~ Request for Pilot Study Applications ~

Due: June 15, 2019

I. INTRODUCTION

The UW Alacrity Center (UWAC) invites pilot study applications that support its mission:

> *The UWAC has a foundational commitment to using multidisciplinary team science, merging expertise in mental health, computer science and engineering, education, and human-centered design, to address critical problems in the implementation of psychosocial interventions.*

All proposals should use the Discover, Design/Build and Test Model (see Figure 1) to design and/or create novel adaptations and accommodations of psychosocial interventions. Responsive proposals will focus on improving implementation of evidence-based psychosocial interventions (EBPIs). Studies should focus on a) methods to ensure clinicians are trained and have necessary supports to implement EBPIs, or b) modifications to EBPIs are made to make them easier to use, or c) methods to support high quality delivery of EBPIs.

To be responsive, proposals must include investigators from *different disciplines* who will mutually benefit from the project. What follows are examples of potential team configurations responsive to this mission:

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

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

Goals – The purpose of the UWAC is to address critical problems in the implementation of evidence-based psychosocial interventions (EBPIs) for mild-to-moderate mental health problems, particularly in underserved communities and primary care medicine settings. Per a recent IOM report on psychosocial intervention standards, access to EBPIs is hampered by (1) poor clinician training, (2) intervention design complexity, and (3) insufficient support to sustain quality of care. The ultimate goal of UWAC pilot study program is to stimulate research based on the Discover, Design/Build and Test (DDBT) framework that that can be used to develop clinical policy or programs that improve clinician capacity, usability, and sustained quality of EBPIs, particularly in primary care medicine or other integrated settings. **UWAC strongly encourages pilot study applications that will lead to federally funded research programs.** Relevant RFAs/NOTs from NIMH include:

https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-18-706.html

https://grants.nih.gov/grants/guide/notice-files/NOT-MH-18-031.html

Background - Numerous systematic reviews and meta–analyses indicate that EBPIs (e.g., psychotherapy, case management, behavioral health interventions) are effective in the treatment of mild to moderate

depression and anxiety.[1-7] Unfortunately, clinician capacity, usability, and sustained quality of EBPIs continues to be a problem.[8,9] Only 32%-42% of people with a mental illness receive EBPIs;[10,11] those who do access EBPIs tend to participate only partially, as the modal number of visits for psychotherapy among people with depression is one session.[12,13] These data are quite surprising when one considers research on treatment preferences; despite the low rates of utilization, when surveyed about their preferences, between 40-60% of all adults prefer to be treated with psychosocial interventions.[14-19] EBPI availability is a major challenge in settings serving low-income, rural and non-English speaking populations. Due to inadequate numbers of providers and serious geographic maldistribution, many parts of the US experience a severe shortage of mental health providers, particularly low-income and rural areas.[8] Addressing the supply-side barriers has reached critical importance considering the US Preventive Services Task Force recommendation for universal screening for depression,[10] as healthcare organizations will be identifying far more patients with depression and will need to deliver high-quality depression care to these patients.

The implementation literature and a recent IOM report on psychosocial interventions[20] note that the limited availability and use of EBPIs are attributable to: organizational and system characteristics (e.g., readiness to adopt, system resources and culture, leadership), clinician/adopter characteristics (e.g., training and perceived efficacy of EBPIs for the patients they serve)[21-23] and incentives to engage in EBPIs.[24,25] Per the Consolidated Framework of Implementation Research (CFIR), even when all other considerations have been met, implementation success may still be compromised by issues specific to the EBPIs, specifically EBPI adaptability, trialability, complexity, design quality and implementation costs.[26] Each of these issues is directly related to the design of the EBPI, *calling for a design-focused solution*. Thus far, solutions for targeting these problems have been few, modestly successful and have largely focused on clinician capacity building and training[27,28] intervention distillation strategies[29,30] and clinician decision support.[31]

