2025 Pilot Projects Program

Request for Applications (RFA)

Awards:
Category 1: Up to $50,000 (direct costs only)
Category 2: Up to $100,000 (direct costs only)

Contact: AdvanceRI@brown.edu

FAQ: Advance RI-CTR Pilot FAQ

Submission Deadlines:

- *Preliminary Applications:* October 28, 2024
- *Invited Full Proposals:* January 13, 2025

PROPOSAL SUBMISSION DEADLINES AND AWARD ANNOUNCEMENTS

Preliminary Application

Interested applicants are **required to submit a Preliminary Application** through the UFunds Portal no later than **Monday, October 28, 2024 at 5pm ET**. Those with Brown emails can directly access the UFunds Portal, those without a Brown email address should reach out to advanceri@brown.edu to be provided with access no later than October 22nd. See below Preliminary Application Submission Instructions Section for instructions to prepare preliminary application.

Invitations to submit a full proposal will be announced on or around **Monday, November 11, 2024**.

Applicants may request a call with Advance RI-CTR Pilot Project Leadership to discuss eligibility requirements, or other questions related to the RFA. However, most Frequently Asked Questions can be found here.If your question is not answered in the FAQ section, and you would like to schedule a call, please email AdvanceRI@brown.edu to schedule a call no later than **October 14, 2024**.

Full Proposal

Invited full proposals must be submitted no later than **Friday, January 13, 2025 at 5pm ET** through the UFunds Portal Pilot Project award announcements are anticipated to be communicated by email to applicants on or around **Friday, March 7, 2025**. See below Full Proposal Submission Instructions Section for instructions to prepare the full application.

OVERVIEW

Advance RI-CTR

The aim of Advance RI-CTR is to support both the infrastructure development and resources required to conduct clinical and translational research in Rhode Island and order to enhance collaboration and coordination of state-wide clinical and translational research activities. Advance RI-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 RI-CTR supports research along the translational science spectrum, including basic science, clinical, and public health efforts, to improve the health of Rhode Island residents.

Advance RI-CTR Pilot Projects Program

The Advance RI-CTR Pilot Projects Program seeks to identify talented young investigators who are new to clinical and translational research and based at Brown University, University of Rhode Island, and/or an affiliated health care system (Lifespan, Care New England, Providence VA). The Pilot Projects Program also aims to support new collaborations among investigators. Pilot projects will be funded for one year.

For the purpose of this Program, 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 applications in humans and/or research aimed at the adoption of best practices in community health care.

AWARD CATEGORIES & ELIGIBILITY REQUIREMENTS

Funding Availability & Categories

The 2025 Pilot Projects Program can award up to 8 pilot projects for one-year research grants. Funding will consist of direct costs ***only.***

Category 1: Proposals with a single PI may apply for up to $50,000 in direct costs.

Category 2: Proposals involving at least two PIs (e.g., Multi-PI's) may apply for up to $100,000 in direct costs.

ELIGIBILITY REQUIREMENTS

All Pilot Projects must meet the below **General Eligibility Requirements**.

1. All PIs (Contact or MPI) need to meet the following requirements:
    a. Must possess health-professional or research doctoral degree(s)
    b. Hold a faculty appointment at Brown University or the University of Rhode Island at the time the Pilot Project award commences.
    c. No concurrent funding from a COBRE project or another IDeA mechanism of support at the same time as Advance RI-CTR Pilot Project funding.
2. All projects must identify at least one mentor. Projects may have more than one mentor, depending on needed expertise. Mentor(s):
    a. Are required to be faculty (*Associate Professor* level or above) at an Advance RI-CTR affiliated health care system (Lifespan [Brown University Health], Care New England, VA Providence), Brown University or the University of Rhode Island.
    b. Should be researchers in the field related to the proposed project with experience and demonstrated success as research supervisors.
3. The proposed Advance RI-CTR Pilot Project should not have significant scientific or budgetary overlap with another funded project.

