UW ICTR Stakeholder & Patient Engaged Research (SPER) Pilot Award 2021 Request for Applications (RFA)

GOAL OF THE SPER PILOT GRANT PROGRAM

Stakeholder and patient engagement in research generates evidence that is more relevant and useful for real-world application, and facilitates both the dissemination and uptake of research findings. Patient-Centered Outcomes Research (PCOR) and comparative effectiveness research (CER) are approaches that emphasize engaging stakeholders throughout the research process, sound methodology, and timely implementation and dissemination of research results. With these new and different emphases, many investigators lack the infrastructure, partnerships and preliminary data to apply for funding opportunities in this area.

Goal: The goal of this Stakeholder and Patient Engaged Research (SPER) RFA is to provide support for activities that will strengthen a competitive application for external funding for research requiring strong stakeholder engagement as a foundation for a successful application. This includes but is not limited to PCOR. New or previously unsuccessful applicants to PCOR funders are encouraged to apply.

We welcome applications that address contemporary and/or emerging health crises related to COVID-19 and/or racial/ethnic disparities in health.

Successful proposals to this RFA must provide rationale for the current gap in their program that precludes a successful extramural application. Examples of activities that would be responsive under this award include:

- Development of a strong stakeholder engagement strategy, including efforts to engage underserved populations as patient advisors/stakeholders (e.g., racial/ethnic minorities or those from rural areas).
- Collection of pilot data directed to a topic aligned with an external funder's mission, using sound stakeholder engagement methodology.

Deliverable: Awardees will use the results of this award to submit an application to an external funder within 6 months of project end-date. This award is not intended to support a project that is independent of an investigator's career path. Examples of external funders include but are not limited to the following:

- PCORI: http://www.pcori.org/funding-opportunities/funding-center
- AHRQ PCOR: https://www.ahrq.gov/pcor/index.html
- NIH: https://grants.nih.gov/funding/index.htm

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AWARD

Each award is for a maximum of **$100,000 for 12 months** of direct support.

ELIGIBILITY OF PRINCIPAL INVESTIGATOR

- PI must be employed by UW-Madison *(either sole appointment, or joint-appointment with VA Hospital, UW Milwaukee)* or Marshfield Clinic.
- The PI of this project must have the following **investigator status**:
    - o Assistant, Associate or Full **Professor** (tenure track, CHS, or clinical) with well-developed plans for an independent research career. The results of this pilot should form a significant part of a subsequent externally-funded peer-reviewed research project.
        - ▪ Associate or Full Professors *must* show evidence of having previously been supported by external, peer-reviewed funding.
        - ▪ Full Professors are encouraged to identify and mentor less experienced investigators and describe specific and substantial roles for the mentee(s) on the research team.
    - o Assistant, Associate or Senior **Scientists** with temporary or permanent PI status and an independent research career. Scientist applicants are required to provide the following *evidence of an independent research career*:
        - ▪ Associate or Senior Scientists must show evidence of previous external funding support, and are *encouraged to identify and mentor* less experienced investigators and describe specific and substantial roles for the mentee(s) on the research team.
        - ▪ All Scientist PI applicants must provide evidence that the proposed research represents an independent area of investigation. Include letters from the faculty supervisor and department chair or dean expressing strong support for this independence and an outline of the PI's proposed academic trajectory. *Letters will be reviewed as part of proposal package*. Additional instructions are included in section 4 of the Application Requirements (Biosketches for Key Personnel).
- Whereas residents, fellows, post-doctoral associates are **NOT** eligible to serve as PIs, they are eligible to serve as co-Investigators.
- **PIs or co-PIs can only apply to a single ICTR funding mechanism in a calendar year.** Investigators can be Key Personnel on another submission.
- Previous ICTR grant awardees are not eligible to receive a second ICTR award as PI or Co-PI if the previous award is **still active.**
- ICTR SPER awardees from past rounds are not eligible to re-apply for this funding mechanism unless there is evidence of successfully receiving external, peer-reviewed funding based on the previous award AND the previous award is closed
- *If awarded,* research teams may be invited to participate in a facilitated Collaboration Planning process as part of the ICTR Team Science initiatives.

