UW ALACRITY CENTER
Working Together to Reimagine Mental Health

CALL FOR PILOT STUDY APPLICATIONS

The UW ALACRITY Center (UWAC) invites pilot study applications that support its mission to uncover and overcome obstacles that prevent quality mental health treatments from reaching traditionally underserved communities.

Indication of Interest Deadline: October 15, 2023
Application Deadline: November 15, 2023
Funding Announcements: December 22, 2023
Project Start Date: January 1, 2024

I. Introduction

The National Institute of Mental Health funded UWAC to provide support and mentorship to early career investigators on the application of innovative methodologies, with a particular focus on investigators from historically marginalized groups. UWAC is soliciting applications for pilot proposals from multidisciplinary teams to improve the usability of evidence-based psychosocial interventions and/or the implementation strategies that support their adoption, reach, fidelity, or sustainment. UWAC intends to fund pilot study applications that will lead to federally funded research programs.

Pilot projects previously funded by the UWAC can be found at https://www.uwalacrity.org/funded-ro3s/.

Pilot studies should focus on adapting psychosocial clinical interventions (CI) and/or implementation strategies (IS) to be accessible and scalable using UWAC's local DDBT framework (https://pubmed.ncbi.nlm.nih.gov/31599736/h)[1] (see Figure 1). Responsive proposals will focus on improving the implementability or implementation of evidence-based psychosocial interventions (EBPIs).

To be responsive, proposals must include investigators from different disciplines who will mutually benefit from the project. Examples of collaborative disciplines that have received funding include:

- Psychiatry and Education
- Communications and Psychology
- Social Work and Human-Centered Design
- Computer Science and Nursing

This list serves as an example and is not exhaustive of the possible teams.

II. Goals

The purpose of the UWAC is to address critical problems in the implementation of evidence-based psychosocial interventions (EBPIs) for mental health problems, particularly in underserved communities, schools, and primary care medicine settings.
The goal of UWAC pilot study program is to stimulate research based on the Discover, Design/Build and Test (DDBT; Figure 1) framework that that focuses on adapting CI/IS to improve patient reach, provider adoption and scalability.

III. Background

The UW ALACRITY Center addresses critical problems in the implementation of evidence-based psychosocial **clinical interventions (CI)** (e.g., psychotherapies) in nonspecialty service settings that are accessible to underserved communities (i.e., primary care clinics and schools). Use of CI is determined by the usability, contextual fit, and engagement both CI and the **implementation strategies (IS)** (e.g., training, consultation models) used to support them. Problems with usability, fit, and engagement also result in high rates of "reactive adaptations" of CI/IS by their intended users in many settings where they are deployed. In response, UWAC developed the DDBT framework, which uses an iterative stepped approach to improving psychosocial CI/IS by 1) understanding the system, practitioner, and client burdens and constraints surrounding the use of psychosocial CI/IS, 2) taking this information to iteratively design solutions with end users, and 3) testing the new solutions in the settings for which the solutions are designed. All research supported by the UW ALACRITY Center uses our DDBT framework, allowing us to evaluate the extent to which these methods result in CI/IS solutions that are scalable and immediately adopted into practice.