4. Meet all other eligibility requirements for the Category they are applying to (see below).

Category 1 (Single PI Projects: up to $50,000)

In addition to the **General Eligibility Requirements**, to be eligible for a Category 1 Pilot, the project must be led by a Single PI (the Contact PI) who must meet the below requirements: The Contact PI **must** either

a. hold a faculty appointment as *Instructor or Assistant Professor** (or equivalent) without current or past external funding in the role of a PI or co-PI from an R01 or equivalent (e.g., VA Merit Review or NSF grant). Being a PI on a Foundation or Mentored grants is allowable. **OR**
b. be of any faculty rank **and** be transitioning to a clinical or translational research focus or who are entering a new area of clinical or translational research. **If you believe you fall into this category, please contact us to confirm your eligibility prior to submission by contacting Emily Mercer at emily_mercer@brown.edu.

**Post-doctoral fellows or resident physician applicants must submit a letter from their Department Chair(s) stating that the applicant will have a faculty appointment by May 1, 2025.*
***Faculty who have served as PI or co-PI on a prior R01 or equivalent are eligible to serve as Contact PI if proposing a pilot project that is in a **new area** of clinical or translational research.*

Category 2 (Multi-PI Projects: up to $100,000)

In addition to the **General Eligibility Requirements**, to be eligible for a Category 2 Pilot, the project must be led by a Multiple PI team and **must**:

1. Be led by two or more Principal Investigators (Multi-PI) from different disciplines or training backgrounds.
    a. A Contact PI must be designated who meets the eligibility requirements for a Contact PI outlined in Category 1 above.
2. Multi-PI's (who are not the contact PI) can be junior or senior investigators.
    a. While not required, a senior investigator serving as the Multi-PI could also be a mentor for the project.
    b. MPIs are allowed to have current or prior external funding in the role of a PI or co-PI from a R01 or equivalent (e.g., VA Merit Review or NSF grant).
    c. A senior investigator serving as a Multi-PI does not need to be changing focus. That restriction is only on senior investigators applying as contact PIs.
3. Partnerships from different departments or institutions are encouraged. Trans-institutional collaborations among faculty at Brown University, University of Rhode Island, and/or Rhode Island healthcare institutions **are highly encouraged**.

Depending on the availability of funding, select awarded projects may be offered the opportunity to apply for additional funding and/or time for their project.

Questions regarding applicant eligibility should be emailed to AdvanceRI@brown.edu.

Performance Period

The anticipated performance period **is 08/01/2025 to 07/31/2026**.

Available Services for Applicants

All applicants are **strongly encouraged** to schedule a consultation with the appropriate **Advance RI-CTR Service Core(s) (Biostatistics and Research Design, Biomedical Informatics, and Community Engagement and Outreach**) to enhance their responsiveness to this RFA. Applicants are encouraged to review the available services on the Advance RI-CTR website and submit service a request.

In addition to providing consultation services, **Advance RI-CTR's** Community Engagement and Outreach Core **has created a** Community Engaged Practice Based Research Network (CEPBRN**)**. The CEPBRN is available for researchers to engage with for their pilot projects. This opportunity is based on availability of the CEPBRN and its practices. Researchers interested in engaging with or learning more about the PBRN should contact the Community Engagement and Outreach Core Project Manager, Tammy Thorson, at tammy_thorson@brown.edu.

NEW In addition to the services noted above, Advance RI-CTR recently purchased a NanoString Molecular Imager that is housed in the Genomics Research Core Facility. Those interested in using this equipment or any of the other

services provided by the Genomics Core should reach out to them directly about current pricing ranges, instrument availability, services offered and other information.

Special Considerations

While the proposals with the highest scientific impact will be prioritized, special consideration will be given to fund projects that incorporate community engagement into the proposed research. For the purpose of the Pilot Projects Program, Advance RI-CTR utilizes the CDC-supported definition of community engagement:

> **Community engagement** is the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people.

Coaching for such applicants will be available from Advance RI-CTR's Community Engagement and Outreach Core.

