Advance RI-CTR
Advance Rhode Island
Clinical & Translational Research
Cite: U54GM115677

Grant Resubmission Awards (Special Opportunity)

Request for Applications

Advance-CTR is pleased to offer the clinical and translational research Grant Resubmission Awards special opportunity, which is open to all investigators with a faculty appointment at a degree-granting institution in Rhode Island.

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Status: *Open*
Applications are accepted/awarded on a rolling basis. Regulatory approvals (e.g., IRB, IACUC) must be in effect at the time of submission.

Funding duration:
Up to 8 months as justified

Funding:
Up to $20,000 direct costs (requests for higher amounts may be accepted if justified); indirects will not be provided.

Contact:
Advance-CTR advanceri@brown.edu

Eligibility

Any faculty member at a degree-granting institution in Rhode Island is eligible for award. Emeritus, adjunct, and visiting faculty, as well as post docs, are not eligible to lead projects, but may be included on the research team.

Investigators with other IDeA funding (e.g., COBRE, INBRE) that would temporally overlap with this award are **not** eligible.

Mentors: Proposals led by investigators who meet the NIH definition of a new investigator **must** identify a suitable mentor, and include the proposed mentor's Letter of Support demonstrating the mentor's willingness to participate as well as support the applicant and project. Mentors with prior experience as PI on a NIH-funded grant are preferred.

Overview

In recent years, funding for research has become increasingly competitive, with success rates for leading federal research agencies well below 20 percent. This means that many highly-rated proposals are not selected for funding, particularly on the first submission, calling for improvements to compete successfully in a subsequent round.

The Advance-CTR Grant Resubmission Awards provide support for investigators to improve an already highly rated clinical or translational science research proposal for re-submission. We encourage individuals with highly rated but unfunded proposals of all sizes to apply.

Advance-CTR was established by an Institutional Development Award to improve program infrastructure for Clinical and Translational Research (IDeA-CTR) from the National Institute of General Medical Sciences (NIGMS). The aim of Advance-CTR is to support both the infrastructure development and resources required to conduct clinical and translational research in Rhode Island in order to enhance collaboration and coordination of state-wide clinical and translational research activities. Advance-CTR seeks to connect researchers and support institutions across Rhode Island with the common goal of advancing clinical and translational research that is responsive to Rhode Island's community health priorities. Through its interdisciplinary model, Advance-CTR supports research along the translational science spectrum, including basic science, clinical, and public health efforts, to improve the health of Rhode Island residents.

For the purpose of these awards, clinical and translational research are defined below:

Clinical research comprises research with human subjects that is:

- Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator directly interacts with human subjects. Excluded from this definition are *in vitro* studies that utilize human tissues that cannot be linked to a living individual.
- Epidemiological and behavioral studies.
- Outcomes research and health services research.

Translational research aims to convert basic research advances to practical applications in humans, and research aimed at the adoption of best practices in community health care.

UFunds will be used for application submissions. A Brown University ID is required to access UFunds. Non-Brown faculty should email advanceri@brown.edu to request a sponsored ID for this application.

Funding Available

Awards are for up to $20,000 (direct costs **only**). Requests for larger awards will be reviewed on a case-by-case basis. If requesting above the $20,000 limit, please include a justification for why a larger amount would be necessary and impactful for your project.

Funds may be used to support activities including data gathering, travel, equipment time, purchase of supplies or other modest activities that could make a significant difference for the competitiveness of the proposal. The funds may be used to support reasonable and necessary costs for the collection of research data or for proposal development. For smaller grants, we would encourage investigators to ask for more modest amounts of support for resubmission.

PI salary is allowed, but will be reviewed carefully considering the scope of PI roles. Investigators providing effort without salary support are considered cost shared and must obtain a letter from an authorized organizational official (e.g., Director of Sponsored Projects Office) approving the cost share. Please reference the Letters of Support section below.

Performance Period

The project performance period will be from the date of award notice through July 31, 2023. While it is anticipated that awards will be released on **a rolling basis,** Notice of Award release is dependent on approval of the project from NIGMS. No expenditures may take place prior to the Notice of Award. No extensions will be given.

Please note: Grant Resubmission Award proposals that will require Human Subjects or vertebrate animals will take longer to acquire approval. Having IRB or IACUC approval from your institution will be required. If the approval is not through Brown, an IAA for human subject projects or collaborative MOU for animal research will need to be completed at the time of selection. Please note: IRB and IACUC approval requirements apply only to the research being proposed to, and to be conducted with funds from,

Advance-CTR's Grant Resubmission Award, not to the general research proposed for the project you intend to resubmit externally.

Application Conditions

Full proposals that received the following agency feedback within the previous two years are eligible. Proposals must have also been discussed during the previous submission:

Agency	Rating
National Institutes of Health*	Must have been discussed, no specific rating required
National Science Foundation*	Excellent or Very Good from the majority of reviewers
Other agencies or foundations – please consult first with Advance-CTR: advanceri@brown.edu	As ratings criteria vary by organization, applicant must demonstrate that the proposal was highly-rated and close to receiving funding.

