**—Request for Applications—**

**Translational Basic & Clinical Research Pilot Awards Program**

**APPLICATION DEADLINE: June 17, 2024**

**PROGRAM OVERVIEW**

One goal of the UW ICTR is to foster development of interdisciplinary translational research teams that will advance drugs, devices, products, and behavioral interventions along a trajectory leading to new preventive or therapeutic options that improve human health and advance health equity. This Pilot Awards funding mechanism will provide support for: clinical research projects that define and develop novel clinical interventions; translational aspects of research incorporated into an investigator-initiated project; or novel technologies supporting such interdisciplinary collaborations. Given the recent COVID-19 pandemic, we welcome novel projects that address contemporary and(or) emerging health crises. We expect applicants to articulate the path to translation of their proposal, including the next steps for their completed project. Potential applicants are encouraged to contact **Peggy Hatfield,** (pmhatfie@wisc.edu), 261-1939) with questions regarding programmatic relevance.

* **Pilot applications MUST have two PIs from different scientific disciplines. Applicants will need to provide justification/evidence the PI team meets this qualification. Differences will also be inferred from areas of specialization and(or) degree training or departmental affiliation.**
* Pilot awards are $50,000 maximum in direct costs for 12 months of support. Funds for this round of pilot awards are contingent upon successful non-competitive renewal of NCATS grant support.
* Projects targeted to pediatric or geriatric sciences, and health disparities are encouraged. So too, are new or expanded collaborations between UW-Madison and Marshfield Clinic and junior-senior investigators.
* Investigators may **NOT** submit more than one application, as PI. **Furthermore,** PIs can only apply to a **single** ICTR Pilot RFA per round of ICTR funding. Investigators can be Key Personnel on another submission.
* **Any project meeting the revised NIH definition of a clinical trial (**https://grants.nih.gov/policy/clinical-trials/definition.htm), **will be subject to additional review criteria** (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-118.html)
* **Previous ICTR pilot grant awardees are ineligible to receive a second grant as PI, regardless of content, if the previous award is still active**.
* *If awarded,* we may invite research teams to participate in a facilitated Collaboration Planning process as part of the [ICTR Team Science](https://ictr.wisc.edu/team-science/) initiatives.

**ELIGIBILITY of LEAD APPLICANTS**

* Proposals must include two PIs (MPI) from different scientific disciplines. MPIs must designate one of the PIs to serve as the Corresponding PI responsible for award account management.
* PIs must be a UW-Madison faculty member or academic staff, sole or joint appointment (VA Hospital, UW Milwaukee), 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; Assistant, Associate, Full); Scientist (all Assistant, Associate, Senior) with temporary or permanent PI status.
* Funds are primarily intended to foster career development of junior to midlevel investigators. Investigators who are Full Professors or Senior Scientists are eligible to apply but must have a documented history of serving as a PI on a federally or nationally funded grant. We encourage all senior PIs to identify and mentor a less experienced investigator(s) as part of the research team and describe specific and substantial roles for the mentee(s).
* Whereas residents, fellows, post-doctoral associates are **NOT** eligible to serve as PIs, they are eligible to serve as co-Investigators.
* MPIs must have well-developed plans for preparing an extramural research application (through NIH or other similar funding source), and results from this pilot award application should form a significant part of the plan. This requirement is especially critical for those in the **Scientist track** wishing to serve as PI/MPI; include detail in the **Personal Statement** of the NIH Biosketch on how the proposed research represents an independent area of investigation. Also, a letter is required from the mentor and(or) department chair or dean expressing strong support for this independence and an outline of the PI’s proposed academic trajectory.

**APPLICATION and SUBMISSION INFORMATION**

Prepare applications using the forms attached to this Announcement. Applicants, who responded to a previous UW ICTR Pilot Award RFA but were NOT funded, must submit a **NEW** application responsive to this Announcement.