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KEY DATES AND DEADLINES

Letter of Intent Due (mandatory)	November 20, 2020 (by 5 pm)
RFA Workshop (Mandatory)	Asynchronous recording
Full Proposal Due	December 21, 2020 (by 5 pm)
Review Period	December-February, 2021
Awards Announced	March 2021
Earliest Project Start Date*	April 1, 2021

*UW ICTR Human Subjects Protections Officer Nichelle Cobb will consult with awardees on regulatory aspects of UW Institutional Review Board (IRB) submission to maximize likelihood of April 1, 2021 start-date.

LETTER OF INTENT (mandatory)

Due Friday, November 20, 2020 by 5 pm. Letters of Intent (LOIs) must be submitted as a single PDF/Word document to capgrants@lists.wisc.edu. The LOI is not used for ranking, but will assist staff in identifying proposal reviewers.

The Letter of Intent - please include the following:

1. PI Name, contact information, department, and funding program to which you are applying.
2. Title of your proposal.
3. Specific aims and *brief* overview of research design and methods. Include enough detail to identify **both** scientific and design/methods reviewers.
4. Description of the knowledge gap that your research will fill.
5. Names and roles of key personnel and all community collaborators/stakeholders
6. Describe your plans for a future external funding submission and how this award will strengthen your application (indicate the potential RFA and research questions to address)
7. Identify the two special criteria* that your project will address *(*see page 6 of this RFA).*
8. Letters of Support. The LOI submission *must include* letters of support from (a) community stakeholders/partners, (b) collaborators associated with the special criteria that you choose, and (c) *if you are a scientist, see the instruction below.*
   a. If you are a scientist – include letters from your faculty supervisor and department chair or dean expressing strong support for this independent line of research and outline the PIs proposed academic research trajectory.
   b. LOI Stage: Letters of support from all collaborators (community-based and academic) should confirm commitment to be involved in the project. If you are collaborating with an ICTR-CAP

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Program or Affiliate – *you must have a letter of support from the Director of that program*. Application Stage: Letters of support in the full application are expected to include much greater detail about the nature of the collaboration and the role of community/stakeholder partners.

RFA WORKSHOP (mandatory)

PIs are REQUIRED to view a recorded workshop by December 1, 2020. Research teams and collaborators are encouraged to view the workshop as well. All those who submit a Letter of Intent will receive a link to the 2021 RFA Workshop.

ICTR Resources for Stakeholder and Patient Engaged Research: Please see the list of resources available to support writing strong applications listed on the final page of this RFA.

APPLICATION REQUIREMENTS

The full application is due on Monday, December 21, 2020 by 5 pm. Note: Applicants who responded to a previous UW ICTR Pilot Award RFA but were NOT funded, must submit a **NEW** application responsive to this announcement. Please note these application instructions:

- A complete application includes items 1-11 below. Please insert page numbers on the full application
- Narrative: Maximum length of 6 pages, 11-point Arial font with ½" margins.
- Templates for the Face Page, Abstracts and Budget are within the 2021 SPER Application Forms on the ICTR Funding Opportunities page.
- Submit the full application as a **single PDF/Word document** to capgrants@lists.wisc.edu by 5 pm on December 21, 2020. If you have any difficulties, please email kjudge@wisc.edu

Full Application: Components (1-12)

1. **Face Page**

2. **Scientific Abstract:** Provide a concise description of the proposed research written for scientific audiences. 500-word maximum. Your scientific abstract must include:

   ✓ Scientific rationale supporting your proposed research.
   ✓ Research aims and project design.
   ✓ Who will be on your research team (including patients and stakeholders), what roles they will play, and what is your plan for patient/stakeholder engagement?
   ✓ Why this ICTR funding is necessary to prepare you for a highly competitive submission for an external federal grant application.

3. **Community Abstract**: The community abstract is an opportunity to express to our *community reviewers* how you anticipate that this project can, in the long-term, impact the health of Wisconsin

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residents. It should ***not*** be a reiteration of the Scientific Abstract but **instead** should *tell a story* that addresses the importance of this research, whose lives will ultimately be improved, and why (500 word maximum). **See Video on writing for community reviewers here:** https://videos.med.wisc.edu/videos/8470

Your community abstract must include:
- ✓ Magnitude of the health issue. How many individuals are affected, what is the scope of this issue in the state, how are costs of health care impacted, does this project address health disparities, etc?
- ✓ Knowledge gap. What gap will your proposed research address; what will your project results tell us that is not already known?
- ✓ Community collaborators. What was the involvement of the stakeholders in developing the research question? Who are the stakeholders of this research project, how will they be involved in your research, what roles will they play? Is the involvement meaningful? Is there evidence that research addressing the health problem is sought by potential end-users? For investigations at the *very* early stages, engagement can be more limited to an initial conversation with a stakeholder about the applicability of the question to daily practice.
- ✓ Longer-term policy implications of your research. How might your research inform/impact organizational or public policies?
- ✓ Potential impact of this stream of research. How will this project, in the context of your larger research career, improve health in Wisconsin? Will the study translate new and existing findings into improvements in clinical practice, community health and/or policy?

