Basic & Clinical Translational Research Pilot Awards Program

— Request for Applications —

Translational Basic & Clinical Research Pilot Awards Program

DEADLINE: March 4, 2016

PROGRAM OVERVIEW

One goal of the UW ICTR is to foster development of translational collaborations that will advance research along a trajectory leading to new therapeutic options that improve human health (see UW ICTR web site for definitions). 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. Applicants will be expected 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 awards are $50,000 maximum in direct costs for 12 months of 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 or as a co-PI. Investigators can be Key Personnel on another submission.
- NEW: PIs or co-PIs can only apply to a single ICTR Pilot RFA in a calendar year.
- Previous ICTR pilot grant awardees are ineligible to receive a second grant as PI or co-PI, regardless of content, if the previous award is still active. Moreover, investigators cannot be PI or co-PI on more than one ICTR pilot award of ANY type concurrently.

ELIGIBILITY of LEAD APPLICANTS

- PIs and co-PIs must have applied for membership to ICTR at Membership Application before submission of the grant application on March 4, 2016. We also highly encourage co-Investigators and key scientific personnel to apply for membership.
- Proposals may include up to two co-PIs, with justification. Nonetheless, only one of the co-PIs will be assigned 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), or a Marshfield Clinic investigator. Eligible UW job titles include Professor (tenure, CHS, or clinical track); Scientist with temporary or permanent PI status; ICTR KL2 Scholar; and comparable Marshfield Clinic job classifications.
- 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 less experienced investigators and describe specific and substantial roles for them on the research team.
- Whereas residents, fellows, post-doctoral associates are NOT eligible to serve as PIs, they are eligible to serve as co-Investigators.
- PIs must have well-developed plans for preparing a national research or career development 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; include detail in the Personal Statement of the new format NIH Biosketch on how the proposed research represents an independent area of investigation. Include a letter 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**
  - Application Receipt: March 4, 2016
  - Peer Review: April-May, 2016
  - Scientific Committee Review: May, 2016
  - Award Announcement: June, 2016
  - Mandatory New Investigator Meeting: June, 2016
  - Earliest Grant Start: July 1, 2016

- **Mandatory Letter of Intent**
  Prospective applicants are REQUIRED to submit a 1-page letter of intent that includes the following information:
  1. Title of proposed research project.
  2. Name, address, telephone number, and email address of the PI and co-PI, if relevant.
  3. Names of other key personnel.
  4. Participating institution(s).
  5. Description of the proposed research with enough detail to assign 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 January 15, 2016.

- **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 Annoucement must include the following components arranged in this order, each page numbered sequentially starting with the Face Page:
  1. Face Page included in Translational Basic & Clinical Research Pilot Application Materials (Abstract + Key Personnel (include name, dept, project role, ERA Commons name)
  2. Project narrative (maximum 5 pages, see below for details)
  3. Other information (maximum 2 pages, see below for details)
  4. Time line for completion of the project (maximum 12 months)
  5. Literature citations
  6. Justification and leadership plan, if multiple PIs are proposed. Indicate which PI will serve as the fiscal agent for the project. Describe how the PIs will share responsibility for completion of the project (roles, progress reports, collaborations)
  7. Biosketches for key personnel and mentors (Follow new 2015 NIH format; example listed on the main RFA web page, [https://ictr.wisc.edu/FundingOpportunities](https://ictr.wisc.edu/FundingOpportunities)).
  8. Other support for key personnel and ICTR 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
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• 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 March 7, 2016.

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 should include the following sections below:
  1. Specific Aims with clear, measurable objectives.
  2. Significance, innovation, and approach.
  3. Preliminary studies, if appropriate.
  4. Does the proposed research address one of the following targeted research areas: pediatric or geriatric sciences, and(or) health disparities (primarily racial and ethnic)?

• Other Information
  1. Collaborative/interdisciplinary aspects of the proposed research.
  2. Relationship of the anticipated pilot study results to future grant submissions, including new collaborations needed to translate findings to the next step.
  3. Specific dissemination plans for translating pilot data, including dissemination scale (local, national, international).
  4. Indicate whether as PI you have solicited 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. Be specific in providing stakeholder details, including a letter of support, if applicable.
  5. Indicate how each member of the team (Key Personnel and Significant Contributors) will contribute to and benefit from the pilot project. **Note**, this is not meant to reiterate information presented in the budget justification (e.g., effort, role).

• 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 may use the PHS 398 budget form. Equally acceptable is to use a word processing program to create a line-item list of each expense. 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). Expenditures covered by other support must be included in the budget with sufficient detail to address feasibility of the overall project and concerns about non-supplanting.

• A **Frequently Asked Questions** (FAQ) document can be accessed at the [UW ICTR web site](http://www.uwictr.org).
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. The preliminary impact scores will be used to determine which applications will be discussed. We will determine scientific merit by averaging these preliminary impact scores from two independent reviewers with appropriate expertise. Applications deemed of high scientific merit will be evaluated and ranked by an ICTR review committee. Among proposals that do not receive funds, the committee may also select those of sufficient merit to warrant special mentoring or program assistance from ICTR. 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 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)? If the project is collaborative or multi-PD/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 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, methodology, and analyses 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?

Following primary review, proposals with the highest scores will be evaluated further by a formal review panel. The panel will consider additional review criteria such as whether the proposed research involves pediatric or geriatric sciences, health disparities, 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 early May. 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 award administrator.
- 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 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.
- Each awardee must meet with the director of the ICTR Pilot Award Program, Dr. Christine Sorkness, to discuss the final report and future directions.

Awardees must acknowledge the support obtained from ICTR on all presentations and publications: Funding for this project was provided by the UW ICTR, grant UL1TR000427, 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.