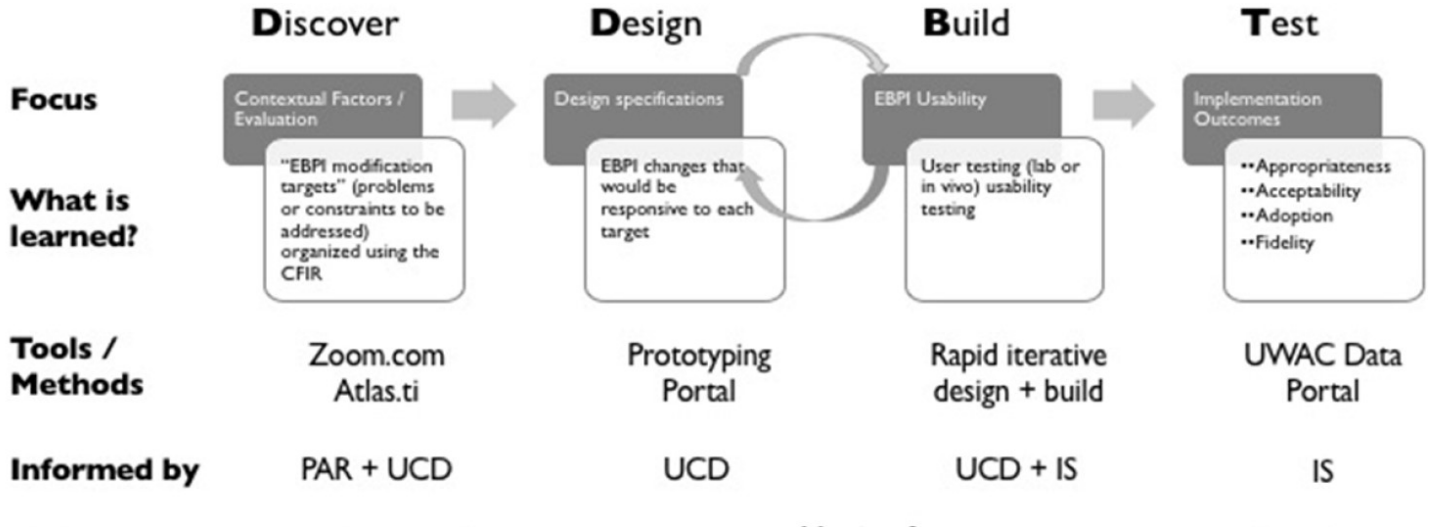
Below are examples of proposals responsive to this RFA:

- ***Capacity Building -*** Methods to enhance the training of front line clinicians or lay workers in elements of evidence-based treatment (e.g., new distance learning methods, the use of Artificial Intelligence [AI] to develop training algorithms, training in decision support);
- ***Usability -*** Modifications to evidence-based treatments to make them user-friendly, intuitive, or efficient for clinicians (e.g., modification of CBT for lay workers, modification of Interpersonal Therapy [IPT] for clinicians in primary care);
- ***Sustained Quality -*** Novel measures of quality delivery of psychosocial treatments (e.g., electronic health record alert systems, use of machine learning to create smart notes, voice recognition tools to measure quality, patient reports of clinician quality).

This list is not exhaustive of the potential projects responsive to this RFA and applicants should note that responsive proposals do not have to be technology-focused.

DDBT Framework Overview and Procedures (Fig. 1). On a conceptual level, participatory action research (PAR), implementation science (IS), and user-centered design (UCD) are all focused on similar goals—enhancing usability, contextual fit, uptake, and effective implementation of an intervention or innovation. Each tradition has a particular focus, and by extension, areas that are not emphasized. IS seeks to facilitate EBPI implementation by modifying real-world setting characteristics (settings, supports, culture). UCD focuses strongly on the end-user (here, the clinician) and their interaction with the tool, innovation, and/or intervention, assuming that modifications to enhance usability reflect the primary pathway to facilitate EBPI uptake. PAR's focus is also user-centered, but focuses primarily on end-user values, culture and needs into the intervention design. Taken together, the UWAC DDBT framework capitalizes on each of these strengths, integrating them into a coherent design incubator to drive effective EBPI modifications for implementation goals (i.e., capacity, usability and quality).

