



## 2024 Pilot Projects Program

*Request for Applications (RFA)*

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**Awards:**

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

**Contact:** [AdvanceRI@brown.edu](mailto:AdvanceRI@brown.edu)

**FAQ:** [Advance-CTR Pilot FAQ](#)

### Submission Deadlines:

- *Preliminary Applications:* October 2, 2023
- *Invited Full Proposals:* December 15, 2023

## PROPOSAL SUBMISSION DEADLINES AND AWARD ANNOUNCEMENTS

### *Preliminary Application*

Interested applicants are **required to submit a Preliminary Application** through the [InfoReady Portal](#) no later than **Monday, October 2, 2023 at 5pm ET**.

Invitations to submit a full proposal will be announced on or around **Monday, October 16, 2023**.

Resources and guidance for preparing a successful Preliminary Application are available on the [Advance-CTR website](#). Applicants may request a call with Advance-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](mailto:AdvanceRI@brown.edu) to schedule a call no later than **September 21, 2023**.

### *Full Proposal*

Invited full proposals must be submitted no later than **Friday, December 15, 2023 at 5pm ET** through the [InfoReady Portal](#).

Pilot Project award announcements are anticipated to be communicated by email to applicants on or around **Friday, February 16, 2024**.

## AWARD CATEGORIES & ELIGIBILITY REQUIREMENTS

### Funding Availability & Categories

The 2024 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-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-CTR affiliated health care system (Lifespan, 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-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:

1. 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](mailto: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, 2024.*

*\*\*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](mailto:AdvanceRI@brown.edu).

## OVERVIEW

### *Advance-CTR*

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.

### *Advance-CTR Pilot Projects Program*

The Advance-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.

### *Performance Period*

The anticipated performance period is **08/01/2024 to 07/31/2025**.

### *Available Services for Applicants*

All applicants are **strongly encouraged** to schedule a consultation with the appropriate **Advance-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-CTR website](#) and [submit service a request](#).

### **\*\*NEW in 2023\*\***

In addition to providing consultation services, **Advance-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, Tania Lobo Paz, at [tania\\_lobo\\_paz@brown.edu](mailto:tania_lobo_paz@brown.edu).

## 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-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-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 including Latinx
  - 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-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.
5. Are from historically underrepresented groups. Advance-CTR uses the current NIH definition of underrepresented groups. More information about the NIH definition can be found [here](#).

## 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 (prior to March 8<sup>th</sup> preferred)**. Applicants are strongly encouraged to have these processes underway as soon as possible.
2. Present a seminar describing the project and progress/results at an [Advance-CTR Seminar Series](#) and, if invited, at the Advance-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-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-CTR 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-CTR sponsorship](#).
10. Report all presentations, publications, and extramural funding that arise from this award to Advance-CTR.
11. Maintain updated Researchers@Brown profiles if Brown University-affiliated.
12. Acquire ORCID identifiers.

13. Utilize Advance-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-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-CTR Mentoring Training Program](#) upon funding of the proposal (if a mentor has already completed the training, please upload the certificate under "Additional Documents" when submitting a preliminary application or full proposal).

## **APPLICATION INSTRUCTIONS**

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

### *Preliminary Application Submission Instructions*

Prospective applicants must submit a Preliminary Application through the [InfoReady Portal](#) no later than **Monday, October 2, 2023 at 5pm ET**.

The Preliminary Application must include the following:

1. Contact and academic information as requested via the InfoReady 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, 2024**.

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 October 16, 2023** if they are invited to submit a full proposal.

Additional guidance for preparing a Preliminary Application is available on the Advance-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-CTR leadership are available to speak with applicants about how to strengthen a preliminary application. Please contact [AdvanceRI@brown.edu](mailto:AdvanceRI@brown.edu) no later than **September 21, 2023** to schedule a conversation. Requests after this date may not be able to be accommodated.

### *Full Proposal Submission Instructions*

Full proposals are due through [InfoReady](#) no later than **Friday, December 15, 2023 5pm ET**. Advance-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 **8/1/2024 to 7/31/2025**. **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.
  - o 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-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).

