Advancing Translational Research & Science (ATRS)
Pilot Awards Program Announcement

PROGRAM OVERVIEW

One goal of the UW Institute for Clinical and Translational Research is to foster development of interdisciplinary collaborations that will advance translational research and science along a trajectory leading to new preventive or therapeutic options that improve human health. Translational science generates innovations that overcome longstanding challenges 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 — including diagnostics, treatments, and interventions — through the application of translational science.

The **overall goal** of the Advancing Translational Research & Science (ATRS) Pilot Awards Program Announcement is to support either innovative translational research or to elucidate novel processes that are generalizable to multiple translational research projects. Applicants will choose from amongst two separate tracks, as outlined below; all submissions must address the overall goal of the program, as stated above. Applicants may only submit **ONE** application to **ONE** track per grant funding year; multiple submissions are not allowed.

Applicants will choose one of two tracks to submit their grant proposal. The two tracks are as follows:

1. **Track 1, Project Planning Grant**: Designed to assist groups of investigators from a diverse range of disciplines refine cutting-edge research ideas, build collaborations, create shared research agendas, and develop strategic action plans for externally funded grant proposals. **Pilot awards are $25,000 maximum in direct costs for 12 months of support** and contingent upon successful non-competitive renewal of NCATS grant support. (See page 3 for instructions).
2. **Track 2, Translational Science Project:** Support for impactful translational science pilot projects **or** for development of novel translational methods addressing either mentorship science, team science, recruitment science, diversity science, or implementation science including projects applicable to Learning Health Systems (LHS). **Pilot awards are $50,000 maximum in direct costs for 12 months of support** and contingent upon successful non-competitive renewal of NCATS grant support. (See page 3 for instructions).

Potential applicants are encouraged to contact **Peggy Hatfield**, **(pmhatfie@wisc.edu)** with questions about programmatic relevance.

- PIs may submit only one application. Previous ICTR pilot grant awardees are ineligible to receive a second pilot award as PI or co-PI, regardless of content, if the previous award is still active.
- **PIs or co-PIs can only apply to a single ICTR Pilot RFA/PA per round of pilot funding per year.**
- Preference will be given to interdisciplinary teams (including different academic departments or non-academic partners), teams comprising multiple institutions, or CTSA sites.
- PIs **must also indicate** if the submitted proposal is under review or will be under review by another granting agency or funding source, including any internal UW sources. If the application is favorably reviewed, ICTR may consider a co-funding arrangement.

ELIGIBILITY of PI/MPI for all Tracks

- For multiple PI teams, only one PI may act as the fiscal representative responsible for award account management.
- PIs must be a UW-Madison faculty member or academic staff, sole or joint appointment (VA Hospital, UW Milwaukee), a UW Health employee, or a Marshfield Clinic investigator. Eligible MC/MCRI positions include PhD-prepared scientists and clinician-researchers allotted with designated research time. Eligible UW job titles include Professor (tenure, CHS, or clinical track) and Scientist with temporary or permanent PI status. Investigators who

are Full Professors or Senior Scientists are eligible to apply but must have a documented history of serving as an externally funded PI. We encourage all senior PIs to identify a less experienced co-I. A specific and substantial role for them on the research team should be described. Investigators from other universities or CTSA hubs are eligible to serve as Key Personnel on these applications.

- Whereas residents, fellows, post-doctoral associates are **NOT** eligible to serve as PIs, they are eligible to serve as co-Investigators.

Application and Submission Information

Prepare applications using the forms associated with this Announcement.

- **Important Dates**

  Mandatory Pre-Proposal Receipt: **February 16, 2024 by 5 pm CST**
  Invitation to Submit a Full Application: **February 26, 2024**
  Application Receipt: **April 1, 2024 by 5 pm CST**
  Peer Review: **April 2024**
  Scientific Committee Review: **May 2024**
  Award Announcement: **May 2024**
  Mandatory New Investigator Meeting: **June - July 2024**
  Earliest Grant Start: **July 1, 2024**

***Note, we are using NIH funding for these pilot awards. As such, the start and end dates are non-negotiable and there is no possibility of a no-cost extension**. Pilot funding is contingent upon successful non-competitive renewal of NCATS grant support.

- **Pre-Proposal Contents**

  Prospective applicants must submit a 2-page pre-proposal that includes the following information:

  1. Title of proposed research project, and selection of the relevant track. **Please note: the title and PI of the pilot project must match the title and PI of any relevant approved/pending IRB or IACUC protocol. Also, the approved IRB protocol must cover only the proposed project activities and cannot be part of a larger, approved parent protocol.**
  2. Name, address, telephone number, and email address of the PI(s).
  3. Names of other key personnel crucial to the design and conduct of the proposed research.
  4. Participating institution(s).
  5. Description of the proposed activities with enough detail to evaluate programmatic relevance (potential for impact on human health through the formation and action of the interdisciplinary translational team – Track 1; potential of the research to develop novel generalizable methods/tools/processes – Track 2).
  6. Plans for future project development including specific grant opportunities, dissemination plans, etc.

  The letter of intent should be sent electronically to **Peggy Hatfield**, **(pmhatfie@wisc.edu)** on or before **February 16, 2024**.

- **Content and Form of Application Submission**

  The pilot award application is comprised of information arranged into separate components that will be uploaded as individual pdf documents. A completed application in response to this Announcement must include the following components.