Figure 1. Overview of Discover, Design, Build, Test (DDBT) Framework



Discover Phase: The first step of our framework leverages important aspects of participatory action research and user-centered design.[32-34] It employs a process that engages target users (i.e., clinicians) and other key stakeholders throughout the design process to ensure that a resulting design both: (1) meets needs of its users and other stakeholders (i.e., is useful), and (2) is easy to use and understand (i.e., is usable). Methodological procedures used in this phase include: *Identification of users.* UCD places strong emphasis on explicitly identifying target users to ensure that new products effectively meet their needs.[16,35] Investigators are expected to compile a list of potential end-users of the EBPI. Clearly articulating primary (and possibly secondary; e.g., patients) end-user groups would be an important part of a successful application. To ensure generalizability and rapid uptake, this should represent a diverse set of clinician types. Examples of discovery phase tasks are:

Identification of user needs. The purpose of these interviews is to identify key challenges end-users face in the use of EBPIs.

Contextual observation of users in their work settings. Although qualitative interviews clarify the perceived challenges in implementation of an EBPI, practical challenges in implementation can sometimes be missed by failure to observe actual clinician behavior. For example, watching video tapes of clinician sessions, and having the clinician explain what they were thinking, the challenges they were faced with in implementation, even how they were feeling in the moment, can offer suggestions for improvement in the design of an EBPI, or offer ideas for tools that could support the clinician in implementing an EBPI.

Usability testing via direct interactions with the EBPI. For a typical evaluation, plan to use the "think-aloud" protocol,[36] in which the end-user verbalizes their experiences and thought processes as they use the tool to complete a task. This approach is particularly useful to guide EBPI tool redesign because it makes clinicians' perceptions of different components of the intervention accessible to evaluators in real time.

Applications that focus primarily on the Discover Phase should clearly indicate how their findings would inform future redesign efforts.

Moreover, 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 barriers to implementation faced specifically by clinicians (the targeted end-users) and when necessary patients.

Design and Build Phase: Based on the information gleaned from the *Discover* phase, the UWAC works with investigators to iteratively build, evaluate, and refine their prototypes. Early prototype testing is based on data from the *Discover* phase and conducted locally with small samples (for instance, $n = 5$) to answer design questions using paper version of modifications or storyboards. Later prototypes may be tested using A/B testing or discrete choice experiments with local end-users, and with our online research community and virtual prototyping sandbox.

Note: the Design and Build phase is meant to link directly to the contextual issues identified in the Discover Phase.

Test Phase: This phase of the UWAC-funded projects involves feasibility testing of the innovation in a form that fully functions as it is intended, with a larger number of users, and in their actual milieu. The emphasis of this testing phase is on user experience, satisfaction with the end design, and reported benefit over alternative or existing processes as identified by the end user design partners. Although patient outcomes may be collected, the intent of this evaluation is not to determine clinical efficacy but rather the potential match of the tools to the intended environment and problem that it seeks to address. Outcomes from the test phase include many standard implementation research outcomes (e.g., appropriateness, feasibility, adoption).[37]

It is likely that proposals for this RFA will be focused on discover and design/build phases of the DDBT framework.

II. Methodological Considerations

Mechanisms of Action: This RFA supports pilot tests of approaches that explicitly address whether the revised psychosocial intervention still engages the target(s)/mechanism(s) known to underlie the intervention effects (i.e., the mechanism that accounts for changes in clinical outcomes), AND/OR that explicitly address whether the implementation strategy engages the target(s)/mechanism(s) presumed to underlie the implementation effects (i.e., the mechanism that accounts for changes in implementation outcomes). Successful pilot study applications will identify EBPI modification targets to improve clinical capacity, EBPI usability, and sustained quality. Successful applications will also leverage the UWAC resources, including the Methods Core and the DDBT framework. The Consolidated Framework for Implementation Research (CFIR), or any implementation framework that clearly specifies innovation-level determinants,[38,39] may be used to identify and categorize modification targets. In the assessment of target engagement, this RFA encourages the use of measures that are as direct and objective as is feasible in the effectiveness setting. Specifically encouraged are empirically validated measures of the construct that extend beyond self-reports and other subjective measures.