* **Important Dates**

**Mandatory** Letter of Intent Receipt: **May 13, 2024 by 5 pm CST**

Application Receipt: **June 17,2024 by 5 pm CST**

Peer Review: **June-August 2024**

Scientific Committee Review: **August 2024**

Award Announcement: **September 2024**

**Mandatory** New Investigator Meeting: **September 2024**

Earliest Grant Start: **September 1, 2024**

* **Mandatory Letter of Intent**

Prospective applicants are **REQUIRED** to submit a 1-page letter of intent (Word document) that includes the following information:

1. Title of proposed research project.
2. Contact information for the PIs.
3. Names of other key personnel.
4. Participating institution(s).
5. Description of the proposed research with enough detail to assign scientific reviewers. Include a sentence that outlines the path to translation of this project and planned next steps.
6. Names of potential **non-conflicted** UW or Marshfield reviewers with appropriate scientific expertise. NOTE, this does not guarantee the named individuals will be contacted.

The **mandatory** letter of intent should be sent electronically to **Peggy Hatfield**, **(pmhatfie@wisc.edu)** on or before **5 pm on** **May 13, 2024**.

* **Content and Form of Application Submission**

The pilot award application is comprised of information arranged into separate components. A completed application in response to this Announcement must include the following components with **each page numbered sequentially** starting with the Face Page:

1. Face Page + Abstract form, included in Translational Basic & Clinical Research Pilot Application Materials, ICTR website
2. Project narrative (maximum 5 pages, see below for details)
3. Other information (maximum 3 pages, see below for details)
4. Timeline for completion of the project (maximum 12 months)
5. Literature citations
6. Justification and leadership plan. Indicate which PI will serve as the Corresponding PI. Describe how the MPI will share responsibility for completion of the project (roles, progress reports, collaborations). PIs must also provide evidence of interdisciplinarity within the MPI (i.e., different departments, different academic discipline training/orientation)
7. Biosketches for key personnel and mentors
8. Other support for key personnel and mentors, if applicable; include notation of overlap with previously funded projects to the proposed research
9. Budget page; budget justification; statement regarding lack of existing resources to carry out project (non-supplanting). Acknowledgement of support, collaboration, and matching funds (include details in the budget)
10. Human subjects, animal protocol, biological safety letters of approval, if available

* **Submission of Completed Application**

1. Submit all applications electronically as a **SINGLE** document, either in Microsoft Word or Adobe pdf format.
2. Applications are not processed by UW Research & Sponsored Programs. Submit completed applications directly to Peggy Hatfield (**pmhatfie@wisc.edu**) **on or before 5 pm on June 17, 2024**.

**APPLICATION SPECIFICS**

* **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 must include the following sections below:

1. Specific Aims with clear, measurable objectives.
2. Significance, innovation, and approach.
3. Preliminary studies, if appropriate.
4. Description of the study design and methods, as well as the proposed statistical analysis plan. Gamble C et al. Guidelines for the Content of Statistical Analysis Plans in Clinical Trials. JAMA 2017;318(23): 2337-2343.
5. Does the proposed research address one of the following targeted research areas: pediatric or geriatric sciences; emergent health crises; and(or) health disparities (primarily racial and ethnic)?

* **Other Information**

Following the Narrative, briefly address the items listed below:

1. Relationship of the anticipated pilot study results to future grant submissions, including new collaborations needed to translate findings to the next step.
2. Dissemination plan for newly developed methods/interventions should include: future collaborators and(or) stakeholders to be engaged; timeline; additional research/development work needed; dissemination scale (local, national, international). Indicate how this method/intervention will contribute to human health, as well as the potential for generalizability. You may also wish to consult with the ICTR Dissemination & Implementation Launchpad.
3. Indicate whether you obtained stakeholder feedback (e.g., patient advocacy groups, community clinicians, health care administrators) on the proposed research project, or whether you intend to do so following completion of the pilot.
4. Collaboration Plan (1-2 pages): Please describe the following:
   1. The team decision making process for the scientific direction and research plan.
   2. The distribution of responsibilities and work processes.
   3. The full engagement of both PIs as co-equal partners.
   4. The meeting frequency and modality.
   5. The method of asynchronous communication (email use; document sharing).
   6. Task and project management.
   7. Process of budget allocation among the collaborators.
   * **Budget**

