

### ICTR Advancing Translational Research & Science Pilot Award

Key Dates and Info		
Funding	<ul> <li>Up to \$50,000 (direct costs only)</li> <li>Up to 12 months</li> <li>Up to 5 applications are expected to be funded</li> </ul>	
Requirements	<ul> <li>Contact PI must have UW-Madison PI status (permanent or limited)</li> <li>Proposal advances innovative translational research that elucidates novel processes that are generalizable to multiple translational research projects, OR</li> <li>Proposal provides solutions to common barriers in the translation of innovations into practice or policy</li> </ul>	
Pre-Proposal Due	On or before February 18, 2025, 11pm CT	
(required)	Submit via email to Bri Deyo, deyo@wisc.edu	
Full Application Due	On or before April 1, 2025, 11pm CT Link to full application will be provided by invitation	
Review Period	April and May 2025	
Notification of Grant Award	May 2025	
Project Period	July 1, 2025 to June 30, 2026	
Contact	Bri Deyo deyo@wisc.edu 608-262-9188	
More Information	https://ictr.wisc.edu/funding/advancing-translational-research-and-science-atrs/  Website includes links to:	



#### **PROGRAM OVERVIEW**

ICTR programs have a long history of fostering clinical and translational research. These programs center around building capacity in translational science by supporting the next generation of biomedical, social, and behavioral scientists; providing investigators and clinicians with critical resources including consultations, technology, and data science; and creating novel solutions to disseminate innovations that improve healthcare practice.

Translational science generates innovations that overcome longstanding barriers along the translational research pipeline. These include scientific, operational, financial, and administrative innovations that transform the way that research is done, making it faster, more efficient, and more impactful.

Translational research seeks to turn biomedical research discoveries into health solutions through the application of translational science. These solutions include efficacious diagnostics, treatments, and interventions. Resources related to translational science principles and practices are available from the National Institutes of Health, National Center for Advancing Translational Sciences (ncats.nih.gov): [links and supporting info]

- About Translational Science | NCATS https://ncats.nih.gov/about/about-translational-science
- Translational Science Spectrum | NCATS https://ncats.nih.gov/about/about-translational-science/spectrum
- Translational Science Principles | NCATS https://ncats.nih.gov/about/about-translational-science/principles
- Biomedical Translation | NCATS YouTube https://www.youtube.com/watch?v=TnHLo-hCssg (a short video)
- Diversity, Equity, Inclusion and Accessibility in Translational Science | NCATS
   https://ncats.nih.gov/about/NCATS-Biennial-Reports/NCATS-Biennial-Report-2021-2022/diversity-equity-inclusion-accessibility
- NIH VideoCast NCATS at 10: Improving Health for All Through Translational Science https://videocast.nih.gov/watch=44278 (a long video)

The ICTR Advancing Translational Research & Science (ATRS) Pilot Award provides support for proposals that aim to **either**:

- advance innovative translational research that elucidates novel processes that are generalizable to multiple translational research projects, OR
- 2. provide solutions to common barriers in the translation of innovations into practice or policy.

Highly valuable project elements include (but are not limited to):

- Mentorship and/or Team Science
- Recruitment Science
- Implementation Science including projects applicable to Learning Health Systems (LHS)
- Considerations of specific ways in which the proposed work may impact health outcomes or inequities and/or inclusion of diverse participants in research

ICTR Pilot Awards are intended to support projects that will further an investigator's career path. Successful proposals will clearly describe how the pilot data collected as a part of this award will be



used to seek further, external, peer-reviewed funding in support of a research career trajectory. Early career investigators with limited PI experience are strongly encouraged to submit proposals as the Contact PI, in partnership with senior investigators who have relevant research methods expertise to serve as Co-Investigators, collaborators or mentors.

#### **FUNDING**

Funding support is contingent upon successful non-competitive renewal of grant support from the NIH National Center for Advancing Translational Sciences (NCATS) for awards administered by the UW Institute for Clinical and Translational Research (ICTR). It is expected that up to 5 applications will be funded.

Proposals that include animal or human subjects research are subject to prior approvals by the NCATS Clinical and Translational Science Award (CTSA) Program. This RFA is not intended to support pilot projects with clinical trial designs (e.g., randomized controlled trials with multiple study arms).

