Community-Academic Partnerships
UW Institute for Clinical and Translational Research

ICTR-CAP Pilot Awards Program
APPLICATION REVIEW PROCESS and CRITERIA

This document describes the multi-step review process for applications submitted to the following award programs: (1) Clinical & Community Outcomes Research (CCOR) Pilot Award Program, (2) Dissemination & Implementation Research (D&I) Award Program, and (3) Stakeholder and Patient Engaged Research (SPER) Award Program. This process does NOT apply to the Translational Basic & Clinical Research Pilot Awards Program; review criteria for that mechanism is provided within the RFA.

I. Overview of the Multi-Step Review Process

(1) **Preliminary Administrative Review:** Pilot Award Program Manager reviews documents to ensure application completeness.
(2) **Individual Scientific/Peer Review:** Up to three experienced researchers conduct a confidential scientific review of the application using NIH's scoring scale to assess scientific merit. Details about the Scientific Merit Review Criteria are in *Section II* of this document. Proposals with an average score indicating a high level of scientific merit will be forwarded for discussion and scoring by the ICTR-CAP Steering Committee.
(3) **ICTR-CAP Steering Committee Scoring:** The ICTR-CAP scoring meeting is similar to the NIH study section meeting. A non-conflicted committee member is assigned as lead reviewer based on content/ methodology expertise. Overall scientific merit scores are assigned by each committee member and mean scores across all reviewers are calculated for each proposal. The Scientific Merit Review Criteria are listed in *Section II* of this document. Only those proposals with a mean score indicating a high level of scientific merit will be forwarded to the External Community Review Committee.
(4) **External Community Review Committee:** Applications that meet a high threshold of scientific merit are reviewed by our UW ICTR-CAP External Community Review Committee (ECRC). The ECRC consists of representatives from agencies and organizations statewide committed to improving health for the people of Wisconsin. The ECRC ensures that a strong community voice is represented in UW ICTR funding decisions, and makes final funding recommendations to ICTR leadership. ECRC Review Criteria are provided in *Section III* of this document.
(5) Finally, **ICTR Leadership** reviews all funding recommendations within the context of the funding available.

All applicants will receive copies of the de-identified reviewer critiques.

II. Scientific Merit Review Criteria

Each proposal is evaluated by up to three experienced researchers using the NIH 9 point rating scale (1= exceptional; 9-poor) scoring system and using the review criteria outlined below.

Please note the three sub-sections of scientific merit review criteria: (1) Standard NIH review criteria, (2) ICTR-CAP specific review criteria, and (3) **New:** Additional review criteria for clinical trials.

Standard NIH Review Criteria

- **Overall Impact.** Does this study address an important problem or critical barrier to progress in the field? If the aims of the application are achieved, will scientific knowledge, clinical practice, community health programs or health policy be affected / advanced? The overall impact score should reflect the reviewer's assessment of the likelihood for the project to exert a sustained and strong influence on the research field(s) involved. Note: 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:** The PI has made a strong case that the project addresses an important problem or addresses a critical barrier to progress in the field.
- **Investigator:** Are the PI and research team well-suited to this project? If the PI is a junior investigator, does s/he have the appropriate experience, training and mentoring? If the PI is a more established PI, has s/he demonstrated an ongoing record of accomplishments that have advanced the field (i.e., publications, external peer-reviewed funding success)?
- **Innovation.** Is the project original and innovative? For example, does the project challenge existing paradigms or practice? Does it address an innovative hypothesis or critical barrier to progress in the field? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
- **Approach:** Do the feasibility, conceptual framework, specific aims, study design, methodology, and data analysis and interpretation, exhibit high scientific quality? Has the PI addressed potential problems and alternative strategies if applicable?
- **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?
- **Appropriateness of budget request**. Is the proposed project feasible under the proposed budget? Is the budget adequately justified? To make sure the available funds benefit as many projects as possible, only essential elements of grant requests will be awarded.

ICTR-CAP Specific Review Criteria: Each ICTR-CAP funding opportunity has some unique requirements which are detailed in the Request for Applications (RFA). Each application will be evaluated in terms of responsiveness to goals and guidance within the particular RFA.

