### Request for Applications

**ICTR MCRI & UW-Madison Collaborative Award**

<table>
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<th>Key Dates and Info</th>
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<tr>
<td><strong>Funding Tracks</strong> (choose one)</td>
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<tr>
<td><strong>Track 1</strong></td>
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<tr>
<td>• $50,000 max (direct costs only)</td>
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<td>• 12 months</td>
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<td>• Supports new MCRI + UW-Madison collaborations</td>
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<td><strong>Track 2</strong></td>
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<td>• $100,000 max (direct costs only)</td>
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<td>• 18 months</td>
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<td>• Supports previously established MCRI + UW-Madison collaborations</td>
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<td><strong>Requirements</strong></td>
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<td>• Co-PIs, one from MCRI and one from UW-Madison</td>
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<td>• Projects address contemporary and/or emerging rural health crises</td>
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<tr>
<td><strong>Letter of Intent Due (required)</strong></td>
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<td>July 1, 2024</td>
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<tr>
<td>Submit via email to Bri Deyo, <a href="mailto:deyo@wisc.edu">deyo@wisc.edu</a></td>
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<tr>
<td><strong>Invitations to Submit Full Application</strong></td>
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<td>July 15, 2024</td>
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<td><strong>Full Application Due</strong></td>
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<td>August 5, 2024</td>
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<td>Submit via REDCap link in invitation</td>
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<tr>
<td><strong>Peer Review</strong></td>
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<tr>
<td>August-September, 2024</td>
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<td><strong>Scientific Review</strong></td>
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<td>October, 2024</td>
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<td><strong>Award Announcement</strong></td>
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<td>October, 2024</td>
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<td><strong>Earliest Grant Start</strong></td>
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<td>November 4, 2024</td>
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<td><strong>Contact</strong></td>
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<tr>
<td>Bri Deyo, ICTR Pilots Awards Program Manager</td>
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<tr>
<td><a href="mailto:deyo@wisc.edu">deyo@wisc.edu</a>, 608-262-9188</td>
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<td><strong>More Information</strong></td>
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<td><a href="https://ictr.wisc.edu/funding-opportunities-2/#marshfield-clinic-uw-collaborative-research">https://ictr.wisc.edu/funding-opportunities-2/#marshfield-clinic-uw-collaborative-research</a></td>
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<tr>
<td>Website includes links to:</td>
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<tr>
<td>• RFA</td>
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<td>• Budget template</td>
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<td>• Info on previously funded projects</td>
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PROGRAM OVERVIEW
With a long history of fostering clinical and translational research, ICTR strongly endorses collaborative partnerships between Marshfield Clinic Research Institute (MCRI) and the University of Wisconsin-Madison. This award serves as a catalyst for new and continued collaborative research endeavors. As such, priority will be afforded to teams that demonstrate the collaboration of interdisciplinary skills and perspectives.

The MCRI & UW-Madison Collaborative Award provides support for proposals that build upon the research interests and infrastructure support of both partners. Projects must be led by Co-Principal Investigators (MPIs), one from Marshfield and one from UW-Madison.

This award particularly focuses on projects that address contemporary and/or emerging rural health crises. This emphasis includes reducing the burden of disease and promoting health equity and addressing longstanding regional health disparities. Links to additional information and definitions are in the table at the end of this document. Examples of relevant human research or highly valuable project elements include (but are not limited to):