The project period is July 1, 2025 to June 30, 2026. No cost extensions are not allowed.

#### **ELIGIBILITY OF PRINCIPAL INVESTIGATOR**

- The Contact PI must hold UW-Madison PI status (may be permanent or limited)
- The Contact PI must have an appointment greater than or equal to 0.5 FTE at UW-Madison (the award funding account will be managed through the Contact PI's UW-Madison department)
  - Faculty with any title, in any track (clinical health sciences, clinician teacher, tenure, research professor, teaching professor or clinical adjunct) are eligible
  - Academic staff must have permanent or limited PI status and must provide confirmation of PI authorization from the Office of the Vice Chancellor for Research upon application
- The Contact PI must be registered with eRA Commons and ORCID
  - eRA Commons (<a href="https://public.era.nih.gov/commonsplus/">https://public.era.nih.gov/commonsplus/</a>)
  - ORCID (https://orcid.org/)

#### A Contact PI may not:

- Be the Contact PI or MPI on any currently active ICTR grant award (serving as Co-I or other Key Personnel is not exclusionary)
- Have been the Contact PI or MPI on another ICTR pilot award application submitted during the current calendar year (serving as Co-I or other Key Personnel is not exclusionary)

Proposals that include multiple PIs (MPIs) must designate one person as the Contact PI, who must meet all eligibility criteria. Individuals who do not meet the criteria for Contact PI may serve as Co-Investigators or other Key Personnel.



#### **APPLICATION AND SUBMISSION**

Please review and follow these instructions carefully. Deadlines, contact information, and submission details are listed in the Key Dates and Info Table on Page 1 of this RFA.

A References and Resources Table is provided at the end of this RFA which contains links to key concepts that are important for this award.

A Frequently Asked Questions (FAQ) document and a list of recently funded ATRS proposals are available for review on the ICTR Funding Opportunities web page for this RFA (https://ictr.wisc.edu/funding/advancing-translational-research-and-science-atrs/).

#### 1. Pre-proposal Submission - REQUIRED

A Pre-proposal must be submitted via email (see the Key Dates and Info Table on Page 1). Once the Pre-proposal is received, the applicant will receive an e-mail acknowledgment. The Pre-proposal serves to determine PI eligibility, responsiveness to the RFA, and to assist in the identification of appropriate peer reviewers. The Pre-proposal will **not** be used for final review or ranking.

After pre-proposals are received and reviewed, Contact PIs will be notified of their status via email. Eligible Contact PIs will be invited to submit a full application and provided with a link to the online application form.

Pre-proposal Format: PDF, 2 pages maximum, single spaced, 0.50" minimum margins, Arial 11-point font

Required Information (a through i), in this order:

- a) Title of proposed research project. IMPORTANT:
  - The title and Contact PI of the proposed pilot project must match the title and Contact PI of all associated IRB or IACUC approvals
  - An approved IRB application must describe <u>only</u> the activities of the proposed pilot project, and cannot be part of a larger parent protocol
- b) For Contact PI and any MPIs:
  - Name
  - Title
  - UW-Madison School and Department
  - Campus mailing address
  - Telephone number
  - Campus email address
- c) Co-Investigators or other key personnel or consultants who are crucial to the design and conduct of the proposed research:
  - Name
  - Title
  - Professional Affiliation
  - Email address
- d) A list of anticipated contributors, collaborators, organizations, community partners, consultants, and/or invested groups, including a brief description of how they will be involved in this research



- e) A brief summary of the proposal
  - Must provide enough detail to evaluate relevance to this RFA, including specific aims, general research design, and methods
- f) A brief description of the potential of the proposed pilot research to:
  - advance innovative translational research that elucidates novel processes that are generalizable to multiple translational research projects, OR
  - provide solutions to common barriers in the translation of innovations into practice or policy
- g) A brief description of the knowledge gap and/or translational barrier this proposal intends to address
- h) A brief description of the potential of the proposed pilot research to impact human health, including anticipated impacts on health equity of this or subsequent research
- i) Plans for future project development including (but not limited to) specific grant opportunities, dissemination plans, etc.