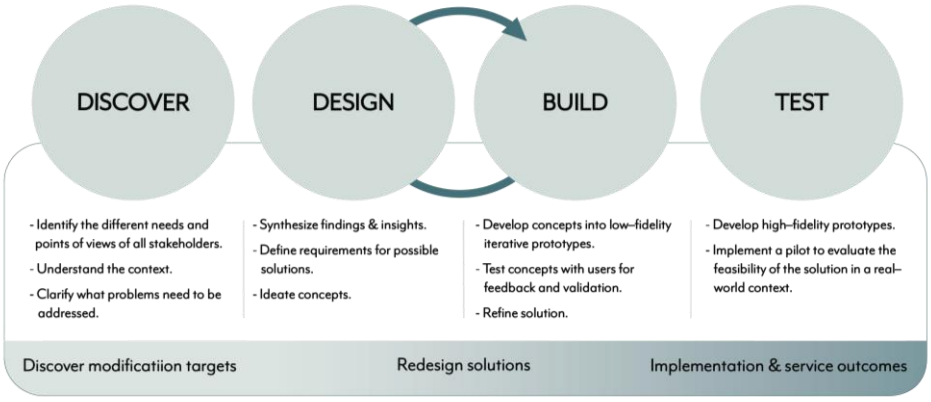

Figure 1: Discover, Design/Build, Test (DDBT)Redesign Framework

<u>Discover, Design/Build, Test Framework Overview and Procedures</u>

The DDBT framework (Figure 1) is informed by human centered design (HCD) and implementation science, both which strive to enhance the adoption of new tools or

innovations[2,3]. DDBT starts by identifying multilevel factors that drive CI/IS usability problems, engagement challenges, and problems with contextual appropriateness (**Discover phase**). Once problems and challenges are identified, modifications are iteratively created between the design team and practitioner/client, until a new version of the CI/IS is developed to address crucial issues and enhance usability, engagement, and appropriateness (Figure 2) (**Design/Build phase**). The product of the Design/Build phase is then tested against the original version to ascertain if the modified product results in improved implementation (e.g., adoption, reach, fidelity), and results in equivalent or better mental and behavioral health outcomes as a result of the changes to usability, engagement, and appropriateness (**Test phase**). We will gather descriptive information about how each team applies the DDBT framework in their unique context. The DDBT framework theorizes that adoption of CI/IS is largely due to *contextual appropriateness* (organizational level; e.g., does the practitioner or client perceive the CI/IS to be compatible with their setting and relevant to the client problem), *user engagement* (individual level; does the practitioner or client demonstrate high participation and enthusiasm for aspects of the innovation that require their involvement), and *usability* (intervention level; is it easy to learn and implement). Key to this model: 1) not all CI/IS are designed for all settings, 2) "there is no implementation without adaptation[5]," 3) unchecked, reactive adaptations have the potential to exclude essential active ingredients[6–9], and 4) adapted CI/IS can result in inferior implementation and clinical outcomes. Thus, when CI/IS are adapted, clinical outcomes are subject to the quality of the adaptations made to increase their usability, engagement, and appropriateness.

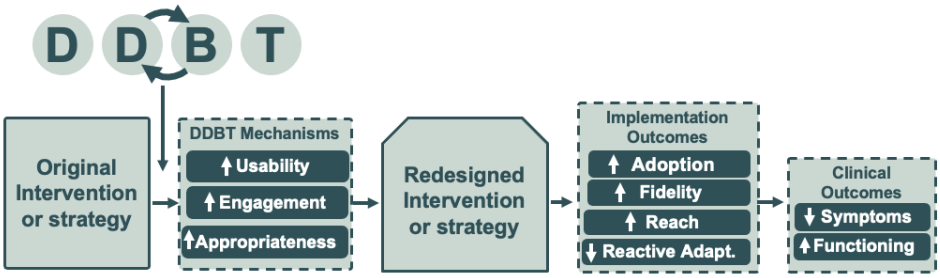

Figure 2: UWAC Theory of Change for Clinical Intervention/ Implementation Strategy Redesign

Applications that focus primarily on the Discover Phase should clearly indicate how their findings would inform future Design/Build Phase efforts. Applicants who feel they have already conducted the Discover Phase of development (and are thus proposing a Design/Build or Test phase) must include such formative information in the proposal. A decent Discover Phase includes an evaluation of the setting/context and CI/IS-specific barriers to

implementation faced specifically by clinical or implementation practitioners (depending on whether a CI or IS is being redesigned) and recipients (clients or the targets of ISs).

IV. Methodological Considerations

Mechanisms of Action
The UW ALACRITY Center focuses both on (1) the mechanisms through which DDBT redesign processes are hypothesized to have their effects on the implementability of CIs and ISs and (2) the mechanisms through which specific CIs or ISs have their effects on their clinical or implementation outcomes.