Use funds to directly support the research project. Examples of allowable expenses include: laboratory supplies and sample testing; research personnel; research participant reimbursement; and essential participant travel/parking expenses. Investigator salary is allowed, but clear justification of the need must be provided and should be modest. 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 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 must use the **TBC Budget form**, included in Translational Basic & Clinical Research Pilot Application Materials, ICTR website. Include cost basis information in the budget justification and justifications for each budget category.

Although cost sharing is not required, the UW ICTR is interested in leveraging its funds with others (e.g., departmental research funds). Expenditures covered by other support must be included in the budget with details sufficient to address feasibility of the overall project and concerns about non-supplanting.

**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 at least two independent reviewers with appropriate expertise. Applications deemed of high scientific merit will be evaluated and ranked by an ICTR scientific review committee. All applicants will receive a brief summary statement explaining the rationale for the scores, funded or unfunded, following completion of the review process.

As noted above, those applications meeting the revised NIH definition of a clinical trial will be subject to the additional review criteria presented following the standard review criteria.

**Standard Review Criteria**:

* + **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 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 the field? If the aims of the project are achieved, how will scientific knowledge, 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 drive this field?
  + **Investigator(s).** Are the PD/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)? Does the MPI 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 current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
  + **Approach.** Are the overall strategy, study design, methodology, and statistical 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? Are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?
  + **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?
  + **Collaboration.** Review criteria for evaluating the Collaboration Plan includes:
    1. Does the plan articulate full engagement of both PIs in proposed activities, resource access, and plan management?
    2. Is there clarity of the roles and areas of responsibility for team member activities and are clear lines of communication established?

**Additional Clinical Trial Review Criteria:**

**Revised NIH Definition:** A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

* **Significance.** Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy?  For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?
* **Investigator(s)**. For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?
* **Approach**. Does the application adequately address the following, if applicable?

Study Design:

* Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?
* Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?
* Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

Data Management and Statistical Analysis Plan:

* Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?
* **Environment**. If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed? Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate? If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial? If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and (4) operate within the proposed organizational structure?

Following primary review, proposals with the highest scores will be evaluated further by a formal scientific review committee. The committee will consider additional review criteria such as whether the proposed research involves pediatric or geriatric sciences, health disparities, contemporary or emergent health crises, new or expanded Marshfield collaborations, new junior-senior partnerships, novel methodologies, or other funding priorities. They will also consider whether the budget is reasonable and justified in relation to the proposed research and may recommend modifications.

**NOTE**: Applicants advancing to this second phase of review will be notified of such in **August of 2024**. The intent of the notification is to afford applicants time to amend or construct necessary regulatory documents (IRB, IACUC, Biological Safety, Stem Cell Research Oversight).

**AWARD ADMINISTRATION INFORMATION**

All applicants receiving pilot awards will be required to attend a **mandatory** investigators’ meeting to discuss administrative requirements. Among those requirements are the following:

* PIs must obtain the appropriate regulatory assurances for all protocols (e.g., IRB or animal committee), and will forward copies of all approval documents to the ICTR Piot Awards Program Manager.
* Progress reports outlining accomplishments to date and spending projections will be required of all awardees quarterly, from the post-award date. **In addition, awardees must acknowledge ICTR funding (and partner co-funding, if applicable) in all publications and presentations**.
* Within 60 days of the project end date, submit a written description of accomplishments, including conference abstracts, publications, grant applications, and plans to further develop the project.

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

Contact **Peggy Hatfield, 261-1939, pmhatfie@wisc.edu**, with any questions.