#### 2. Full Application - REQUIRED

Contact Pls who have submitted a Pre-Proposal application before the deadline (see the Key Dates and Info Table on Page 1) and have been confirmed to be eligible will receive a confirmation via email that contains a link to the online application submission form. All application materials are submitted via the online submission form.

#### Online Form Fields

The REDCap form contains fields that collect academic (required) and demographic (optional) information about the Contact PI. The Contact PI should enter their information first, and then add information about a MPI (if applicable) in the "Partner PI Information" section. Additional information that must be entered for all PIs includes: ORCID, eRA Commons ID, and institutional mailing address.

A complete application must include all the following components, in this order, **combined into one PDF file and submitted via the online submission form**.

- Scientific Abstract
- Narrative (including sections a through k)
- Citations
- Timeline
- Regulatory Approvals
- Biosketches
- Other Support
- Letters of Support

Full Application Format: Files must be PDF and should follow NIH guidelines (<a href="https://grants.nih.gov/grants-process/write-application/how-to-apply-application-guide/format-attachments">https://grants.nih.gov/grants-process/write-application/how-to-apply-application-guide/format-attachments</a>).

- Margins: Provide at least one-half inch margins (0.5") top, bottom, left, and right for all pages.
- Font size: Must be 11 points or larger. Smaller text in graphics, figures, graphs, diagrams, and charts is acceptable, as long as it is legible when the page is viewed at 100%.
  - Arial font is highly recommended and meets all requirements. Do not use Aptos.



- Some PDF conversion software reduces font size. It is important to confirm that the final PDF document complies with the font requirements.
- Type density: Must be no more than 15 characters per linear inch (including characters and spaces).
- Line spacing: Must be no more than six lines per vertical inch.
- Text color: No restriction. Though not required, black or other high-contrast text colors are recommended since they print well and are legible to the largest audience.
- Headers and Footers: Do not use headers or footers except for page numbers. Letters of Support that are on letterhead which includes headers and footers are acceptable.

Page or word limits are specified for each section. If no page or word limit is specified below, there is no such limit.

#### Scientific Abstract

500 words, maximum. Provide a concise description of the proposed research written for scientific audiences.

- Resource:
  - Writing to Convince: The 1-page Abstract and More | UW-Madison Video Library: https://videos.med.wisc.edu/videos/8470

#### The Scientific Abstract must include:

- Scientific rationale supporting the proposed research
- Specific hypothesis or hypotheses to be generated or tested
- Research aim(s)
- Research design or framework
- Research methods and analytical plan
- Brief description of how this project will inform your next grant, including potential funders who
  have identified your research topic as a health priority

#### Narrative

7 pages, maximum. Must include all following sections (a through k), in this order:

- a) Specific Aims
  - Include clearly defined and measurable objectives
- b) Background and Significance
  - Include a strong statement regarding the ways the project will directly impact those who will benefit from the research, how that will happen, and potential for impact on human health and anticipated equity outcomes of subsequent research
  - Describe the involvement of the patients, community, and/or other impacted entities in developing the research question, if relevant
  - Describe feedback from community partners and/or the study population (e.g., patient advocacy groups, community clinicians, health care administrators) on the proposed work, if relevant
- c) Innovation
  - Describe how this project addresses the specific aims in a new way
  - Describe any barriers to current research, therapeutic approaches, clinical practices or policies that this project addresses



#### d) Approach

- Any preliminary research and experience relevant to this proposal
- Describe study design, including study procedures and data collection
- Describe qualitative and/or quantitative methodologies
- If proposing new methodology, describe how this project improves upon current methods
- Describe potential difficulties and limitations, and how to overcome or mitigate them
- Describe how research plans are justified for the (1) protection of human research participants from research-related risks, and (2) inclusion of marginalized populations, members of all sexes and/or genders, and/or vulnerable subjects.
- Resources:
  - i. ICTR Research and Protocol Development free consult: https://ictr.wisc.edu/research-resources/protocol-development
  - ii. NIH Pilot Studies, Common Uses and Misuses: https://www.nccih.nih.gov/grants/pilot-studies-common-uses-and-misuses