In addition, special consideration, in no particular order, will be given to investigators who:

1. Pursue research that addresses the health goals and priorities set forth by the Rhode Island Department of Health's Strategic Framework. Priority areas (in no particular order) include, but are not limited to:

- Access to healthcare services especially among underserved populations
- Mental health in adults and youth - including prevention, services, programs, community resources and related stigma
- Food access and nutrition
- Chronic illnesses (e.g., diabetes, heart disease, asthma, cancer)
- Substance use disorder
- Obesity
- Health of mothers and their children
- General community well-being, health awareness and improvement of community health resources

2. Employ robust use of Advance RI-CTR Service Cores and/or CEPBRN

3. Are **clinician-scientists** defined as investigators with professional degrees who have training in clinical care and who are engaged in biomedical research

4. Propose projects that involve interdisciplinary, and/or interinstitutional teams.

AWARDEE AND MENTOR RESPONSIBILITIES

Awardee Responsibilities

Investigators selected for a Pilot Project award will be required to:

1. Obtain IRB and IACUC approval, as applicable, before funding can be awarded, no later than **May 1, 2024 (please note: it is preferred that this is obtained prior to March 24th when the other JIT materials will be due)**. Applicants are strongly encouraged to have these processes underway as soon as possible.
    - Please note: If a project has IRB approval through one of the healthcare systems, **and** has a Brown-employed individual on their project **and/or** has funds allocated for Brown University, an **IAA will need to be completed** between the healthcare system and Brown University as well regardless of if that person is working with any Human Subjects related items.
2. Present a seminar describing the project and progress/results at an Advance RI-CTR Seminar Series and, if invited, at the Advance RI-CTR External Advisory Committee Meeting.
3. Present a poster at the RI NIH IDeA Symposium and a talk, if invited.
4. Complete FCOI assurance and training as detailed under their respective organization's policy.
5. Attend all required program-related seminars and conferences (to be specified).
6. Complete quarterly progress reports based on the Advance RI-CTR grant year.
7. Complete a formal year-end report within one month of funding end.
8. Complete a participant evaluation survey at the end of the funding year.
9. Acknowledge sponsorship from Advance RI-CTR (and its relevant Cores) supported by the IDeA-CTR grant (U54GM115677) in all research publications during the performance period. Future publications related to this

research must also acknowledge Advance RI-CTR sponsorship.
10. Report all presentations, publications, and extramural funding that arise from this award to Advance RI-CTR.
11. Maintain updated Researchers@Brown profiles if Brown University-affiliated.
12. Acquire ORCID identifiers.
13. Utilize Advance RI-CTR Service Core(s) as outlined in the provided Letter of Support(s) and/or request use of services per each Core's policy, as appropriate.
14. Respond to Advance RI-CTR queries for information after the grant ends.

Mentor Responsibilities

Mentors will be required to provide the awarded investigators with research guidance toward an independent research career through a planned series of meetings and activities as well as frequent discussions and guidance as needed. Mentors are also expected to complete the Advance RI-CTR Mentoring Training Program upon funding of the proposal.

APPLICATION INSTRUCTIONS

To apply for a Pilot Project award, investigators must first submit a Preliminary Application to Advance RI-CTR. Selected applicants will then be invited to submit full proposals.

Preliminary Application Submission Instructions

Prospective applicants must submit a Preliminary Application through the UFunds Portal no later than **Monday, October 28, 2024 at 5pm ET**.

The Preliminary Application must include the following:

1. Contact and academic information as requested via the UFunds application page.
2. Indication of the award category to which the investigator is applying.
3. Structured one-page overview of research aims, significance, and approach.
4. References.
5. NIH-formatted biosketch for each investigator and mentor.
6. If the applicant is a postdoctoral fellow or resident physician, a letter from Department Chair(s) stating they will have a faculty appointment by **May 1, 2025**.

Preliminary Applications will be reviewed according to criteria outlined in the Review Process and Selection Criteria section below. Applicants will be notified on or around **Monday November 11, 2024** if they are invited to submit a full proposal.

Additional guidance for preparing a Preliminary Application is available on the Advance RI-CTR website:

- 8 Elements of a Successful Preliminary Application
- Tips for Preparing Your Preliminary Application
- Examples of Successful Preliminary Applications (Please note: These are examples only, and are not intended to serve as templates)

Advance RI-CTR leadership are available to speak with applicants about how to strengthen a preliminary application. Please contact AdvanceRI@brown.edu no later than **October 14, 2024** to schedule a conversation. Requests after this date may not be able to be accommodated.

Full Proposal Submission Instructions

Full proposals are due through the UFunds Portal no later than **Monday, January 13, 2025 5pm ET**. Advance RI-CTR will not consider incomplete applications. Complete applications must include the following sections:

Proposal Content

Face Page: (PHS 398 Form Page 1)
The Face Page should include Contact PI name, academic title, institution, address, title of project, and the name of the institutional grant management official. (Note: This form does **not** need to be signed by an institutional official at the time of submission.)