4. **Biosketches for Key Personnel:** Please use the NIH biosketch format with the "personal   statement" section; an example can be found **here**.
   - ✓ **Scientist PI applicants:** The Personal Statement of the NIH Biosketch must include detail on how the proposed research represents an independent area of investigation for the applicant. Letters from the faculty supervisor and department chair or dean expressing strong support for this independence and an outline of the PI's proposed academic trajectory must also be included.
   - ✓ For non-academic stakeholders, please submit resumes.

5. **Budget (up to $100,000 for 12 months of direct support) - Requirements**

   - ✓ Use the budget template which is bundled with the face page in the application materials.
   - ✓ "*Months of effort" for each key personnel must be listed*, even if no money is being requested to support their work under this pilot program.
   - ✓ Budget Justification is required (maximum 2 pages).
   - ✓ Signed Non-Supplanting (NS) Questionnaire is required. Download NS form here: https://ictr.wisc.edu/documents/non-supplanting-questionnaire/
   - ✓ For more on our supplanting policy see here: https://www.med.wisc.edu/media/medwiscedu/documents/service/wisconsin-partnership-program/grant-materials/wpp-supplanting-policy-012020.pdf

   When creating your budget, please note the following parameters:

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- All activity under this award is subject to the University and Wisconsin Partnership Program (WPP) policies, **please see WPP policy on allowable-unallowable costs here:** https://www.med.wisc.edu/media/medwiscedu/documents/service/wisconsin-partnership-program/grant-materials/allowable-unallowable-expenses-policy-1-1-20.pdf
- Funds are available for personnel, supplies and other allowable expenses including payments to your community collaborators and/or stakeholders. Because ICTR is a NIH-funded Institute, pilot budgets must follow the same rules/spending limitations as federal grants.
- Investigator salary support is allowed, but *clear justification* of why it is necessary should be provided
  - Requested funds should be limited and used principally to directly support the research.
  - Effort must be reported even when salary is donated.
  - PIs proposing effort without salary support must provide documentation from your Department Chair attesting to dedicated research time for the proposed research.
- **Indirect costs are *not* allowed.**
- Funding of education per se is *not* allowed under this program. However, tuition remission can be included for students who are budgeted to be paid as UW research or project assistants, whose efforts are integral to the research endeavor.
- Only travel funds *necessary for study conduct* (e.g., participant travel) are allowed.
- Equipment that is essential for the study, and is not otherwise available, may be requested, but large equipment expenditures are strongly discouraged.
- Matching resources are encouraged and can be monetary or non-monetary. A letter of support is *required* that details matching resources.

6. **Narrative**: The narrative should not exceed 6 pages and should address each of the following components (sections a-i below).

   a. **Specific Aims.**

   b. **Rationale for Pilot Funding.** Please explain how this ICTR Stakeholder and Patient Engaged Research (SPER) award will increase the likelihood of submitting a highly competitive subsequent grant.
      - What specific gaps do you propose to fill with this funding (e.g., building stakeholder engagement, collecting pilot data)?
      - Are you collecting pilot data aligned with external funder's mission, using sound stakeholder engagement methodology? Are you developing strong stakeholder engagement necessary for an external funding application?

   c. **Background and Significance.**

   d. **Investigator.** Please explain how the PI and research team are especially suited to this project (i.e., their expertise). If you are a junior investigator, explain how you and your research team have the appropriate experience, training and mentoring. If you are a more established PI, have you demonstrated an ongoing record of accomplishments that has advanced your field (i.e., publications, external peer-reviewed funding, and/or sustained practice/program/policy change)?