#### e) Data Analysis Plan

- Describe how quantitative data, as applicable will be evaluated and interpreted
- Describe how data evaluation methods and techniques were selected
- Describe sample size justification, if applicable
- Resources:
  - i. General SAP Guidance: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4552232
  - ii. SAP Guidance for Clinical Trials: https://pubmed.ncbi.nlm.nih.gov/29260229
  - iii. ICTR Biostatistics and Epidemiology Research and Design free consult: https://ictr.wisc.edu/consults/biostatistics-2
  - iv. UW Data Science Institute free consult: <a href="https://dsi.wisc.edu/services/data-science-services">https://dsi.wisc.edu/services/data-science-services</a>
  - v. NIH Strategic Plan for Data Science: <a href="https://datascience.nih.gov/nih-strategic-plan-data-science">https://datascience.nih.gov/nih-strategic-plan-data-science</a>

#### f) Special Criteria

These criteria are used by ICTR as a means of assessing our own impacts on workforce development and health equity, and inclusion of these criteria are not required for funding. Please identify and describe how this proposal incorporates any of the following circumstances:

- New Junior Senior Investigator collaboration The project involves a new partnership between an early career investigator, as the Contact PI, and a senior investigator. A new partnership refers to two investigators who have not co- authored a manuscript.
- <u>UW-Madison Marshfield collaboration</u> The project involves collaboration between a UW-Madison investigator, as the Contact PI, and a Marshfield Clinic Research Institute (MCRI) investigator.
- Interdisciplinary collaboration The project involves collaboration among faculty investigators from different UW-Madison schools or colleges. For the purposes of this grant program, an interdisciplinary collaboration is not among different departments within the same UW-Madison school or college.
- Special Populations This project specifically addresses health inequities that are unique to people who are: in rural communities, from sexual and/or gender minoritized groups, from racial and/or ethnic minoritized groups, experiencing poverty, and/or with disabilities.



 Special Health Focus – This project specifically addresses challenges that are related to: contemporary and/or emerging health crises, maternal or fetal health, mental or behavioral health, pediatric or geriatric health, and/or substance use disorders.

#### g) Investigator

- Describe how the Contact PI, research team, and collaborators are especially suited to this project
- If the Contact PI is an early-career investigator, describe experience, training, and mentorship related to the proposed work
- If the Contact PI is an established investigator, describe accomplishments (i.e. publications, external funding, sustained practice, and/or policy change) related to the proposed work
- Describe previous experience working directly with the community organizations, patients, and/or other impacted entities involved in this application, if relevant

#### h) Environment

- Describe the scientific environment in which the work will be done
- Describe how this environment will contribute to the success of the project
- Describe how the project will benefit from the unique features of the environment

#### i) Collaboration Plan

- Describe planned processes for team decision-making and scientific direction, including
   PI engagement as equal partners, if relevant for a multiple-PI mechanism
- Describe the planned distribution of responsibilities and work processes, including protocol procedures, administrative responsibilities, project management, and dissemination activities
- Describe planned collaboration activities, including communications and informationsharing methods, and meeting frequency and modality
- Resource:
  - i. ICTR Team Science Collaboration Planning free consult: <a href="https://ictr.wisc.edu/team-science/team-science-collaboration-planning">https://ictr.wisc.edu/team-science/team-science-collaboration-planning</a>

#### i) Dissemination Plan

- Describe the audience(s) to which results from this project will be disseminated (e.g. scientific audiences, patients, community partners, and/or other specific clinical practices, advocacy groups or policy makers, if relevant)
- Describe how and when the results from this project will reach the specified audience(s)
- Identify the dissemination scale (local, national, international)
- Resource:
  - i. ICTR Dissemination and Implementation Launchpad free consult: https://ictr.wisc.edu/research-resources/dissemination-implementation-launchpad/di-research-consultation/

#### k) Future Considerations

- Funding An expectation of this program is that the research team must have plans to apply for external, peer-reviewed funding. What is the next step in this research project's trajectory and what are your plans for acquiring subsequent funding?
- Examples of other future considerations might include:
  - i. Research Implications What is the five-year trajectory envisioned for this pilot research to move toward impact? What is the potential for generalizability of this



work? What kinds of collaborators and/or community partners will need to be engaged for future work?

ii. Policy Implications – If applicable, address how this research might inform or impact organizational or public policies.

