilot Program and regulatory requirements. Applicants are strongly encouraged to demonstrate capacity in their application to obtain regulatory approvals as soon as possible upon notification of selection for the award.

Active Awards: PIs will have until April 2021 to complete their projects. No-cost extensions are granted on a very limited basis for extraordinary circumstances and may not be allowed on all programs.

Annual Reporting: The CCTSI is required to submit a detailed annual progress report to the NIH that includes the progress of all funded pilot projects. In December 2021, PIs will be asked for brief information on publications and follow-on funding resulting from CCTSI-funded pilot projects. Prompt cooperation in providing the required information is expected. PIs must complete tracking and evaluation requirements for 3 years after award.

Citing CCTSI Funding: Please refer to the CCTSI webpage on [How to Cite the CCTSI Grant](#) for all publications, patents, or other tangible outcomes from this project during and after project completion.

XVI. Questions

Please refer to the CCTSI [C2R2-Pilot Program](#) website for information regarding: Frequently Asked Questions, Informational Calls, CCTSI Resources, Application Guidelines and Checklist, and for Award Information, etc. For questions not addressed in the RFA or FAQs, please contact:

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