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e. **Environment.** Will the scientific environment in which the work will be done contribute to the probability of success? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

f. **Approach.** Describe how the proposed project will be carried out, including a description of methods and analyses to be used to accomplish the specific aims of the project. Include preliminary studies (if appropriate), research design, methodologies, analyses, potential problems and alternative strategies. Address the specific strategies and resources you will use to create an inclusive research team environment and engage a diverse group of people as study participants and/or patient advisors. Address potential problems you may encounter and strategies for solving them. Address feasibility to achieve goals within 12-month time-frame. If collecting pilot data to support a PCORI/AHRQ PCOR/NIH application, note that within this application you should discuss the aims, research design, methodology, and analyses for the pilot work, not the ultimate PCORI/AHRQ PCOR/NIH application.

g. **Engagement Plan:** Describe the plan to engage patients and stakeholders meaningfully in the various phases of the proposed research *(e.g., planning, conducting, disseminating).* How will patients/stakeholders be identified and engaged in the research? Are the roles of patients/stakeholders significant, meaningful, and well described? Are the stakeholder roles likely to be effective? Is the research focused on questions that are of interest to patients and their caregivers (relevance to patients/stakeholders)? As you complete your engagement plan, consider the six PCORI Engagement Principles and refer to the [PCORI Engagement Rubric](#) for assistance. **ICTR has many resources to assist researchers in crafting engagement plans, see the list of resources on the final page of this RFA.**

h. **Future considerations–policy implications.** If applicable, please address how your research might inform/impact organizational or public policies. If you'd like assistance assessing the policy implications of your research, please contact please contact UW Pop Health policy consultant Victoria Faust (vnfaust@wisc.edu). For definitions and key terms, see the side-bar of the ICTR Funding Opportunities page.

i. **Special Criteria.** Applicants must address how they will incorporate **<u>two</u>** of the following special criteria in their research project.
   - **New Junior-Senior Investigator collaboration**: The project involves a **new** partnership between a junior investigator (the PI) and a senior investigator. A new partnership refers to one between two investigators who have not co-authored a manuscript. The junior investigator is expected to be the Principal Investigator of the project.
   - **UW-Madison - Marshfield collaboration**: The study involves collaboration between a UW-Madison faculty member/scientist and a Marshfield Clinic/Marshfield Clinic Research Institute investigator.
   - **Interdisciplinary collaboration:** The project involves collaboration between/among faculty from different UW-Madison schools/colleges. To be considered interdisciplinary for the

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purposes of this grant program, it *cannot* be between/among departments within a UW-Madison school/college.

- **UW-System school / UW Extension collaboration:** A collaboration between a UW-Madison/ Marshfield PI and another UW System investigator (http://www.wisconsin.edu/campuses/).

- **ICTR-CAP collaboration**: The PI and/or research team works with an ICTR-CAP Program/Affiliate in the design, implementation and/or evaluation stages of the proposed research.

  - See the *Directory of ICTR-CAP Programs/Affiliate Programs* available on the UW ICTR Funding Opportunities webpage in the sidebar of Additional Requirements and Information
  - If using this category to meet a special criteria requirement, you must have a letter of support from the Director of the ICTR-CAP Program or Affiliate.
- **Science of Community Engagement**: One of the specific aims for the proposed research will evaluate different approaches to stakeholder engagement. For definition of "science of community engagement" and other key terms, see the definition of key terms on the side-bar of the ICTR Funding Opportunities page
- **Targeted Topic Area:** COVID-19 or contemporary and/or emerging health crises, racial/ethnic disparities in health, rural health disparities, social determinants of health, pediatrics, geriatrics, mental/behavioral health, substance abuse disorders. **Please be aware of the ICTR-WPP supported resources below related to some targeted topic areas.** In some cases, proposals using a resource below will meet the two special criteria requirement, e.g., ICTR-CAP collaboration plus Targeted Topic Area.
  - WCHQ 2019 Wisconsin Health Disparities Report identifies statewide racial/ethnic health disparities. Watch for the release of the 2020 report with a focus on rural/urban disparities on November 12, 2020. URL: https://www.hipxchange.org/WCHQDisparities
  - Patient experience data is available via HealthExperiencesUSA on the following health conditions: Depression in Young Adults, Cancer Risk that Runs in Families, Traumatic Brain Injury in Veterans. This data is available for use to support pilot grant proposals. URL: https://www.healthexperiencesusa.org
  - Neighborhood Health Partnership (NHP) program delivers local health data to inspire action. Reports are available for many WI neighborhoods (zip codes) covering 27 health outcomes and care measures spanning the care continuum including wellness, prevention, risk factors for chronic diseases and chronic disease care. URL: https://nhp.wisc.edu/

The required application components below do not count against your 6-page narrative.