#### Citations

List all citations referenced. No specific formatting style is required (e.g., APA or MLA), however, the style must be consistent within the list and full citations must be referenced for all relevant and cited literature. Include the PMC reference number (PMCID) and/or Digital Object Identifier (DOI), where applicable.

#### Timeline

Describe how all proposed activities are feasible within the grant period. Include a table that shows all project activities and milestones, examples include (but are not limited to):

- IRB application
- Development of project tools/data collection forms
- Participant recruitment
- Data collection, extraction/abstraction, validation, analysis
- Dissemination activities: presentations of results, manuscript preparation, etc.

#### Regulatory Approvals

Must be addressed for all proposed projects that involve activities with human or animal subjects and/or biological samples.

For projects with proposed human participants and/or human biologic samples, describe what existing or planned regulatory reviews will be required (e.g., Institutional Review Board, Certificate of Confidentiality, biological/laboratory safety certifications, etc.). Documentation of IRB approval for the proposed pilot project (with matching title and PI) must be obtained prior to release of grant funds. Amending an existing IRB approval from another existing project is NOT allowed.

While regulatory approval is not required at the time of application, grant funding cannot be released until a letter Approval or Exemption is issued from a Human Subjects Institutional Review Board.

For projects with proposed animal participants and/or animal biologic samples, the Contact PI must provide current IACUC approval or proof of a pending IACUC application.

#### Biosketches

Must be submitted for all Investigators (Contact PI, and any MPIs or Co-Is), using the current NIH template.

- Resources:
  - NIH Biosketch Template: https://grants.nih.gov/grants/forms/biosketch.htm
  - NIH 2025 Updates: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-163.html

#### Other Support

Must be submitted for all Investigators and all other Key Personnel listed in the Budget, using the current NIH template. Must include a statement of overlap between previously funded projects and the proposed research.

Resources:



- NIH Other Support Template: <a href="https://grants.nih.gov/grants-process/write-application/forms-directory/other-support">https://grants.nih.gov/grants-process/write-application/forms-directory/other-support</a>
- NIH 2025 Updates: <a href="https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-163.html">https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-163.html</a>
- UW-Madison Other Support Guidance: <a href="https://rsp.wisc.edu/other-support-information.cfm">https://rsp.wisc.edu/other-support-information.cfm</a>

#### Letters of Support

Signed (ink or electronic) letters of support from all collaborators must be included. Letters from collaborators should specify:

- The support they are offering the project, the role/s they will play, and how they intend to use
  the results of the project towards next research step or health practice, program, and/or policy
  change, if applicable
- Their specific, meaningful role in the project

Pls who are Academic Staff with non-faculty titles must include a letter of support from their department chair or dean expressing strong support for independence on this specific proposal and an outline of the Pl's proposed academic trajectory.

#### **Budget and Justification**

The budget and justification must be submitted using the template provided and include all expenses that directly support the proposed project. Total budgets may not exceed the cap listed for this award. **Indirect and/or administrative costs are not allowed.** Budgets are subject to review and approval by ICTR and/or the NCATS CTSA.

Budgets must include, with justification for each line item:

- Personnel
  - Include the percent effort to be committed to the project for all contributors, with fringe where applicable, including Co-Investigators, mentors, collaborators, staff, and students
    - i. Investigator salary is only allowed for work related to this award, with justification
    - ii. Graduate student and post-doctoral associate stipends are allowed for work related to the pilot, with justification. Include any proposed tuition remission in the budget, per UW-Madison policy. Direct tuition payments are not allowed.
    - iii. List all contributors, even those with in-kind or zero-dollar contributions
    - iv. The utilization of research staff (i.e. research coordinators or project coordinators) is highly recommended
    - v. NIH salary caps apply
- Collaborators and/or Contractual Costs
  - Include payments to individuals and/or organizations that are outside of UW-Madison, and could be in the form of stipends or fees for services
- Research Participant Costs
  - Include any costs associated with paying research participants for their participation, and/or food, travel, parking or other items provided directly to participants for the purpose of contributing to this research
  - All research participant incentives (including food, materials, and/or payments) must be approved by the IRB