Project Summary, NIH Page 2: (PHS 398 Form Page 2)
The Project Summary should be a succinct and accurate description of the proposed work. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Concisely describe the research design and methods for achieving the stated goals. The summary should be informative to other persons working in the same or related fields and, insofar as possible, understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of first person.

Additionally, the following sections of the Project Summary form should be completed:

- *Relevance:* Describe the relevance of this research to public health. Be succinct (using no more than two or three sentences) and use plain language that can be understood by a general, lay audience.
- *Project/Performance Site Primary Location:* Include the information pertinent to the contact PI's home institution.
- *Additional Project/Performance Site Location:* Include the information pertaining to any additional performance sites. If more than two performance sites will be used, list additional sites on the PHS 398 Project/Performance Site Format Page.
- *Senior/ Key Personnel:* Include the Contact PI, and multi-PI's (if Category 2). Anyone listed in Senior/ Key Personnel must include a biosketch in the application.
- *Other Significant Contributors:* Mentors should be included in this section (unless they are also a multi-PI). Please include mentor biosketches in the application.

Budget: (PHS 398 Form Page 4)
The anticipated budget period **is 8/1/2025 to 7/31/2026. A separate budget must be submitted for each institution requesting support.** Together, the budgets must total no more than total allowable direct costs based on the selected category of funding. **Funding will cover direct costs only.**

All PIs must devote some effort. The amount of PI effort 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.

The below guidelines should be used to complete the PHS 398 budget form for each institution involved:

- *Personnel:* Indicate the investigator's name on the "PD/PI" line, number of calendar months dedicated to the proposed research, institutional base salary, requested salary, and associated fringe benefits. Investigators not receiving salary support should still be listed in the budget with effort indicated.
    - Please note: Funds cannot be used for graduate student or postdoctoral stipends; however, salary is allowable.
- *Consultant Costs:* If consultant costs are budgeted, include the consultant's rate and total costs.
- *Equipment:* Equipment (durable items valued at $5,000+) are *not allowed* for this award.
- *Supplies:* Allowable supply costs include computer software necessary for the project, laboratory supplies and services, animal and per diem housing expenses, publication costs, and participant stipends. General office supplies are *not allowed* for this award.
- *Travel:* Up to $2,000 can be budgeted for travel related to research performance or dissemination of results.
- *Inpatient Care Costs:* Indicate costs related to proposed research, if any.
- *Outpatient Care Costs:* Indicate costs related to proposed research, if any.
- *Other Expenses:* List any other costs itemized by category, if any.
- *Consortium/Contractual Costs:* Include consortium or contractual costs required to accomplish the proposed research, if any.

Salary support for mentors is not allowed, unless the mentor is a Multi-PI project and in a faculty-track deemed allowable for support, as outlined above.

Support costs will be covered by Advance RI-CTR as resources are available. Submit a service request for inquiries regarding available services.

Budget Justification: (PHS 398 Continuation Format Page)
Provide detailed justifications for all items requested in the budget(s). Separate justifications must be submitted **for**

each institution requesting support.

Biographical Sketch (5-page maximum): (Biographical Sketch Format Page) A NIH-formatted biosketch is required for each investigator and mentor. If you do not have an eRA Commons user name, you must obtain one to include in the biosketch. Biosketches should not exceed 5 pages.

The personal statement in the biosketch should briefly describe why your experience and qualifications make you particularly well-suited for a Pilot Project award. In the Research Funding section, include other grant support and explain the relationship of each grant to the proposed project, including any scientific or budgetary overlap. Please adhere to the NIH guidelines for your biographical sketch.

Resources: (PHS 398 Resources Format page)
Describe space, equipment, and other facilities available for the applicants to accomplish this research project. The Resources Format page must be completed for each Performance Site listed on PHS 398 Form Page 2.

Checklist: (PHS 398 Checklist Form Page)
Complete **Section 3 (Brown University budgets only)**, "Facilities and Administrative Costs" using the home institution's F&A rate.

Research Plan (6-page maximum): (PHS 398 Continuation Format Page)

The format of the Research Plan should follow the outline below exactly. Begin each section of the Research Plan with a section header (e.g., Specific Aims, Significance, etc.).