Measurement of Outcomes: These R03 projects will provide valuable information about the utility of the DDBT framework in creating usable and scalable EBPI solutions, common EBPI targets, and promising EBPI modifications. Learnings from the R03s will be disseminated, along with other outcomes from the UWAC, to the broader research and clinician communities. Thus, when applicable, studies must test the effects of modification targets of implementation outcomes (time to train, clinician skill drift), system usability, EBPI system burden, system acceptability, and patient-reported outcomes. Where appropriate, these studies should collect shared outcomes on (1) implementation costs (training time, skill drift over time), (2) burden on clinician (the User Burden Scale, System Usability Scale, and/or Intervention Usability Scale), (3) EBPI acceptability (Acceptability of Intervention Measure, Intervention Appropriateness Measure, and Feasibility of Intervention Measure), and (4) patient-reported outcomes (the Sheehan Disability Scale, the Patient Health Questionnaire [PHQ-9]). Please See Appendix E for a list of required measures.

Methods Core Experts: 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 primary care, communications technologies (mHealth, remote consultation, and telehealth), and adult learning, which may be explored by the R03 projects. If you are unsure of who to contact as a Methods Core advisor, please contact Katie Osterhage at katieost@uw.edu for assistance.

Community partners and WPRN: If applicable to their study, investigators may consider working with the WPRN (WWAMI region Practice and Research Network; a collaborative group of primary care practices through the states of Washington, Wyoming, Alaska, Montana and Idaho) to facilitate innovative community-based research. The WPRN will engage R03 investigator teams with clinicians (both primary care and behavioral health providers) and clinical organizations as research partners.

Investigators should contact the WPRN Coordinating Center (CC) to discuss their study idea 4 weeks or more in advance of the due date. The WPRN CC staff and faculty will work with investigators to ensure their proposed methodology is feasible for WPRN practice settings. Investigators will be asked to provide a 1-page description of their study (template provided by WPRN) to the WPRN CC to review with its Steering Committee for approval at least 3 weeks in advance of the submission. In the case of extenuating circumstances, please contact the WPRN CC with concerns about this timeline.

The WPRN Coordinating Center will work with investigators to develop a budget that is appropriate for working with WPRN practice sites. Budget requirements include a practice champion to facilitate implementation at the site (<10% FTE), compensation to the clinic for participating in the research (general overhead, e.g. to support space and leadership/staff time), and any other costs to conduct the research on site. For example, this might include IT staff time to query electronic medical records, staff time to identify patients, and incentives for provider or patient participants, among others.

As soon as a project is funded, the WPRN Coordinator will start working on recruiting relevant site(s).

To discuss working with the WPRN, please contact Katie Osterhage at katieost@uw.edu

III. 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**. Funding will be prioritized for multidisciplinary investigator teams affiliated with the School of Social Work, Department of Psychiatry and Behavioral Sciences, Department of Family Medicine, Department of Human Centered Design and Engineering, Department of Computer Science and Engineering, and Department of Communications. Investigator teams must be comprised of two Co-Principal Investigators (Co-PIs) who represent different disciplines and must include at least one senior mentor as co-investigator. 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 not accepting proposals for international research. Our reasons are 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 under this *Request for Pilot Study Applications* is $50,000 per year. As is the case for NIH R03 grant mechanisms, investigators may request up to two years of support (not to exceed $50,000 in any given year).

Budget and Timeline – Pilot Studies 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 year (June 1st – May 30th) 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 etc. on standard NIH forms. Funds for investigator salary are eligible, but travel to conferences/trainings and IT equipment may not be included.

Submission Process – Pilot study applications will be accepted three times per year (February 15, June 15, and October 15). Applications must be submitted by **5:00PM PT** on the due date. If the due date falls on a Saturday or Sunday, applications will be due the following Monday by 5:00PM PT. Investigators must receive approval from a UWAC Methods Core faculty member to submit the pilot study application (see Appendix A for potential faculty advisors). 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 your final application as a SINGLE PDF document to Katie Osterhage, katieost@uw.edu.

Application – The pilot study application should be submitted as a single PDF document, consisting of a face page (see Appendix B), 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 C 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.

   A webinar was held on Wednesday Aug 29, 2018 to discuss the DDBT framework. You can access this webinar here.

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; see Appendix A). 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, Drs. Areán and Fortney 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 implementation or usability of an evidence-based psychosocial intervention;
(3) address one or more key issues described in the RFA, namely, clinician capacity, usability, and sustained quality;
(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 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 this 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, 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 (February 15, June 15, and October 15). NOTE: Potential investigators may (re)submit their application a maximum of 3 times.
- 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, Drs. Areán and Fortney 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;
- IRB approval letter; and
- Proof of Clinical Trials Registry for any clinical trials.