DDBT Mechanisms: This RFA requires pilot tests of approaches that explicitly address DDBT mechanisms of usability, appropriateness, and/or user engagement. These mechanisms are the direct targets of DDBT-driven redesign.

- CI/IS Usability: The extent to which a CI/IS can be used by specified users to achieve the specified goals of effectiveness, efficiency, and satisfaction[10]
- CI/IS Appropriateness: Perceived fit, relevance, or compatibility of a CI/IS for a given practice setting, practitioner, and/or consumer[11]
- User Engagement: The degree of user participation and enthusiasm for the aspects of a CI/IS that require user involvement[12,13]

CI/IS Mechanisms: Successful pilot study applications also will examine whether (1) the revised CI still engages the target(s)/mechanism(s) known to underlie the intervention effects (i.e., the mechanism that accounts for changes in clinical outcomes[14]), (2) the IS engages the target(s)/mechanism(s) presumed to underlie the implementation effects (i.e., the mechanism that accounts for changes in implementation outcomes[10]). Examples of CI mechanisms include rumination for a treatment focused on depression or avoidance of triggering stimuli for a treatment focused on posttraumatic stress disorder. Examples of IS mechanisms include skill and/or knowledge acquisition for a strategy focused on training providers in a new psychotherapy or changes in implementation climate for a strategy focused on supporting organizational leaders surrounding implementation[10].

Measurement of Outcomes
Quantitative: These R03 projects will provide valuable information about the utility of the DDBT framework. Learnings from the R03s will be disseminated, along with other outcomes from the UWAC, to the broader research and clinician communities. Therefore, **studies must collect shared quantitative outcomes on (1) CI/IS usability** (System Usability Scale, Intervention Usability Scale[15], and/or Implementation Strategy Usability Scale[16]); **(2) Engagement** (User Responsiveness Scale, adapted from the Patient Responsiveness Scale[17]);

(3) Appropriateness (Intervention Appropriateness Measure[18] and/or modified Goodness of Fit Interview[19,20]); and, when appropriate, **(4) patient-reported clinical outcomes** relevant to the specific project. Measures used will be mutually agreed upon by the project team and Methods Core.

Qualitative: In the assessment of DDBT mechanisms, this RFA also encourages the use of measurement approaches that are direct and objective as is feasible in the effectiveness setting, such as observations of user engagement during interactions with original or redesigned versions of a CI or IS. Projects are encouraged to consult with the UWAC Methods Core surrounding the identification of these measures.

Additionally, Successful pilot study applications will identify, through the application of the DDBT framework and UWAC Methods, (1) usability issues for the CI or IS and (2) CI/IS redesign solutions.

Usability issues are aspects of a CI/IS or its components and/or a demand on the CI/IS user which make it unpleasant, inefficient, onerous, or impossible for the user to achieve their goals in typical usage situations[21]. UWAC's previous work[2] identified 12 usability issue categories, including:

1. complex and/or cognitively overwhelming,
2. required time exceeding available time,
3. incompatibility with interventionist preference or practice,
4. incompatibility with existing workflow,
5. insufficient customization to clients/recipients,
6. intervention buy-in (value),
7. interventionist buy-in (trust),
8. overreliance on technology,
9. requires unavailable infrastructure,
10. inadequate scaffolding for client/recipient,
11. inadequate training and scaffolding for interventionists, and
12. lack of support for necessary communication.

These usability issues categories are not expected to be exhaustive but are listed above to demonstrate the range of issues identified to date. The Consolidated Framework for Implementation Research (CFIR), or any implementation framework that clearly specifies *innovation-level* determinants (i.e., barriers or facilitators) of implementation success[14,22], may be used to support the identification of CI/IS usability issues.