- *Specific aims:* Describe the goals and objectives of the research project (up to 1 page). Note: This needs to be the first page of your research plan.
- *Significance:* Include overall significance of the project, including the previous research in the area and relevance to health care needs in Rhode Island (up to 0.5 page).
- *Innovation:* Describe both the conceptual and technical innovation of the proposed project (up to 0.5 page).
- *Approach:* Describe the experimental design and methods, including an appropriate analysis plan. Present preliminary data if available (up to 3.5 pages).
    - Up to 0.5 page of the 3.5-page approach should focus on detailing the statistical analysis plan for the proposed project.
- *Timeline:* Include approximate completion dates for the defined specific aims and "next steps" (publications, presentations, grant proposals, etc.) (up to 0.5 page).

Lay Summary (250 word maximum)

Advance RI-CTR will be utilizing a community member reviewer in our review process (where appropriate). This reviewer will be selected from our Community Engagement Core's Community Advisory & Action Board (CAAB). To facilitate this portion of the review, we ask that each applicant submit a lay summary of no more than 250 words. The lay summary should include a summary of the proposed project and the impact on the community. The amount of impact (e.g. none, some significant) should be include as well. The community reviewer will be engaged to provide insight into how the research will impact the community and the feasibility of the project within the community.

References
Provide a bibliography of any references cited in the Research Plan.

Multiple PD/PI Leadership Plan: (PHS 398 Continuation Format Page)
A multi-PI plan must be included; it should describe the role of each of the PI's. Investigators may find it helpful to consider the following elements in their plan for collaboration and include those that are relevant to their proposed project:

- Data collection
- Data analysis
- Communication
- Conflict resolution
- Authorship
- Responsibility for regulatory oversight (IRB/IACUC, etc.)
- Responsibility for financial oversight

- Training/supervision of technicians/assistants/trainees
- Change in institution
- Plans for intellectual property resulting from the project

Refer to Section 5.5.7 PHS 398 Instructions. Do not exceed 0.5 page.

Future Funding Plans (500-word maximum, submitted in UFunds)
Describe plans to submit applications for future funding.

The below table summarizes required proposal content outlined in this section:

Section	Description	Page Limits
Face Page	Provide the requested administrative information.	n/a
Project Summary	Complete the Project Summary, Relevance, Project/Performance Site Primary Location, and Senior Key Personnel.	n/a
Budget	Complete Page 4 of the NIH 398 form for each institution requesting support.	n/a
Budget Justification	Provide clear, succinct justification for each requested budget item for each institution requesting support.	n/a
Biographical Sketches	Include for all proposed key personnel, including mentors.	5 pages (each)
Resources	Detail space, equipment, and other resources available for research.	n/a
Checklist	Complete Section 3 of PHS 398 Resources Format page.	n/a
Research Plan		6 pages
Specific Aims	Project specific aims.	1 page
Significance	Overall significance of the project, including pertinent background information, previous research in the area, and relevance to health care needs in Rhode Island.	5 pages
Innovation	Outline both conceptual and technical innovation.	
Approach	Preliminary data* and research plan, including expected results, alternative approaches, and analysis plan. Include discussion of scientific rigor and biological variables and the statistical analysis plan.	
Timeline	Indicate dates for completion of Specific Aims, manuscript submission, and extramural grant applications submission.	
*Lay Summary	Community-engaged research should provide a lay summary (not included in the 6-page maximum). See below for more information.	1 page
References	Provide citations for any references used in the Research Plan.	n/a
Multiple PI Leadership Plan	Describe the role of each Multi-PI and plans for collaboration.	0.5 page
Future Funding Plans	Describe plans to submit application for future funding.	500 words

*Preliminary data are encouraged, but not required.

Letters of Support (required):

1. Research Administration: If the Contact PI or a Multi-PI is **not employed by Brown University**, a signed Letter of Intent (LOI) from the Contact PI and/or Multi-PI's office of research administration must be included. If the Contact PI/Multi-PI is not receiving salary support, the LOI(s) must explicitly approve of the cost share and list the dollar amount of the cost share.