*Applicants preparing a grant resubmission that involves a two-stage application (pre-application and full-application) must have resubmitted the pre-application and have been invited to submit a full application to be eligible.

Grant Resubmission Award funds are meant to be a modest and narrowly targeted investment that could make a significant difference in the success of a specific proposal resubmission.

If your project needs are more substantial, we encourage you to contact Advance-CTR to discuss other ways the CTR could assist you. Please inform Advance-CTR if subsequent to either Grant Resubmission Award application or award, the PI receives agency notification of funding or likelihood of funding of the original proposal.

Proposal Submission Instructions

Proposals for funding must be submitted electronically via the UFunds application portal. Proposals are accepted, reviewed, and selected for funding on a rolling basis. Applicants must have regulatory approvals (e.g., IRB, IACUC) in place before submitting an application.

Proposal Content

All proposal materials must be submitted in UFunds. Your submission must contain:

1. Administrative information, including PI contact information, titles, departments, proposal title (as requested by the UFunds application page).
2. Signed NIH Face Page
3. Project Summary (PHS 398 Form Page 2)
4. No more than a two-page project description including:
    a. List of limitations in the original application identified by sponsor reviewers and a description of the work that would be completed through this Grant Resubmission Award to address those limitations. Include discussion of how this award will lead to a successful resubmission of the original application.
    b. Timeline for the work proposed to be completed through this award mechanism, including the planned resubmission timeframe.
    c. Sponsor name and sponsor program to which the PI plans to re-apply.
5. Grant Resubmission Award Budget (PHS 398 Form Page 4)
    a. Itemize categories of expenses for which award funds will be used.
    b. Use a performance period of up to 8 months with an end date of 07/31/23 when completing this form.
    c. If funds would be distributed across institutions, a separate budget must be submitted for each institution.
6. Grant Resubmission Award Budget Justification
    a. Provide a brief justification for the expenses identified in PHS 398 Form Page 4.

    b. If funds would be distributed across institutions, a separate justification must be submitted for each institution.
7. For Brown University budgets only: Checklist Form indicating Indirects (PHS 398 Checklist Form Page)
    a. Complete **Section 3 only**, "Facilities and Administrative Costs" using the home institution's F&A rate.
8. A short (two-pages maximum) list of references/bibliography may be appended but is not required.
9. Active/Pending Other Support for all Key Personnel (PHS 398 Other Support Format Page).
    a. Example available here for reference.
10. For projects including Human Subjects include CITI, and HIPAA training certificates for all Key Personnel. If appropriate, also include Good Clinical Practice training certificates.
11. IRB and/or IACUC approval letters, if applicable to the proposed research under the Grant Resubmission Award.
    a. If the project title and the title of the IRB are different, a letter from the PI of the IRB project stating the provided IRB approval covers the scope of the proposed project is required.
12. A copy of the original proposal and the reviewer comments (submitted as separate PDFs).
13. Rough estimate of the total budget for resubmission: direct and indirect costs for each budget year of the project and the total for full project period. Please use PHS 398 Form Page 4 and Page 5.

All application materials will be kept confidential within Advance-CTR.

Regulatory Information

If either Human Subjects or Vertebrate Animals are used in the proposed research for the Grant Resubmission Award, be sure to address these sections as described below. Be sure to include all IRB and IACUC approval letters as applicable to your proposed research (**note: approvals must be obtained prior to submission**). Human Subjects education certification must be up-to-date and uploaded in the Other Attachment Section of UFunds.

Human Subjects and Clinical Trial Information

The Advance-CTR Human Subjects and Clinical Trial Information Form must be completed for ALL projects.

Non-Human Subjects projects are required to complete the Advance-CTR Human Subjects and Clinical Trial Information Form, items i.- iii.

Human Subjects projects must include:

- The Advance-CTR Human Subjects and Clinical Trial Information Form and associated Study Record. Complete the form using the built-in instructions.
- The Advance-CTR Enrollment Report form following NIH instructions.
- HIPAA and CITI certificates (and Good Clinical Practice, if applicable) for all Key Personnel

Vertebrate Animals Section

Refer to Section 5.5.10 PHS 398 Instructions and the Worksheet for Applications Involving Animals. All applicants must complete the vertebrate animals section questions on the G.220 – R&R Other Project Information Form (questions 3-12 should not be completed). Please follow the form-specific instructions.

If vertebrate animals are involved, address each point below. Provide a concise, complete description of the animals and proposed procedures. While additional details may be included in the Research Plan, the responses to the four required points must be cohesive and include sufficient detail.

If all or part of the proposed research involving vertebrate animals will take place at alternate sites (such as project/performance or collaborating site(s)), identify those sites and describe the activities at those locations.