7. **Impact Statement.** Please respond to **ONE of the three** following questions regarding impact that is best aligned with your research question:
   a. Identify the specific metrics that you will use to identify the effects of your research on health outcomes (including physical, mental, and/or social), or the effects of your research on specific, well-established **determinants of health** (PI must be able to justify determinants chosen).

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    b. If specific metrics will not be measured in your pilot, describe the metrics that you will use to identify the effects of your **subsequent research** on health outcomes or on specific, well-established determinants of health.

    c. If you are not be able to measure specific health outcomes directly**, describe other possible impacts of this pilot or subsequent research**, where **impact is defined as**: any permanent new or revised structures, policies, or processes in the delivery of health care services or community health programs that are the result of this project/collaboration.

8. **Timeline**: Project must be completed within **12** months of start date. Are your proposed activities meaningful and feasible within the 12-month time-frame? Please include a depiction of what tasks will be completed during which months **and** a narrative that indicates how you will address timeline and deadline issues/potential challenges with your collaborators and stakeholders. This timeline and description does not count against your 6-page narrative described above.

9. **Literature citations**: Please attach.

10. **Letters of collaboration/support:** Please include *signed* (can be electronic) letters of support (LOS) from your collaborators—including those associated with the special criteria that you choose.
    o Collaborator letters should both indicate support for the project, and should fully describe the role that they will play in the research and how they intend to use the results of this project towards practice, program or policy change.
    o Provide a LOS from **community partners** outlining their commitment to the research and their specific, meaningful role in the project. For guidance on letters of support from community partners, and planning for stakeholder engagement, see this [guide](link) developed by the Wisconsin Network for Research Support (WINRS).
    o If you are collaborating with an **ICTR-CAP Program or Affiliate** – *you must have a letter of support from the Director of that program*.

11. **Do not include/attach appendices.**

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RESOURCES FOR APPLICANTS

1. **Grant Writing Group: UW Health Innovation Program**
   - Numerous previous awardees have utilized the HIP Grant Writing Group (GWG)
   - Applicants are encouraged to start the group as early as the *Letter of Intent* stage and continue with monthly feedback through full proposal submission.
   - For information about how the HIP GWG works, see https://hip.wisc.edu/GrantWritingGroup
   - For information about joining the group, **please email gwg@hip.wisc.edu**

2. **ICTR Resources for Stakeholder and Patient Engaged Research (SPER)**
   - **Consultations:** ICTR-CAP partner programs are available to support patient/stakeholder engagement across the translational research spectrum. For brief descriptions of these programs see the here.
   - **Online Tools and Toolkits on HIPxChange**.
     - URL: https://www.hipxchange.org/StakeholderEngagementTools
   - **UW ICTR Stakeholder Engagement Research Resources**
     - URL: https://ictr.wisc.edu/stakeholder-engagement-resources/
   - If you need help determining which program best fits your research needs, request a consult with Kate Judge (kjudge@wisc.edu).

3. **Projects Funded in Previous Rounds**
   - Descriptions of previous awards are available on the ICTR Funding Opportunities pages
   - URL: https://ictr.wisc.edu/documents/stakeholder-and-patient-engaged-research-awards-2013-2019/

4. **ICTR-CAP Review Process and Criteria**
   - See the side-bar of the ICTR Funding Opportunities page (Additional Requirements and Information)
   - URL: https://ictr.wisc.edu/documents/review-process-for-community-engaged-research/

5. **Definitions and Key Terms**
   - See the side-bar of the ICTR Funding Opportunities page (Additional Requirements and Information)
   - Also see definitions per Wisconsin Partnership Program: https://www.med.wisc.edu/media/medwiscedu/documents/service/wisconsin-partnership-program/grant-materials/wpp-definitions.pdf

6. **What Populations of Interest Does PCORI Want to Address With Research?**
   - See the PCORI list of diverse/lesser-studied populations here
   - URL: https://help.pcori.org/hc/en-us/articles/213231988-What-populations-of-interest-does-PCORI-want-to-address-with-its-research-

7. **Directory of ICTR-CAP Programs/Affiliate Programs**
   - For a *Directory of ICTR-CAP Programs/Affiliate Programs* see the side-bar of the ICTR Funding Opportunities page (Additional Requirements and Information)

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