2. Department Chair(s): Letter(s) from the Department Chair(s) and/or supervisor(s) **for each investigator** documenting the Investigator name and title along with availability of protected time for research must be included. If a Brown University PI is not requesting salary support, the letter must explicitly approve cost share and list the dollar amount of the cost share.

3. Mentor(s): Letter(s) from the mentor(s) agreeing to advise on the conduct of the proposed research and describing plans for mentoring the junior investigator(s) must be included with the application. The mentors' letter should outline a mentorship plan demonstrating mentors' commitment, assessment of the applicant, research proposal and training plan that is aligned with the proposed work. The mentorship plan should also include the frequency and method (e.g.: virtual, in-person meetings, email, etc.) of mentor-mentee communication and check-ins to ensure timely completion of the project and any relevant training.

Regulatory Information

Be sure to address the Human Subjects, Vertebrate Animals, and Biosafety/Safety Agents sections as described below. Be sure to indicate status and submit all IRB and IACUC approvals as applicable to your proposed research. Human Subjects education certification(s) must be up-to-date and available upon request for all personnel involved in the conduct of human subjects research.

Regulatory Applications and Approvals

Please submit a PDF upload detailing the current status of all regulatory approvals that will be needed for this project and/or upload documents. This includes, all initial IRB or IACUC approval(s), as well as any IRB Authorization Agreement (alliance agreements between two institutions with IRBs when work is of a collaborative nature) needed to be implemented and their status. The NIH prefers that regulatory titles match project application titles. If your project application and regulatory title are different, a letter from the PI of the regulatory protocol will be required stating that the regulatory protocol covers the project proposed in the pilot application.

This upload should include:

- For IRB
    - The title of the IRB protocol(s), the PI(s) of the protocols, the institution approving the protocol, and the approval status (approved, pending review, date submitted, etc.), and information on if this project will require an IAA with any institution for research purposes. Please include what institution(s), and submission status(es) and/or approval letters.
- For IACUC
    - The title of the IACUC protocol(s), the PI(s) of the protocols, the initiation approving the protocol, and the approval status (approved, pending review, date submitted, etc.).
    - Information on if this project will require any congruency agreements with any institution for research purposes. Please include what institution(s), and submission status(es) and/or approval letters.

Human Subjects and Clinical Trial Information

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

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

Human Subjects projects must include:

- The Advance RI-CTR Human Subjects and Clinical Trial Information Form and associated Study Record. Complete the form using the built-in instructions.
- The Advance RI-CTR Enrollment Report form following NIH instructions.

To determine whether human subjects are involved, complete the "Am I doing Human Subjects Research?" Questionnaire. To help identify whether research that involves the use of human data or biological specimens is human subjects research, refer to this flowchart.

Vertebrate Animals Section

Refer to Vertebrate Animals NIH Instructions and the Worksheet for Applications Involving Animals. 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:

2. 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.
3. 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).
4. 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.
5. Method of Euthanasia**:** Provide a justification for methods of euthanasia that are consistent with the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If answer is "No" to the question "Is method consistent with AVMA guidelines?", describe the method and provide scientific justification in the text field provided.

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

Biosafety/Select Agents
Refer to Select Agents NIH Instructions. Indicate Institutional Safety Committee approvals.

Service Core Usage Response (if applicable)
Applicants who consulted with any of the Advance RI-CTR Service Cores should include a short statement (500 words or less) detailing their response to CTR Service Provider suggestions. Please include what recommendation(s) you incorporated into your project. Additionally, if applicable, please detail reasons why you chose to not incorporate certain recommendations.

Summary Statement Response (if applicable)
Applicants who are re-submitting a proposal from a prior Advance RI-CTR Pilot Projects Program must provide a one-page response (maximum) to the summary statement they received. Please detail how you addressed previous concerns in your application.

Applications with any missing components will be considered incomplete and will be withdrawn without review.

APPLICATION FORMAT

Applications should follow an abbreviated NIH format with minor modifications. This application requires the use of the most recent version of the PHS 398 Forms.

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.

REVIEW PROCESS AND SELECTION CRITERIA

Preliminary Applications

Reviews of Preliminary Applications will be conducted by the Advance RI-CTR Pilot Projects Program Council. Reviews of Preliminary Applications will focus on:

1. Responsiveness to eligibility requirements and program goals.
2. Special considerations.
3. Feasibility of the proposed research.