- **Special Criteria.** The Clinical & Community Outcomes Research (CCOR) and the Dissemination and Implementation Research (DnI) award require applicants to incorporate two special criteria as outlined in the RFA. Is there evidence that the applicant has chosen two special criteria and incorporated them in a manner that strengthens the proposal?
- **Potential for External Funding:** Strong evidence to suggest this project, if funded, is likely to lead to new peer-reviewed grant submissions.
- **Future Considerations:** Has the researcher adequately addressed the potential for this research (if successful) to inform organizational or public policies in the future?

- **Plans for collaboration / engagement / dissemination.** Meeting these criteria will depend on the type of funding sought by the PI. See criteria by funding mechanism below.

Clinical & Community Outcomes Research (CCOR) Pilot RFA: Has the PI sufficiently explained the constituency or group that will benefit from this research and how a representative is involved in the research – including how and when the results will be disseminated to stakeholders/collaborators?

- For early stage research questions, does the PI show evidence of communicating with logical end-users of the research?
- For more advanced pilots, does the PI involve community-based collaborators in the research design, use community-based study sites, and/or involve the group targeted for an intervention in aspects of the study?
- Does the proposal include a viable dissemination plan that is appropriate for the scope of the project, intended audience and tailors dissemination efforts to that audience?
- Do letters of support confirm collaborator interest in the research question as well as their role in the project (if applicable)?

Dissemination and Implementation (D&I) Research RFA: A vital component of dissemination and implementation research involves the participation of community/stakeholders groups/partners in the research process. Reviewers will evaluate Dissemination / Implementation Research applications for evidence of the following:

- Did the applicant show evidence that the research question is relevant to and sought out by patients/stakeholders?
- Did the project involve the stakeholders most appropriate to the research question and did the applicant make a convincing argument for why these stakeholders were chosen for engagement?
- Does the application show evidence that the applicant undertook strong efforts to include the perspectives, input, and participation from different populations? If not, did the applicant sufficiently justify why these populations were not incorporated into the research process?
- How strong is the engagement plan and how it illustrates genuine involvement of stakeholders (i.e., well-defined roles, shared resources, frequency of engagement)?
- Sustainability: How well did the applicant explain how engagement efforts will continue after research funding is completed?

Stakeholder and Patient Engaged Research (SPER) RFA: This RFA focuses on the development of strong stakeholder/ patient engagement methodology and is evaluated accordingly.

- Does the applicant show evidence that the research question is relevant to and sought out by patients/stakeholders?
- Does the project involve the stakeholders most appropriate to the research question? Does the applicant provide a strong rationale for engaging with these particular stakeholders?
- Does the application show evidence that the applicant undertook strong efforts to include the perspectives, input, and participation from diverse populations? If not, did the applicant sufficiently justify why these populations were not incorporated into the research process?
- How strong is the engagement plan? Is there genuine involvement of stakeholders (i.e., well-defined roles, shared resources, frequency of engagement)?
- How well did the applicant explain how engagement efforts will continue after research funding is completed?

NEW: Additional Review Criteria for Clinical Trials (as defined by NIH)

Some applications may meet the new NIH definition of a clinical trial, i.e., 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. Not sure if your proposal meets the definition of a clinical trial? Check out the NIH decision tool here: https://grants.nih.gov/ct-decision/index.htm

In September 2017, NIH announced new review criteria for research applications involving clinical trials.

Reviewers will consider the following additional questions for proposals that meet the NIH definition of clinical trial.

- ***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)***. With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? 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?
- ***Innovation***. Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?
- ***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? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? 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****:* 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?
- ***Study Timeline.*** Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate? Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

III. External Community Review Committee Review Criteria

If a proposal reaches a high level of scientific merit, it will be forwarded to the External Community Review Committee (ECRC) for final funding recommendations. This body of reviewers—individuals representing agencies and organizations statewide that are committed to improving health—is chosen based on their roles in the Wisconsin health community to ensure that the community voice is represented in UW ICTR funding priorities.

Proposals are evaluated by the ECRC based on the following criteria:

- **Significance and Future Potential**: Does this research area address important problems in clinical practice, community health and/or health policy? Does this research area have long-term potential to contribute to the advancement of health?
- **Priority for funding:** The aims of this proposal should be a research priority for UW-Madison and Marshfield Clinic.
- **Community:** This research project effectively and meaningfully incorporates the input of community partners/end-users/stakeholders.