Please note: if you are offered and accept UWAC pilot funding, your application will be available to UWAC affiliates on out internal website.

Beginning your project: Funded projects will be matched with a UWAC Methods Core faculty member for consultation (as needed; approx. 12-20 hours over the funding period).This faculty member will work with funded projects to ensure data is collected in line with overarching ALACRITY Center aims, methods, and specific measurement instruments. This faculty member will track the progress of your Pilot Study. It is expected that it should take about 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 Dr. Fortney to discuss the situation. If after 6 months, you have not yet received IRB approval, Dr. Fortney 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.

Please also note that if funded, both co-investigators will be provided training and required to serve on a review committee for future ALACRITY Center R03 submissions.

Webinar, Website, and Other Resources

Webinar

As mentioned above, a webinar with UWAC Core Faculty (Drs. Areán and Lyon) was hosted on **Wednesday August 29, 2018.** This webinar was recorded and can be viewed on our UWAC website here.

Please contact Katie Osterhage (katieost@uw.edu) with any questions about this webinar.

Additional Resources

- Refer to our website for a copy of this request and related content
    - Please note, there are additional resources linked on the right side of the page such as a budget template, measures for investigators to use in their proposals, and readings relevant to the DDBT framework.
- If you are interested in viewing an example funded submission or you have any other questions and submissions, please contact:

    Katie Osterhage, MMS
    Research Scientist
    katieost@uw.edu

Appendix A

UWAC Methods Core Faculty Members

Faculty Name	Home Department	Email
Patricia Areán, PhD	Psychiatry & Behavioral Sciences	parean@uw.edu
Ian Bennett, MD, PhD	Family Medicine; Psychiatry & Behavioral Sciences	ibennett@uw.edu
Carmen Gonzalez, PhD	Communication	cmgonzal@uw.edu
Aaron Lyon, PhD	Psychiatry & Behavioral Sciences	lyona@uw.edu
Sean Munson, PhD	Human Centered Design & Engineering	smunson@uw.edu
Patrick Raue, PhD	Psychiatry & Behavioral Sciences	praue@uw.edu

If you are unsure of who to contact as a Methods Core advisor, please contact Katie Osterhage at katieost@uw.edu for assistance.

Appendix B

Face Page

1. **Submission Date:**

2. **Title of Project:**

3. **Co-Principal Investigator #1**
    a. Name:
    b. Title:
    c. Contact Information
        i. Email:
        ii. Phone:

    d. Signature_____

4. **Co-Principal Investigator #2**
    a. Name:
    b. Title:
    c. Contact Information
        i. Email:
        ii. Phone:

    d. Signature_____

5. **Senior Mentor**
    a. Name:
    b. Title:
    c. Contact Information
        i. Email:
        ii. Phone:

    d. Signature_____

6. **Total amount requested:** _____

7. **UW Alacrity Center Sponsoring Core Faculty Member**
    a. Name:
    b. Title:
    c. Contact Information
        i. Email:
        ii. Phone:

    d. Signature_____

Appendix C

UW Alacrity Center DDBT Intake

DDBT Intake Rubric

This document is intended to be used with UWAC projects (R34, R03) and other projects applying the DDBT framework to specify the DDBT methods and data elements that will be included. Please note that all measures and articles discussed in the intake rubric are available on the ALACRITY site under "Resources." If you experience difficulty finding or accessing these materials, you can email katieost@uw.edu to request them.

We recommend that project leads first complete this document independently, so much as possible, and then bring their responses to a meeting with the UWAC Methods Core for additional conversation, clarification, and mentorship.

1. What is the existing evidence-based program, practice, or implementation strategy that will be redesigned in this project? *(If you are primarily redesigning an intervention program or practice, consider whether you will be redesigning any aspects of accompanying implementation strategies. Similarly, if you are primarily redesigning an implementation strategy, consider whether any redesign of the intervention program or practice will occur)*

2. How does this project define the **"destination context"** that it will be studying **(i.e., the setting for which the program, practice, or strategy listed above is being redesigned)**? Destination context may be operationalized based on some combination of place (e.g., rural primary care clinics), organization (e.g., Kaiser Permanente behavioral health), professional roles (e.g., bachelors-level service providers), etc.