Redesign solutions are the modifications made in response to identified usability issues to improve CI/IS usability, CI/IS appropriateness, and user engagement. Examples of

modifications include removing components, reorganizing components, or creating digital versions of materials, among others. In UWAC, redesign solutions are typically captured using the Framework for Reporting Adaptations and Modifications – Expanded (FRAME[23]) for CIs and the Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS[6]) for ISs.

Methods Core Experts

Prior to submission, investigators are required to consult with Methods Core faculty while developing their ideas to ensure best fit with UWAC aims and resources (see Submission Process, below). The Methods Core consists of faculty with expertise managing and executing interdisciplinary team science projects. Specifically, the Methods Core faculty members are available to consult with R03 study teams on applying the DDBT framework and relevant methodology and statistics. Select faculty members have expertise in school based mental health, primary care, communications technologies (mHealth, remote consultation, and telehealth), and adult learning, which may be explored by the R03 projects. **This contact will be facilitated by indicating your interest by submitting an initial proposal summary (title, investigators, and ~250 word abstract) to Brittany Mosser (bmosser@uw.edu) no later than October 15, 2023.**

V. Pilot Project Supports

Mentoring Program: Funded teams will be required to participate in a monthly mentoring meeting led by UWAC leadership for the first 6 months of their award. Monthly mentoring meetings will be group meetings with all currently funded teams and will focus on assisting the teams in implementing their project, starting with supporting compliance with UWAC requirements for data collection and submission via the data portal. Teams will be supported through IRB approval; creating a timeline; addressing recruitment and procedural barriers, including unintended events—such as was experienced during the COVID pandemic—and analyzing data from the project for the purpose of preparing a next-step proposal to NIMH or similar funding agencies. Topics also include Team Science and use of the local DDBT process. After these 6 months (which may be extended another 3 months, depending on each team's progress), teams will then be expected to participate in the Grant Writers' Boot Camp.

Grant Writers' Boot Camp: The Boot Camp is repeated 2-3x/year and is scheduled so that final review of proposals is completed 2 months before the next NIH deadline. Participants must have a set of aims and a draft proposal ready at the start of the boot camp. By the end, participants will have applications ready to submit. Each Boot Camp cohort meets 2x/month for 3 months. Sessions are a mix of didactics and experiential learning. The experiential

portion involves review of participants' proposals in the context of the topic covered, with hands-on direction from the session mentors.

Methods Core Supports

Project and Methodological Support: The UWAC Methods Core (MC) will provide routine consultation during all DDBT phases, as well as usable templates and resources to guide the application of key HCD methods (e.g., user identification, data collection planning, usability issue articulation). The MC will collaborate with Drs. Fortney and Darnell in the Monthly Mentorship Meetings. Additionally, the MC will provide data management for all UWAC studies, including the facilitation of the use of REDCap via Methods Core team members building and maintaining all study databases to ensure high quality data management. The MC will also provide standard statistical and methodological support for designing pilot studies, conducting research projects, and analyzing results; and will provide support for both quantitative and qualitative data collection.

Diversity, Equity, and Inclusion (DEI): The UWAC Methods Core will provide support and consultation to projects to increase DEI orientation of project implementation efforts and participant representation (e.g., we will provide training and consultation on the ASPIRE method, a 3-step process we have developed for adapting IS to promote implementation reach and equity)[24]. Similarly, we will provide expertise in emerging methods for explicitly incorporating equity into the measurement of implementation outcomes[24]. For recruitment, we will work with each project to ensure diverse representation in the Discover and Design/Build phases of DDBT, when it is especially important to collect diverse viewpoints on design problems and solutions.

Institutional Review Board (IRB) and Human Subjects: MC staff will provide consultation to pilot project teams on the development of each study's IRB application and concerns related to human subjects. Clinical trials will be registered by the project team prior to their initiation. When indicated, MC will support the establishment of a Data and Safety Monitoring Board (DSMB) for each project. UW IRB is experienced with the review and management of research projects covering diverse and vulnerable populations (e.g., pregnant women, children, school-based populations); it will serve as the IRB for all the studies. MC staff will support study teams in communications with the IRB to ensure all concerns are addressed immediately and carry out reporting of any adverse events. MC staff will meet regularly with study investigators to review and update administrative requirements for the protection of human subjects.