Full Applications

Reviewers of the full applications will include the Steering Committee and 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 and occasional external expert reviewers, as needed. For community-engaged projects, reviewers may be members of relevant community groups. Final selections will be made by a Council comprised of Advance RI-CTR leadership with approval of the Advance RI-CTR Steering Committee.

Applications will be reviewed using the following criteria:

1. Responsiveness to the RFA, including the relevance to RI health priorities and the clinical or translational nature of the research.
2. Scientific impact and soundness of the experimental design, including plans for data analysis.
3. Technical and conceptual innovation.
4. Training and expertise of the (Multi-) PI's and their ability to perform the proposed research.
5. Scientific and mentoring expertise of the mentor(s).
6. Project environment, including facilities and adequacy of the patient population, if applicable.
7. Reasonable and justified budget that is appropriate for the proposed research.
8. Likelihood that the project will lead to external funding.

Award is dependent upon final review and approval by the Advance RI-CTR External Advisory Committee and by NIGMS.

PLEASE NOTE:

Funding:

There is no pre-award spending allowable for pilot projects and any expenses incurred prior to the receipt of the Notice of Award will not be covered. While the award period is anticipated to start August 1, 2025 (but not earlier than August 1, 2025), the exact start date of funding is contingent upon institutional, regulatory, External Advisory Committee and NIGMS approval and therefore may begin later. Funding will begin upon receipt of the Notice of Award issued once all approvals have been received.

Prior to project initiation, a package of documents from the application and JIT phase must be submitted to the NIH All proposals require approval by NIGMS before funding can be issued. Currently, this approval process is taking approximately 2-4 months from submission of the application packet to NIGMS to receiving their approval. The NIGMS approval timeline begins once the project package has been submitted to NIGMS; it does not include time for gathering Just in Time materials, making any necessary revisions, or for institutional and regulatory approval processes.

Regulatory Approvals (IRB, IACUC, etc.)

Awardee-selected projects that involve clinical trials or studies involving greater than minimal risk to human subjects require prior approval by NIH prior to initiation and no projects with animal or human subjects may begin before IRB or IACUC approval has been received. It is understood that no pilot project awardee will be permitted to work on any project involving live vertebrate animals or human subjects that has not been approved by the IACUC and/or IRB, as appropriate. If any pilot project awardee undertakes a project that includes human subject research studies, these must conform to the NIH policies on the inclusion of women,

minorities, and children in study populations.

The application packet to NIGMS must include regulatory approval documents from IRB, IACUC and/or IBC as applicable. Therefore, applicants are strongly urged to have commenced the regulatory approval process(es) as soon as possible and prior to notification of recommendation for funding. The deadline to submit IRB and IACUC approval documents to Advance CTR is May 1, 2025 (prior to March 24th preferred). The applicants risk loss of consideration for award if the regulatory documents are not received in a timely manner.

If any projects have an IRB approval through a healthcare institution AND have a Brown-employed individual on the project, an IAA will be required as well. This holds true even if the Brown-based individual will not be engaged in the human subjects' portion of the research.

Funding Period Extensions and Additional Funds

Awardees should be aware No Cost Extensions **will only be given in exceptional circumstances**. Any request for a No Cost Extension will also need to be **submitted at least 90 days prior** to the end of the award period to be eligible for consideration.

Advance RI-CTR is unable to provide additional funding for the originally proposed scope of work. The budget justification should delineate how Advance RI-CTR funds will be spent.

Depending on the availability of funds and appropriate scientific and budgetary justification, projects may be offered the opportunity to apply for additional funding and/or time to increase the scope of their project.

DATES AND DEADLINES

Monday, October 14 ,2024:	Last day to schedule calls with leadership (optional)
Monday, October 28, 2024:	Preliminary Applications due
Monday, November 11, 2024:	Selected applicants invited to submit a Full Proposal
Monday, January 13, 2025:	Full Proposals due
Friday, March 7, 2025	Notification of Projects Recommended for Funding
Monday, March 24, 2025:	JIT Materials Due
Friday, August 01, 2025:	Pilot funding begins (anticipated)

QUESTIONS

Please email AdvanceRI@brown.edu with any questions about the Pilot Projects Program or review process. Reponses to common questions are posted on the FAQ page of the Advance RI-CTR website.