—Request for Applications—
Novel Methods Pilot Awards Program
APPLICATION DEADLINE: December 2, 2016

PROGRAM OVERVIEW

One goal of the UW ICTR is to foster development of translational and clinical collaborations that will advance research along a trajectory leading to new preventive or therapeutic options that improve human health. Specifically, this funding mechanism will provide support for translational research methods broadly defined, that can be generalizable to other projects. The proposed method should **NOT** be directly project-specific. Examples of applicable T0-T2 methods include, but are not limited to: translational analytic methods; precision medicine methods. Applicable T2-T4 methods include, but are not limited to: dissemination and implementation research methods; patient-centered outcomes methods; and community/stakeholder engagement methods. Potential applicants are encouraged to contact **Peggy Hatfield**, (**pmhatfie@wisc.edu, 608-261-1939)** with questions about programmatic relevance.

- Pilot awards are $50,000 maximum in direct costs for 12 months of support.
- 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 in a calendar year.**
- Preference will be given to interdisciplinary teams (including different academic departments or private partners), teams comprising multiple institutions or CTSA sites.

ELIGIBILITY of LEAD APPLICANTS

- PIs and co-PIs must have applied for membership to ICTR at Membership Application before submission of the grant application.
- Proposals may designate two PIs with justification. Nonetheless, only one PI 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; and comparable Marshfield Clinic job classifications. Investigators who are Full Professors or Senior Scientists are eligible to apply, but must have a documented history of serving as a federally funded PI. We encourage all senior PIs to identify a less experienced co-I and describe a specific and substantial role 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.

APPLICATION and SUBMISSION INFORMATION

Prepare applications using the forms attached to this Announcement.

- **Important Dates**

Mandatory Letter of Intent Receipt Date	**November 1, 2016**
Application Receipt Date	**December 2, 2016**
Peer Review Date	**January, 2017**
Committee Review Date	**February, 2017**
Award Announcement Date	**February-March, 2017**
NCATS Prior Approval submission	**May, 2017**
Grant Start Date	**July 1, 2017***
Grant End Date	**June 30, 2018***
*Note, we are using NIH funding for these pilot awards. As such, the start and end dates are set and there is no possibility of a no-cost extension.	

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- **Letter of Intent**

    Prospective applicants must 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 Lead Applicant.
    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 assign reviewers.
    6. Names of potential **non-conflicted** reviewers with appropriate scientific expertise. NOTE, this does not guarantee the named individuals will be contacted. Applicants may also indicate reviewers that should not be invited.

    The letter of intent should be sent electronically to **Peggy Hatfield**, **(pmhatfie@wisc.edu)** on or before **November 1, 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 Announcement must include the following components arranged **in this order**, **each page numbered sequentially** starting with the Face Page:
    1. Face Page included in Novel Methods Pilot Award Application Materials (Abstract + Key Personnel (include name, dept, project role, ERA Commons name)
    2. Project Narrative (maximum 5 pages; see details below)
    3. Time line for completion of the project (see above for start and end dates)
    4. Other Information (see details below)
    5. NIH Human Subjects 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 using the new NIH biosketch format
    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. 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 **December 2, 2016.**

APPLICATION CHARACTERISTICS

- **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, if appropriate.

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- **Other Information**
  Following the Narrative, address the three items listed below:
  1. Relationship of anticipated pilot study results to future grant submissions, or demonstration of immediate needs.
  2. Dissemination plan for newly developed methods with specific details (collaborators and(or) stakeholders to be engaged; time line; additional research/development work needed; dissemination scale (local, national, international). Indicate how this method will contribute to human health, as well as the potential for generalizability. For example, you may propose to post the tool on HIPxChange (https://www.hipxchange.org/); email HIPxChange@hip.wisc.edu for more information. You may also wish to consult with the ICTR Dissemination & Implementation resource to develop a plan; you may schedule a consult using this [consult form](#) or contact Melody Bockenfeld at bockenfeld@wisc.edu.
  3. Outline the team members that will be engaged in this pilot award application (eg., specific disciplines, research training and/or expertise).

- **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 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). 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. Applications will be evaluated and ranked by an ICTR review panel. The panel will also consider review criteria such as the applicability to discovery and development of preventive or therapeutic interventions, and 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 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 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

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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 methodologies? Are the concepts, approaches or methodologies novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, or instrumentation 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?
  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?

AWARD ADMINISTRATION INFORMATION

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

- PIs must obtain the appropriate regulatory assurances for all protocols (e.g., IRB , IACUC), and will forward copies of all approval documents to the ICTR award administrator. Awarded applications dealing with human subjects **must undergo prior approval from NCATS program** staff before funding will be released on July 1, 2017.
- 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, and notify ICTR of such publication submissions/acceptances, as well as any grant applications using data generated from the pilot project.**
- Within 60 days of the project end date, submit a written description of accomplishments, including publications, new grant applications/awards, and plans to further develop the novel methodology, including plans for dissemination.
- Each awardee must meet with the director of the ICTR pilot award program, Dr. Chris 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 Institute for Clinical and Translational Research, grant UL1TR000427, 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.

Contact Peggy Hatfield, 608-261-1939, pmhatfie@wisc.edu, with any questions.

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