Dissemination Support

UWAC has prioritized support of pilot project dissemination activities (e.g., publications, conference presentations) through the development of the Pilot Projects Dissemination Fund. Pilot projects can apply to UWAC for additional funds beyond their awarded amount to support activities such as but not limited to publications, conference travel, and membership in relevant professional organizations.

VI. Expectations of Funded Pilot Projects

Pilot projects that receive funding from the UW ALACRITY Center will be expected to provide consistent reports on study progress to UWAC, contribute data for center-wide analyses, and to remain communicative and connected with UWAC throughout the duration of UW ALACRITY Center's parent grant funding, which may exceed the length of time that pilot projects are funded for.

Monthly Reporting During Funding Period
Funded pilot projects will be expected to report monthly on study progress including start up tasks, participant recruitment, data analysis, etc. UWAC Methods and Admin Core team members will track pilot projects' progress towards completion of study aims, collection of outcome measures, and data analysis.

Publication and Grant Tracking
Pilot projects funded by UWAC serve as critically important members of the UWAC team and further the overall success of UWAC. During the period of pilot funding and extending throughout the duration of the UWAC, pilot project teams will be expected to report any publications (e.g., papers, presentation) and grant applications related to the funded pilot project and/or that received mentorship support from the Grant Writers' Boot Camp, Methods Core, or other UWAC supports. These successes will be reported to NIMH along with other metrics to quantify UWAC's ability to foster and support early career investigators. As noted above, UWAC has prioritized supporting pilot project dissemination efforts; study teams can apply for additional funds beyond their awarded amount to support these activities.

Contribution to UWAC Outcomes and Deliverables
Facilitated by the Methods Core, all data collected by funded pilot projects will be analyzed in support of UWAC's center wide outcomes and deliverables. Data may include shared outcomes:

(1) CI/IS usability (System Usability Scale, Intervention Usability Scale[15], and/or Implementation Strategy Usability Scale[16]);
(2) (2) Engagement (User Responsiveness Scale, adapted from the Patient Responsiveness Scale[17]);

(3) (3) Appropriateness (Intervention Appropriateness Measure[18] and/or modified Goodness of Fit Interview[19,20]); and
(4) (4) patient-reported clinical outcomes relevant to the specific project.

Additionally, teams will be required to complete interviews with the Methods Core to describe and document methodologies, usability issues, and other pertinent factors. All investigators will be invited to be authors on relevant Center publications per protocol.

VII. Submission Requirements and Review Process

Eligibility Criteria

UW faculty and fellows and are eligible to apply for pilot studies. Extraordinary graduate students may also be considered. Non-UW* applicants will be considered on a case-by-case basis. Investigator teams must be comprised of two Co-Principal Investigators (Co-PIs) who represent different disciplines. Co-PIs must make explicit in their application the degree to which their team is interdisciplinary and how this contributes to advancing the research study and to furthering their respective fields. For example, collaborators from Psychiatry and Computer Science might develop a psychotherapy support tool using natural language processing that would contribute to both mental health and computer science.

**We are unable to accept proposals for international research due to the extensive federal review process needed to fund such approvals (additional review by NIMH program and approval from the Department of State).*

Award Amount

The maximum award amount under this RFA is $50,000. While we anticipate most pilot projects will be approximately one year in duration, investigators may request up to two years of support, as is the case for NIH R03 grant mechanisms.

Budget and Timeline

Pilot projects are expected to be approximately one year in duration but may be up to two years in duration. For pilot studies projected to last for more than one year, the budget should be specified separately for each project year. When funds are awarded, it will be necessary to submit budget requests separately for each budget during which the pilot study will be conducted. Depending on the start date, one year pilot studies may be conducted across two budget years and two year pilot studies may be conducted across three fiscal years. The budget and budget justification should provide projected costs associated with staffing, supplies, and travel for local research activities on standard NIH forms. Funds for investigator salary are eligible, but travel to conferences and/or trainings and IT equipment

may not be included. UWAC has funds earmarked to provide support for costs related to publication, conferences, and trainings for pilot project investigators.