- Supplies
  - Laboratory and computing supplies, research equipment, office supplies, etc., that are essential, solely for the study, and not otherwise available may be requested
  - Large equipment expenditures (> \$5,000) are not allowed
- Travel
  - Include any travel, made by UW-Madison personnel, which is necessary for the conduct of the research
- Other Expenses
  - List any expenses which do not fit into any of the previous categories
- Community Collaborators/Partners, if relevant
  - List all non-UW-Madison collaborators, including the organization they represent, and their role on the project
  - Additional rows may be added, as needed
- Project/Performance Site: Primary Location
  - List the address where the study activities will be taking place
  - Additional rows may be added, as needed
- Budget Justification
  - Include cost basis information for all listed expenses
  - Create a list of justifications in the same order as the Detailed Budget Table
  - All categories that have proposed spending must be justified in this section

Please refer to UW-Madison budget policies, including allowable and unallowable expenses, payments to personnel, and payments to research participants. It is strongly encouraged that a fiscal administrator from the Contact Pl's home department review the budget prior to submission.

- Budget resources (please note that additional policies may apply, depending on the specific proposed spending):
  - UW-Madison Allowable costs: https://rsp.wisc.edu/awardmgt/directcosts.cfm
  - UW-Madison Tuition Remission: https://rsp.wisc.edu/policies/tuitionremission\_faq.cfm



#### **REVIEW CRITERIA**

Each full application will be evaluated by at least 2 independent peer reviewers using the Simplified Framework for NIH Peer Review. Merit will be determined by averaging the Overall Impact scores from each independent peer reviewer. Meritorious applications will then be evaluated and ranked by an ICTR Scientific Review Committee (SRC). The SRC may request further clarification and/or modifications.

All applicants, regardless of funding decision, will receive a summary statement and aggregate comments, explaining the rationale for the scores following completion of the entire review process.

The Simplified Framework for NIH Peer Review Criteria retains the five regulatory criteria (Significance, Investigators, Innovation, Approach, Environment) but reorganizes them into three factors; two will receive numerical criterion scores and one will be evaluated for sufficiency. All three factors will be considered in arriving at the Overall Impact score. The reframing of the criteria serves to focus reviewers on three central questions reviewers should be evaluating: How important is the proposed research, how rigorous and feasible are the methods, and whether the investigators and institution have the expertise/resources necessary to carry out the project.

Resource: Simplifying Review of Research Project Grant Applications | NIH
 https://grants.nih.gov/policy-and-compliance/policy-topics/peer-review/simplifying-review

#### **Overall Impact**

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Factor 1: Importance of the Research, scored (1 = exceptional; 9 = poor)

- Significance
  - Evaluate the importance of the proposed research in the context of current scientific challenges and opportunities, either for advancing knowledge within the field, or more broadly. Assess whether the application addresses an important gap in knowledge in the field, would solve a critical problem, or create a valuable conceptual or technical advance.
  - Evaluate the rationale for undertaking the study, the rigor of the scientific background for the work (e.g., prior literature and/or preliminary data) and whether the scientific background justifies the proposed study.

#### Innovation

- Evaluate the extent to which innovation influences the importance of undertaking the proposed research. Note that while technical or conceptual innovation can influence the importance of the proposed research, a project that is not applying novel concepts or approaches may be of critical importance for the field.
- Evaluate whether the proposed work applies novel concepts, methods or technologies or uses existing concepts, methods, technologies in novel ways, to enhance the overall impact of the project.



<u>Factor 2</u>: Rigor and Feasibility, scored (1 = exceptional; 9 = poor)

- Approach
  - Evaluate the scientific quality of the proposed work. Evaluate the likelihood that compelling, reproducible findings will result (rigor) and assess whether the proposed studies can be done well and within the timeframes proposed (feasibility).