Although no specific page limitation applies to this section, be succinct. Failure to address the following four points will result in the application being designated as incomplete and will be grounds for NIGMS to defer approval of the application. The three points are as follows:

1. Description of Procedures: Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the "Research Plan" attachment. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.
2. Justifications: Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g. computational, human, invertebrate, in vitro).
3. Minimization of Pain and Distress: Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints that will be used to minimize discomfort, distress, pain, and injury.

Do not use the vertebrate animal section to circumvent the page limits of the Research Plan.

Biosafety/Select Agents (if applicable)
Refer to Section 5.5.11 PHS 398 Instructions. Indicate Institutional Safety Committee approvals.

Letters of Support

1. Research Administration:
    a. If the Contact PI is **not employed by Brown University**, a signed Letter of Intent from the Contact PI's office of research administration should be included.
    b. For co-PI's **not employed by Brown University**, a signed letter from the co-PI's Research Administration should be included.
2. Department Chair(s): Letter(s) from the Department Chair(s) and/or supervisor(s) **for each investigator** documenting the availability of protected time for research must be included. The Investigator name(s) and title(s) must be included in the letter.
3. Mentor(s): Letter(s) from the Mentor(s) agreeing to advise on the conduct of the proposed research and describing plans for mentoring investigators who meet NIH criteria for "new" investigators must be included with the application.
4. Investigators providing effort without salary support are considered cost shared and must obtain a letter from an authorized organizational official (e.g., Director of Sponsored Projects Office) approving the cost share.

Application Format

Please use the following formatting for your application:

Font: Arial, Helvetica, Palatino Linotype or Georgia typeface and a font size of 11 points or larger must be used. A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies. A smaller font size may be used for figures, graphs, diagrams, charts, tables, figure legends, and footnotes, but this type must follow the font typeface requirement and be readily legible.

Margins: Margins should be 0.5 inch.

Assistance with Resubmission

Advance-CTR offers Service Cores (Biostatistics, Epidemiology, and Research Design, Biomedical Informatics, and Clinical Engagement & Outreach Core) that can provide advice and assistance with Grant Resubmission Awards and the resubmission of proposals to original agencies. Applicants are

strongly encouraged to review available services on the Advance-CTR website and submit service requests for any inquiries.

Criteria for Selection

The overall merit of the research project and the likelihood that funding will make the proposal more competitive will be considered and evaluated by a Council comprised of Advance-CTR Leadership in consultation with other faculty reviewers, as needed. The final selection will be made based on the following criteria:

- Responsiveness to the RFA
- Potential for the award to provide a basis for a more competitive re-submission to external sponsors
- Likelihood that the proposed work will be completed during the award period
- Size and significance of the research award being sought
- Rating of the original submission
- Community Engaged Research
- Potential impact of the research on the clinical or translational field of study
- Relevance to the RI health priorities, as defined by the Department of Health:
    - Communicable Diseases (HIV, Hepatitis C)
    - Substance use
    - Obesity
    - Chronic illnesses (diabetes, heart disease, asthma, cancer)
    - Health of mothers and their children
    - Senior health
    - Behavioral health and wellness
    - Recovery and rehabilitation
    - Pediatric/Perinatal care

Preference will be given to projects that propose utilization of the Advance-CTR Service Cores. Junior investigators will also be prioritized.

Review Process

Reviews of applications will be conducted by the Advance-CTR leadership and potentially others who have content area or methods expertise relevant to the individual proposals. All reviewers will be highly qualified faculty from Brown University, University of Rhode Island, and/or affiliated hospitals.

Funding is dependent upon final review and approval by the Advance-CTR External Advisory Committee and by NIGMS. Since **NIGMS requires IACUC and IRB approval PRIOR to funding,** applicants must have obtained all regulatory approvals by the time of application to this grant mechanism. Please be aware that awards that do not involve Human Subjects or vertebrate animals will be able to be funded more expeditiously.

Expectations

Investigators selected for an award will be expected to:

1. Present a seminar describing their project and results at a translational research seminar series.
2. Complete FCOI assurance and training as detailed under their respective organization's policy.
3. Acquire an ORCID identifier.
4. Maintain an updated VIVO profile if Brown University-affiliated.
5. Attend all required Advance-CTR-related seminars and conferences (to be specified).
6. Complete quarterly progress reports.
7. Complete a project-end report within one month of award completion.
8. Complete an Advance-CTR survey at the end of the funding period.

9. Acknowledge sponsorship from Advance-CTR supported by the IDeA-CTR grant (U54GM115677) in all publications stemming from this research.
10. Report all presentations, publications, and extramural funding that arises from this award to Advance-CTR.
11. Respond to Advance-CTR queries for information after the grant ends.

Questions

Address inquiries regarding the Advance-CTR Grant Resubmission Awards to advanceri@brown.edu.