Submission Process

Pilot study applications are due November 15, 2023 by 5:00 PM PT. Investigators must receive approval from a UWAC Methods Core faculty member to submit the pilot study application. Contact Brittany Mosser (bmosser@uw.edu) by October 15, 2023 to indicate your interest in submitting an application; Ms. Mosser will facilitate connectivity to the Methods Core for the pre-application approval. Investigators are strongly encouraged to work with the UWAC Methods Core as early as possible in the application process to ensure goodness of fit between the proposal and the Center aims.

Email final applications as a single PDF document to Brittany Mosser (bmosser@uw.edu) by 5:00 PM PT on November 15, 2023.

Application

The pilot study application should be submitted as a single PDF document, consisting of a face page (see Appendix A), 250 word abstract, the grant narrative, citations, budget, budget justification, and a NIH biosketch for key personnel (i.e., each Co-PI, the senior mentor, consultants, etc.). The grant narrative should be no longer than 4 pages (single-spaced, half inch margins, and Arial 11pt font), exclusive of references. The grant narrative should include the following sections:

1. Specific Aims (1/2 page) – State concisely and realistically what the research is intended to accomplish. Indicate how the research relates to the overall mission of the UW ALACRITY Center.
2. Background and Significance (1 page) – Briefly sketch the scientific literature pertinent to the proposed pilot study (and future grant application) by critically evaluating existing knowledge and identifying the gaps that the pilot study are intended to fill.
3. Methods (2 pages) – Briefly describe the study design and the procedures to be used to accomplish the specific aims of the project. Include the means by which the data will be collected, analyzed, and interpreted. **Applications must follow the methods detailed above under the Discover, Design/Build and Test Model (DDBT).** See Appendix B for the DDBT Intake Form, which will be completed in the post-award phase by investigators and Methods Core faculty advisors for all funded projects. However, applicants are encouraged to apply this Intake Form to their project as they develop their proposal to ensure alignment with the DDBT framework.
4. Research Team, Timeline, and Future Plans (1/2 page) – Briefly describe the qualifications and roles of the research team. The research team MUST be multidisciplinary. Include a timeline for the work planned, including a projected

completion date. Describe any new instruments, tools, or materials that will be generated. Describe plans for how the proposed pilot study will support a grant application to the NIH, PCORI, VA, NSF, SAMSHA, or other federal funding agency

Review Process and Criteria

Pilot study applications will be reviewed by a team of three ALACRITY faculty members for scientific merit. These faculty may consult with content or methodological experts as needed. Pilot study applications will be subject to three levels of review. At the first level, a UWAC Methods Core faculty member will meet with investigators during the proposal development stage to determine when pilot studies are ready for submission (including a sign-off on the application). At the second level, UWAC study section members will review the pilot study applications and recommend that those determined to have high impact be considered for funding. At the third level, the UWAC Executive Committee will decide which pilot studies should be prioritized for funding. By relying on the explicitly stated review criteria during each level of the review process, the UWAC pilot study program will emphasize scientific objectivity during each level of review.

Successful proposals will:

(1) be proposed by a multidisciplinary team;
(2) focus on improving the usability of an evidence-based psychosocial interventions and/or the implementation strategies that support their adoption, reach, fidelity, or sustainability;
(3) measure the mechanisms and outcomes described in this RFA;
(4) use the DDBT model; and
(5) fall on the T2 or higher phase of the translational continuum (https://www.iths.org/investigators/definitions/translational-research/).

Review criteria will include: 1) clinical or public health significance, 2) methodological approach, to include use of the DDBT framework, 3) innovation, 4) investigator qualifications, and 5) potential for external funding.