- **Design and/or test innovative strategies to increase access to clinical trials to rural populations** (e.g., use of mobile research units/teams, virtual/digital technology, at-home sample collection methods, etc.)
- **Intentional recruitment and inclusion of diverse populations in rural Wisconsin** (e.g., tribal, plain/Anabaptist, Hmong, Black, Latine, and/or LGBTQ+ communities)
- **Utilize social determinants in bidirectional community planning and/or large data sets** (e.g., Neighborhood Health Partnerships Program, occupational industry codes in the electronic health record; enhance the intake or quality of similar kinds of data)
- **Operationalize understanding of the social and cultural community factors influencing the degree of public trust/perception of science and medicine by rural populations.**
- **Implement and assess new clinical and public health interventions for rural trauma care and injury prevention** (e.g., prevention of roadway incidents with agricultural machinery or horse-drawn equipment; prevention of youth injury in agricultural environments; suicide prevention; etc.)
- **Develop tools/methods that enhance mental health diagnosis, treatment, and/or preventive care in economically disadvantaged communities.**
- **Design and/or test innovative strategies that prevent or treat opioid addiction, methamphetamine use, and/or other substance misuse in rural youth.**
- **Design and/or test innovative strategies that tailor suicide prevention strategies to rural populations.**

**FUNDING**
Awards are contingent upon available funding. Each award is funded partially by the UW-Madison Institute for Clinical and Translational Research (ICTR), and partially by the Marshfield Clinic Health System Foundation (MCHSF). Applicants must submit a budget for each site that totals no more than the maximum listed for the respective award Track. ICTR will fund UW-Madison budgets, while MCHSF will fund Marshfield budgets.

**ELIGIBILITY**
- One PI from each organization
  - The UW-Madison PI must be a UW-Madison faculty member or academic staff, sole or joint appointment (VA Hospital, UW System). Eligible UW titles include Professor (tenure, CHS, or clinical track; Assistant, Associate, Full); Scientist (Assistant, Associate, Senior) with temporary or permanent PI status.
The MCRI PI must be a Marshfield Clinic Research Institute (MCRI) scientist or clinician investigator with contracted, protected time for conducting research Clinician Dedicated Research Time (CDRT). Eligible MCRI titles include Scientist (Associate, Research, Senior) and Clinician-researcher.

- Individuals that do not fit the criteria to serve as a PI (residents, fellows, post-doctoral associates, adjunct professors) may serve as Co-Investigators (Co-I).
- Individuals may be listed as the PI on only one application
  - An individual serving as PI on an application may serve as a Co-I for additional proposals under the lead of another PI.
- PIs may not have another active ICTR pilot award.
  - An individual serving as PI on an active pilot award may serve as a Co-I for additional proposals.
- Junior to mid-level investigators, with limited experience leading projects are strongly encouraged to partner with senior investigators who serve as Co-Is or mentors for the proposed project.

APPLICATION AND SUBMISSION
These instructions apply to both Track 1 and Track 2 applications. Deadlines, contact info, and submission details are listed in the table on Page 1 of this RFA.

Letter of Intent (LOI) - REQUIRED
An LOI must be submitted prior to completing any other items in the application process. Once the LOI is received, the PIs will receive an e-mail acknowledgment. The LOI will assist in identification of appropriate peer reviewers and is not used to exclude applicants.

The Letter of Intent must include the following information:
- Title of proposed research project
- Specify one: Track 1 or Track 2
- Names, addresses, telephone numbers, and email addresses of the Co-PIs
- Names and roles of key personnel crucial to the design and conduct of the proposed research
- Participating institutions, organizations, community partners and/or consultants
- A very brief description of the proposed activities
- Format: 1 page maximum, single spaced, 0.75” minimum margins, Arial 11-point font

After LOIs are received and reviewed, eligible proposals will be selected, and Co-PIs will be invited via email to submit a full application.

Full Application
Co-PIs of projects that are selected for full application will receive an invitation via email that contains a link to the online submission form.

Online Form Fields
The online submission form contains fields that collect academic information about the contact PIs from each institution, and demographic information about the PI completing the form. The PI completing the form should enter their information first, and then add information about the second PI in the “Partner PI Information” section. Additional information that must be entered for both PIs includes: ORCID, eRA Commons ID, and institution mailing address.
A complete application must include all the following components, **combined into one PDF file and submitted via the online submission form:**

**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” per side, in 11-point Arial font. The narrative should include the following sections in this order:

- **Specific Aims:** List clearly defined, measurable objectives. A statement of hypothesis may or may not be appropriate, depending upon the proposed research.
- **Significance, innovation, and approach:** Address the clinical impact of the new strategies, models, and tools. Indicate how the proposed work may address health and healthcare challenges in rural and other inequitably served populations.
- **Study design and methods:** Describe study procedures and data collection.
- **Statistical analysis plan:** Describe according to guidance by Gamble C et al. Guidelines for the Content of Statistical Analysis Plans in Clinical Trials. JAMA 2017;318(23): 2337-2343.
- **Preliminary studies:** List and/or refer as appropriate throughout (full citations go in the Citations section)

**Timeline**
Include all project activities and milestones, including (but not limited to):

- Development of project tools/case report forms
- Participant recruitment
- Data collection, extraction/abstraction, validation, analysis
- Case/control matching
- Report, presentation, and/or manuscript preparation and submission

**Citations**
List all citations referenced. No particular 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.

**Letters of Support**
PIs in a Scientist track must include a letter of support 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.

**Other Information**
In addition to the Narrative, applications must address each of the following:

- **Collaboration/Leadership Plan (1-2 pages), which describes:**
  - The team decision making process for the scientific direction and research plan.
  - The distribution of responsibilities and work processes (roles, progress reports, collaborations).
  - The full engagement of both PIs as co-equal partners.
  - The meeting frequency and modality.
  - The method of asynchronous communication (e.g., email, document sharing methods, etc.).
  - Task and project management.
  - Track 2 Projects should describe the successful past performance of the team and relevant outcomes.

- Relationship of the anticipated pilot study results to future grant submissions, including new collaborations needed to translate findings to the next step (1-2 paragraphs).
• Dissemination plan (1-2 paragraphs), which describes how the tools, materials, and/or results from the project will be disseminated, including:
  o Future collaborators and/or community partners to be engaged
  o Timelines
  o Additional research/development work needed
  o Anticipated funding needs
  o Dissemination scale (local, national, international)
  o Potential for generalizability

• Community partner and/or study population feedback (e.g., patient advocacy groups, community clinicians, health care administrators) on the proposed work (1-2 paragraphs), including:
  o Any completed or planned feedback
  o Specific partner/population details
  o Include a letter of support, if applicable

Biosketches
Must be submitted for all Co-PIs, Co-Is, and all other Key Personnel listed in the Budget, using the current NIH template. PIs in the Scientist track must include detail in the Personal Statement on how the proposed research represents an independent area of investigation.

Other Support
Must be submitted for all Co-PIs, Co-Is, 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.

Budget and Justification
Budgets must be submitted in the template provided, one form for each site (Marshfield and UW), and include all expenses that directly support the proposed project may not exceed the cap listed for the selected Track. Budget sections should include:
  • 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.
    o Investigator salary is only allowed for work related to this award, with justification.
    o Graduate student and post-doctoral associate stipends are allowed for work related to the pilot, with justification. Include tuition remission in the budget, per UW-Madison policy.
    o List all contributors, even those with in-kind or zero-dollar contributions.
  • Allowable Expenses: include laboratory and computing supplies, research subject incentives, and other expenses, according to UW-Madison policy. Specific to this RFA:
    o Equipment that is essential, solely for the study, and not otherwise available may be requested.
    o Large equipment expenditures (> $5,000) are not allowed.
    o Indirect and/or administrative costs are not allowed.
  • Budget Justification: Include cost basis information for all listed expenses.

Regulatory Approvals
Indicate whether or not the project involves contact with human research subjects and/or biologic samples. If so, describe what existing or planned regulatory reviews will be required (e.g., Institutional Review Board, Certificate of Confidentiality, biological/laboratory safety certifications, etc.).
REVIEW CRITERIA

Each full application will be evaluated using the NIH 9-point (1 = exceptional; 9 = poor) scoring system. Each application will receive a separate score for Overall Impact and each of five core review criteria (Significance, Investigators, Innovation, Approach, and Environment). Merit will be determined by averaging the preliminary scores from two independent reviewers with appropriate expertise. Applications will be evaluated and ranked by an ICTR review panel. The panel will strongly consider review criteria such as the impact on rural health and/or rural health disparities, and new collaborations (UW-Madison with 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 request 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 and rural health, 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 of rural health? 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?