  1. Applicant Information
  2. Project Narrative (maximum 5 pages, including Specific Aims; see details below)
  3. Timeline for completion of the project (see above for start and end dates)
  4. Other Information (see details below)
  5. NIH Human Subjects or Vertebrate Animal section (if applicable)

6. Literature citations
7. Budget page; budget justification (maximum ½ page); lack of existing resources to carry out project (maximum ½ page)
8. Biosketches for key personnel
9. Other support for key personnel; include notation of overlap with previously funded projects to the proposed research
10. Essential letters of support, collaboration, and matching funds (if applicable)
11. Human subjects, animal protocol, biological safety letters of approval, if available

- **Submission of Completed Application**
  1. Research teams who submit a preproposal will receive specific information by email regarding the process for submitting a full application through REDCap.
  2. Applications are not processed by UW Research & Sponsored Programs. Submit completed applications on or before **5 pm CST on April 1, 2024.**

APPLICATION SPECIFICS

- **Project Narrative**

  The project narrative is limited to 5 pages in length, 8.5" X 11", single-spaced, with margins set at no less than 0.75 inches, each side. Use the font face Arial, 11-point. The narrative should include the following sections in the order presented below:
  - Specific Aims with clear, measurable objectives.
  - Significance, innovation, and approach. (A statement of hypothesis may not be appropriate, depending upon the proposed research.)
  - Preliminary studies/concepts.
  - Description of the study design and methods, as well as the proposed analytical plan.

- **Other Required Information**

  Following the Narrative, please describe the following <u>two</u> (Track 1) or <u>three</u> (Track 2) items listed below:
  - **Track 1 and Track 2:** Relationship of anticipated pilot study results to **future grant submissions**.
  - **Track 1 and Track 2: Dissemination plan** (up to 1 page). Indicate how the new translational team (Track 1) or novel method (Track 2) will contribute to human health, as well as the potential for generalizability. For new methods provide specific details regarding future collaborators and(or) stakeholders to be engaged; timeline; additional research/development work needed; dissemination scale (local, national, international).
  - **Track 2 only: Collaboration Plan** (1-2 pages):
    - The team decision making process for the scientific direction and research plan.
    - The distribution of responsibilities and work processes.
    - The full engagement of MPIs as co-equal partners.
    - The meeting frequency and modality.
    - The method of asynchronous communication (email use; document sharing).
    - Task and project management.
    - Process of budget allocation among the collaborators.

- **Budget**

  Use funds to directly support the research project. Examples of allowable expenses include: laboratory and computing supplies, research subject incentives, and research personnel. Investigator salary is allowed, but clear justification of the need must be provided. Graduate student and post-doctoral associate stipends are similarly allowed with justification; include graduate student tuition remission in the budget, as mandated by the UW. Equipment that is essential and solely for the study and not otherwise available may be requested, but large equipment expenditures (> $5,000) are prohibited. **Indirect administrative costs are not allowed**.

Applicants may use the PHS 398 budget form, or a just a line-item budget. Include cost basis information in the budget justification. Although cost sharing is not required, the UW ICTR is interested in leveraging its funds with others (e.g., departmental research funds). Letters detailing the scope of such support must be included in the application.

APPLICATION REVIEW INFORMATION

Each proposal will be evaluated using the NIH 9-point rating scale (1 = exceptional; 9 = poor) scoring system. Each application will receive a separate score for each of five core review criteria (Significance, Investigator(s), Innovation, Approach, and Environment) and Overall Impact. We will determine scientific merit by averaging these preliminary impact scores from two independent reviewers with appropriate expertise. An ICTR review panel will evaluate and rank applications. The panel will also consider review criteria such as new collaborations (Marshfield, or junior-senior, or interdisciplinary). They will also consider whether the budget is reasonable and justified in relation to the proposed research and may recommend further clarification and(or) modifications. All applicants will receive a brief summary statement explaining the rationale for the scores, funded or unfunded, following completion of the review process.

- **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 process of translation, in consideration of the following five core review criteria, and additional review criteria (as applicable for the project proposed). An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.
- **Significance.** Does the project address an important problem or a critical barrier to progress in translational research? If the aims of the project are achieved, how will technical capability and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that broadly impact translational science?
- **Investigator(s).** Are the MPI/PIs, collaborators, and other researchers well suited to the project? If Early-Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or MPI/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?
- **Innovation.** Does the application challenge and seek to shift the current paradigm? Are the concepts, approaches or methodologies novel in a broad sense?
- **Approach.** Is the overall strategy, study design, methodology, and analysis plan well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
- **Environment.** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?
- **Translational Team Building (Track 2).** Review criteria for evaluating the Collaboration Plan includes:
  i. Does the plan articulate full engagement of PIs in proposed activities, resource access, and plan management?
  ii. Is there clarity of the roles and areas of responsibility for team member activities and are clear lines of communication established?

AWARD ADMINISTRATION INFORMATION

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

- PIs for Track 1 and 2 applications must obtain the appropriate regulatory assurances for all protocols (e.g., IRB, IACUC); add ICTR funding to approved protocols; and forward copies of all approval documents to the ICTR award administrator. Awarded applications dealing with human subjects and vertebrate animals **must undergo prior approval from NCATS program staff before funding will be released on July 1, 2024.**
- Quarterly and final progress reports outlining accomplishments to date are required of all awardees.
- Within 60 days of the project end date, submit a final written description of accomplishments, including publications, new grant applications/awards, and plans to develop further the novel methodology, including plans for dissemination.

Awardees must acknowledge the support obtained from ICTR on all presentations and publications: *Funding for this project was provided by the UW Institute for Clinical and Translational Research, grant 1UL1TR002373, from the Clinical and Translational Science Award of the NCATS/NIH.* In addition, all grantees must adhere to the NIH Public Access Policy and obtain PMCID numbers for every publication utilizing pilot data.