- **Clinical or Public Health Significance**: Does this study address an important problem facing EBPI delivery in school, primary care medicine or other integrated settings? Of particular interest are studies addressing rural and underserved communities.
- **Methodological Approach**: Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well-integrated, well-reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Does the study use the DDBT model?

- **Innovation**: Is the project original and innovative? Does the project challenge existing paradigms or clinical practice? Does the project develop or employ novel concepts, approaches or methodologies, tools, or technologies?
- **Investigator Qualifications**: Are the investigators and other key personnel appropriately trained and well suited to carry out the proposed work? Is the work proposed appropriate to the experience of the principal investigators? Do the investigators and/or senior mentor have a demonstrated track record of peer reviewed publications commensurate with past funding? Are the investigators comprised of different disciplines in such a way that advances the science of the proposal while also contributing to their respective fields/disciplines?
- **Potential for External Funding**: If successful, will the proposed pilot study lead to a competitive grant application for external funding from federal funding agencies (e.g., NIH, PCORI, IES, VA, NSF, SAMSHA), or private foundation.

Reviewers will note strengths and weaknesses for each of the scored review criteria. Reviewers will also summarize the factors that informed the overall score. The scoring system that we use is based on the NIH scoring system, which is a 9-point scale for the overall impact/priority score and individual scores for five core criteria. A score of 1 indicates an exceptionally strong application and a score of 9 indicates an application with serious weaknesses. The average score is considered to be 5. The table below describes the scoring system in more detail:

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses

Note that an application does not need to be strong in all categories to be judged likely to have strong scientific merit. For example, an investigator may propose to carry out important work that by its nature is not innovative, but is essential to move a field forward.

- Investigators submitting pilot study applications considered to have *low impact* will not be asked to revise and resubmit the application.

- Investigators submitting pilot study applications considered to have *medium impact* will be asked to revise their application (including a 1-page introduction to the revised application) and resubmit it for the next submission cycle.
- Investigators submitting pilot study applications considered to have *high impact*, but also considered to have *minor* weaknesses, will be asked to submit a 1-page modification letter prior to the next submission cycle.
- Pilot study applications considered to have *high impact* with *no or negligible weaknesses* will compete for available pilot funds. Based on reviewer recommendations, the UWAC Executive Committee will make funding decisions, at their discretion, based on scientific merit, availability of funds, and contribution to the UWAC mission.

Funding Requirements

Once the Pilot Study application is approved for funding, the following items must be completed. These items must be received before your research begins. Funds will be transferred upon receipt of all required documentation:

- UWAC Funding Agreement (see Appendix D);
- Local certificates of training in Human Subjects Protection;
- Confirmation (Zipline screenshot) that the IRB has received the complete study protocol for review; and
- Proof of Clinical Trials Registry for any clinical trials.

Please note: if you are offered and accept UWAC pilot funding, your application may be shared up request with UWAC affiliates (e.g., future grant applicants, grant writing boot camp attendees, funders). This is in keeping with NIH requirements that make grant applications publicly available via appropriate channels.

Beginning Your Project

Funded projects will receive primary mentorship from Drs. Fortney, Darnell, and Pullmann, who will connect projects with topic specific mentors as needed throughout the project timeline. Monthly mentorship meetings will start immediately upon funding. Additionally, all teams will meet with the Methods Core to ensure data is collected in line with overarching ALACRITY Center aims, methods, and specific measurement instruments. The UWAC Center Manager will track the progress of each pilot project and provide support with attaining IRB approval. It is expected that it should take less than 3 months from the time you receive your funding letter to obtain IRB approval. If after 5 months, you have not received IRB approval, you will be required to meet with UWAC leadership to discuss the situation. If after 6 months, you have not yet received IRB approval, UWAC leadership will decide whether to withdraw funding for the pilot study. If you have not received IRB approval and completed the funding

requirements described above within 6 months from the date of your funding letter, you run the risk of losing your pilot funding.

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