#### Rigor

- Evaluate the potential to produce unbiased, reproducible, robust data.
- Evaluate the rigor of experimental design and whether appropriate controls are in place.
- Evaluate whether the sample size is sufficient and well-justified.
- Assess the quality of the plans for analysis, interpretation, and reporting of results.
- Evaluate whether the investigators presented adequate plans to address relevant biological variables, such as sex or age, in the design, analysis, and reporting.
- For applications involving human subjects or vertebrate animals, also evaluate:
- the rigor of the intervention or study manipulation (if applicable to the study design).
- whether outcome variables are justified.
- whether the results will be generalizable or, in the case of a rare disease/special group, relevant to the particular subgroup.
- whether the sample is appropriate and sufficiently diverse to address the proposed question(s).
- For applications involving human subjects, including clinical trials, assess the adequacy
  of inclusion plans as appropriate for the scientific goals of the research. Considerations
  of appropriateness may include disease/condition/behavior incidence, prevalence, or
  population burden, population representation, and/or current state of the science.

#### Feasibility

- Evaluate whether the proposed approach is sound and achievable, including plans to address problems or new challenges that emerge in the work. For proposed studies in which feasibility may be less certain, evaluate whether the uncertainty is balanced by the potential for major advances.
- For applications involving human subjects, including clinical trials, evaluate the adequacy and feasibility of the plan to recruit and retain an appropriately diverse population of participants. Additionally, evaluate the likelihood of successfully achieving the proposed enrollment based on age, racial, ethnic, and sex/gender categories.
- For clinical trial applications, evaluate whether the study timeline and milestones are feasible.

Factor 3: Expertise and Resources, evaluated as either sufficient for the proposed research or not

- Investigator(s)
  - Evaluate whether the investigator(s) have demonstrated background, training, and expertise, as appropriate for their career stage, to conduct the proposed work. For Multiple Principal Investigator (MPI) applications, assess the quality of the leadership plan to facilitate coordination and collaboration.

#### Environment

- Evaluate whether the institutional resources are appropriate to ensure the successful execution of the proposed work.
- Evaluate whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.



#### **AWARD ADMINISTRATION**

All applicants receiving ICTR pilot awards must adhere to the following administrative requirements:

- Pre-award survey. Awardees must complete a survey that allows ICTR to collect information on awardees' experiences and perspectives as an investigator, departmental fiscal contacts, and project-specific regulatory considerations.
- Regulatory approvals. Copies of all applicable human and/or animal subjects approval documents (including updates) must be forwarded to ICTR award administrators.
- Quarterly Progress Reports are required throughout the award period, beginning on July 1, 2025. These will be collected via online survey, and will address accomplishments to date, spending projections, and impacts of any ICTR research resources and/or trainings that may have been utilized during the guarter.
- Final report. Within 60 days of the project end date, June 30, 2026, submit via online survey a written description of accomplishments, including conference abstracts, publications, grant applications, and plans to further develop the project.
- Timely account closure. At least 60 days prior to the project end date, June 30, 2026, submit any final invoices, and ensure that all funds will be drawn from the account by the end date.
- Alumni Surveys will be requested annually for 5 years beyond the end date of the project. These
  will be collected via online survey, and address evaluation metrics of populations/communities
  involved in the research, grants and dissemination products, and impact on rural health and
  inequities. Follow up interviews may be requested.
- Awardees must adhere to the NIH Public Access Policy and obtain PMCID numbers for every publication utilizing pilot data.
- Awardees must acknowledge Pilot award funders in NIH biosketches and all publications, presentations, and dissemination activities, and notify ICTR of such publication submissions/acceptances, as well as any grant submissions/awards, using data generated from the pilot project. Specific instructions will be provided in the Notice of Grant Award Letter.