Investigators

Are the PIs, collaborators, and other researchers well suited to the project? As the project is truly collaborative, do the investigators have complementary and integrated expertise, and are their leadership approach, governance, and organizational structures appropriate for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel approaches or methodologies? Are the concepts, approaches or methodologies 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 proposed?

Approach

Are overall strategy, study design, methodology, and statistical analysis plans well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success clearly presented? If the project is in the early stages of development, will the strategy establish feasibility and adequately manage risks? If the project involves clinical research, are the plans for the protection of human subjects, justified in terms of the scientific goals and research strategy proposed? Does the plan adequately plan for the inclusion of minorities, members of all sexes/genders, vulnerable populations, and/or children?

Environment
Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional supports and resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, and/or collaborative arrangements?

Special Focus on Rural Health Equity
This RFA strongly encourages projects that address contemporary and/or emerging rural health crises, especially those that directly impact rural populations or other communities with significant health and health care inequities. The implications and impact of the project for rural or other special populations with significant disparities should be well described.

To the extent the proposed project targets rural populations, the applicant should also describe and justify the definition of rural that they are using. This topic will serve as an additional scored criterion in the evaluation process.

- Common definitions and CDC priorities for rural health research can be found in the Additional References and Resources table at the end of this RFA.
- In summary, rural is an inexact term that can mean different things to different people, organizations, and governments. Trying to define “rural” is a challenging task in a nation with diverse geography and changing demographics. However, a precise definition of rural is important to those interested in rural issues. Federal and state policymakers, funders, service providers, and researchers need a clearly stated definition that is current in its interpretation.
- Whereas some definitions of rural are very broad or merely what is left over after urban is defined, several government agencies have created details and nuanced definitions of rural to inform rural-specific research, policies, and programs. These definitions permit some flexibility, such as allowing users to select from varying degrees of rurality. Agencies involved with rural health services will continue to adapt their definitions, striving to better serve the needs of the rural population.

Special Focus on Collaborations
Review criteria for evaluating the Collaboration Plan includes:

- Does the plan articulate full engagement of both PIs in proposed activities, resource access, and plan management?
- Is there clarity of the roles and areas of responsibility for team member activities and are clear lines of communication established?
- If a Track 2 Project is being proposed, is it clear that the team has had a successful history of collaboration?

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

- Regulatory approvals. Copies of all human subjects approval documents (including updates) must be forwarded to ICTR and Marshfield award administrators.
- Quarterly Progress Reports are required throughout the award period, beginning at the award start date. These will be collected via online survey, and will address accomplishments to date, spending projections, and impacts of research resources and training provided by ICTR (e.g. Collaboration Planning, Design for Dissemination training, etc.).
- Timely account closure. Within 60 days of the project end date, submit any final invoices along with a written description of accomplishments, including conference abstracts, publications, grant applications, and plans to further develop the project.
- 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.
- Awardees must adhere to the NIH Public Access Policy and obtain PMCID numbers for every publication utilizing pilot data.
- Awardees must acknowledge ICTR and Marshfield Clinic Health System Foundation’s research programs in 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.
  - “Funding for this project was provided by UW ICTR, grant UL1TR002373, from the Clinical and Translational Science Award of the NCATS/NIH and through philanthropic support of Marshfield Clinic Health System Foundation’s research programs.”

### Additional References and Resources

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<th>Topic</th>
<th>Link</th>
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<tr>
<td>What is “rural”</td>
<td>Rural Health Information Hub: <a href="https://www.ruralhealthinfo.org/topics/what-is-rural">https://www.ruralhealthinfo.org/topics/what-is-rural</a></td>
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<td>Health Resources and Services Administration: <a href="https://www.hrsa.gov/rural-health/about-us/what-is-rural">https://www.hrsa.gov/rural-health/about-us/what-is-rural</a></td>
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