**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   | • Responsibility for financial oversight                     |
| • Data analysis   | • Training/supervision of technicians/assistants/trainees    |
| • Communication   | • Change in institution                                      |
| • Conflict resolution                                       | • Plans for intellectual property resulting from the project |
| • Authorship  |  |
| • Responsibility for regulatory oversight (IRB/IACUC, etc.) |  |

Refer to [Section 5.5.7 PHS 398 Instructions](#). Do not exceed 0.5 page.

**Future Funding Plans (500-word maximum, submitted in InfoReady)**

Describe plans to submit applications for future funding. This response should not be uploaded, but submitted via the appropriate InfoReady query field.

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

Section	Description	Limits
<b>Face Page</b>	Provide the requested administrative information.	n/a
<b>Project Summary</b>	Complete the Project Summary, Relevance, Project/Performance Site Primary Location, and Senior Key Personnel.	n/a
<b>Budget</b>	Complete Page 4 of the NIH 398 form for each institution requesting support.	n/a
<b>Budget Justification</b>	Provide clear, succinct justification for each requested budget item for each institution requesting support.	n/a
<b>Biographical Sketches</b>	Include for all proposed key personnel, including mentors.	5 pages (each)
<b>Resources</b>	Detail space, equipment, and other resources available for research.	n/a
<b>Checklist</b>	Complete Section 3 of PHS 398 Resources Format page.	n/a
<b>Research Plan</b>		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.	0.5 page
Innovation	Outline both conceptual and technical innovation.	0.5 page
Approach	Preliminary data* and research plan, including expected results, alternative approaches, and analysis plan. Include discussion of scientific rigor and biological variables. (Note: up to 0.5 page should focus on detailing the statistical analysis plan for the proposed project.)	3.5 pages
Timeline	Indicate dates for completion of Specific Aims, manuscript submission, and extramural grant applications submission.	0.5 page
<b>References</b>	Provide citations for any references used in the Research Plan.	n/a
<b>Multiple PI Leadership Plan</b>	Describe the role of each Multi-PI and plans for collaboration.	0.5 page
<b>Future Funding Plans</b>	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 institution 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-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](#).

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-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-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-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-CTR leadership with approval of the Advance-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-CTR External Advisory Committee and by NIGMS.

**PLEASE NOTE: All proposals require approval by NIGMS before award 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. 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 selection. The deadline to submit IRB and IACUC approval documents to Advance CTR is May 1, 2024 (prior to March 8<sup>th</sup> preferred). The applicants risk loss of consideration for award if the regulatory documents are not received in a timely manner.**

**While the award period is anticipated to start August 1, 2024 (projects can start no earlier than August 1, 2024), the exact start date is contingent upon institutional, regulatory, External Advisory Committee and NIGMS approval and therefore may begin later. The project may not begin until a Notice of Award has been issued once all approvals have been received. Pre-award spending is not allowable on this award and no expenditures incurred prior to receipt of the Notice of Award will be covered.**

*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-CTR is unable to provide additional funding for the originally proposed scope of work. Please be sure any budgets are designed to adequately cover the project costs.

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**

<b>Thursday, September 21 ,2023:</b>	Last day to schedule calls with leadership (optional)
<b>Monday, October 2, 2023:</b>	Preliminary Applications due
<b>Monday, October 16, 2023:</b>	Selected applicants invited to submit a Full Proposal
<b>Friday, December 15, 2023:</b>	Full Proposals due
<b>Friday, February 16, 2024</b>	Notification of Projects Recommended for Funding
<b>Thursday, March 8, 2024</b>	JIT Materials Due
<b>Tuesday, August 01, 2024:</b>	Pilot funding begins (anticipated)

**QUESTIONS**

Please email [AdvanceRI@brown.edu](mailto:AdvanceRI@brown.edu) with any questions about the Pilot Projects Program or review process. Responses to common questions are posted on [the FAQ page](#) of the [Advance-CTR website](#).