References and Resources		
	About Translational Science: https://ncats.nih.gov/about/about-translational-science	
Resources on Translational Science	Translational Science Spectrum: <a href="https://ncats.nih.gov/about/about-translational-science/spectrum">https://ncats.nih.gov/about/about-translational-science/spectrum</a>	
	Translational Science Principles: <a href="https://ncats.nih.gov/about/about-translational-science/principles">https://ncats.nih.gov/about/about-translational-science/principles</a>	
	Biomedical Translation   NCATS YouTube: <a href="https://www.youtube.com/watch?v=TnHLo-hCssg">https://www.youtube.com/watch?v=TnHLo-hCssg</a> (a short video)	
	Diversity, Equity, Inclusion and Accessibility in Translational Science: <a href="https://ncats.nih.gov/about/NCATS-Biennial-Reports/NCA&lt;/td&gt;&lt;/tr&gt;&lt;tr&gt;&lt;td&gt;NIH VideoCast - NCATS at 10: Improving Health for All Through Translational Science: &lt;a href=" https:="" videocast.nih.gov="" watch='44278"'>https://videocast.nih.gov/watch=44278</a> (a long video)	
	Introduction to Translational Science   Coursera: <a href="https://www.coursera.org/learn/intro-translational-science#modules">https://www.coursera.org/learn/intro-translational-science#modules</a>	
	NIH Resources	Application Guide – Format Attachments   NIH: https://grants.nih.gov/grants-process/write-application/how-to-apply-application-guide/format-attachments
eRA Commons (https://public.era.nih.gov/commonsplus/)		
ORCID (https://orcid.org/)		
Pilot Studies, Common Uses and Misuses   NIH: https://www.nccih.nih.gov/grants/pilot-studies-common-uses-and-misuses		
Salary Cap Summary   NIH: https://grants.nih.gov/policy-and-compliance/policy-topics/nih-fiscal-policies/salary-cap-summary		
Simplified Peer Review Framework   NIH: https://grants.nih.gov/policy-and-compliance/policy-topics/peer-review/simplifying-review/framework		
Abstract Writing	https://videos.med.wisc.edu/videos/8470	
ICTR Research and Protocol Development	FREE CONSULT: https://ictr.wisc.edu/research-resources/protocol-development	
Data Science and Analysis Planning	General SAP Guidance: <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4552232">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4552232</a>	
	SAP for Clinical Trials: https://pubmed.ncbi.nlm.nih.gov/29260229	
	ICTR Biostatistics and Epidemiology Research and Design FREE CONSULT: https://ictr.wisc.edu/consults/biostatistics-2	
	UW Data Science Institute FREE CONSULT: https://dsi.wisc.edu/services/data-science-services	
	NIH Strategic Plan for Data Science: https://datascience.nih.gov/nih-strategic-plan-data-science	
ICTR Collaboration Planning and Team Science	ICTR Team Science Collaboration Planning FREE CONSULT: <a href="https://ictr.wisc.edu/team-science/team-science-collaboration-planning">https://ictr.wisc.edu/team-science/team-science-collaboration-planning</a>	

#### **UW ICTR Partners**



References and Resources		
ICTR Dissemination and Implementation Launchpad	FREE CONSULT: https://ictr.wisc.edu/research-resources/dissemination-implementation-launchpad/di-research-consultation/	
NIH Biosketch and Other Support	NIH Biosketch Template: <a href="https://grants.nih.gov/grants/forms/biosketch.htm">https://grants.nih.gov/grants/forms/biosketch.htm</a> NIH Other Support Template: <a href="https://grants.nih.gov/grants/forms/othersupport.htm">https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-163.html</a>	
UW-Madison Budget Policies	UW-Madison Other Support Guidance: <a href="https://rsp.wisc.edu/other-support-information.cfm">https://rsp.wisc.edu/other-support-information.cfm</a> Allowable costs: <a href="https://rsp.wisc.edu/awardmgt/directcosts.cfm">https://rsp.wisc.edu/awardmgt/directcosts.cfm</a> Tuition Remission: <a href="https://rsp.wisc.edu/policies/tuitionremission_faq.cfm">https://rsp.wisc.edu/policies/tuitionremission_faq.cfm</a>	
Restoring public trust in science and medicine	https://www.hhs.gov/about/strategic-plan/2022-2026/goal-4/index.html https://www.hhs.gov/about/strategic-plan/2022-2026/goal-5/index.html	
Intellectual Property Policies	UW-Madison IP Policy: <a href="https://policy.wisc.edu/library/UW-4008">https://policy.wisc.edu/library/UW-4008</a> UW-Madison IP Policies and Forms: <a href="https://research.wisc.edu/intellectual-property/ip-policies-and-forms">https://research.wisc.edu/intellectual-property/ip-policies-and-forms</a>	