3. Who are the primary (and secondary) users for the selected program, practice, or strategy?
    - Service providers / front-line personnel (e.g., clinicians, case managers, teachers, etc.)
      Describe: _____
    - Service recipients (e.g., patients, clients, students)
      Describe: _____
    - Implementation practitioners / intermediaries / instructors / consultants (i.e., the professionals who deliver any selected implementation strategies)
      Describe: _____
    - Administrators or supervisors
      Describe: _____
    - Other: _____

4. Are there any a priori decisions (or assumptions) about the redesign solution that have already been made (e.g., that a design solution is digital; that specific therapeutic program, practices, or strategy elements to be included / excluded)? Research plans should make explicit if/how they will test those assumptions as the research progresses.

DISCOVER

The Discover phase of the DDBT framework focuses on evaluating both (1) aspects of the intended destination context that will inform the redesign of the program, practice, or strategy, as well as (2) the original/unadapted program, practice, or strategy to identify design issues that may need to be addressed in the subsequent redesign effort. However, different projects may differentially emphasize #1 and #2.

5. Is the project focusing (in part or in full) on the **DISCOVER** phase of the DDBT framework? Even if some a priori decisions have been made about the anticipated redesign solution (see #4 above), it is common that some DISCOVER phase work will still need to occur.
    - No (skip to #12)
    - Yes (continue below)

6. What aspects of the destination context (see #2 above) will be evaluated in the DISCOVER phase (check all that apply)?
    - ○ Tasks and workflows

    Briefly describe: _____

    - ○ Existing clinical practices / psychosocial intervention technologies

    Briefly describe: _____

    - ○ Existing implementation strategies or supports

    Briefly describe: _____

    - ○ Existing digital technologies

    Briefly describe: _____

    - ○ User (e.g., clinician, client) values and other characteristics (e.g., experience, training background)

    Briefly describe: _____

    - ○ Other: _____

7. What qualitative and quantitative methods will be used to evaluate each aspect of the destination context selected above in the DISCOVER phase? *(Note that observational methods are often superior to interview or focus group methods, though the strongest discovery phases will triangulate different types of data)*

8. What aspects of the original program, practice, or strategy will be evaluated in the DISCOVER phase (check all that apply)?
    - Content elements *(Discrete techniques or strategies used in during direct interactions)*
    - Structures *(Processes that guide the dynamic selection, organization, and maintenance of content; such as goal setting, data-driven decision making, or structured algorithms)*
    - Artifacts *(Tangible, digital, or visual materials that exist to support task completion)*
    - Parameters *(Static properties that define and constrain the program, practice, or strategy"space," such as content sequencing, modality, language, dosage)*
    - Other: _____

9. What, if any, are the known or anticipated usability issues as you adapt the original program, practice, or strategy to the selected context? *(outline below based on adapted User Action Framework [UAF])*

    - *Planning issues* (i.e., issues impacting whether the user can understand, plan, and/or decide what to do):

    - *Translation issues* (i.e., issues impacting whether the user can translate plans into actions):

- *Action issues* (i.e., issues impacting whether the user can successfully perform actions within typical use cases):

- *Assessment/Feedback issues* (i.e., issues impacting whether the user can understand the effects of actions):

- Other: _____

10. What methods will be used to evaluate the usability of the original program, practice, or strategy in the DISCOVER stage? (check all that apply) *(see Lyon et al., in prep for more info)*
    - Quantitative instruments (e.g., Intervention Usability Scale)
    - Heuristic evaluation checklist (e.g., Heuristic Evaluation Rubric for EBPIs) – completed by design team
    - Cognitive Walkthroughs (with anticipated success ratings, qualitative feedback and anticipated errors)
    - Task-based, scenario-driven testing
    - In-vivo / naturalistic observation of the innovation (observing typical use of an existing innovation to identify common questions that arise for users [e.g., tracking the most common implementation problems discussed in clinical supervision or the most common questions brought to a "help desk")

    Please list any standardized measures or scales you plan to collect as part of the methods in the DISCOVER stage: _____

11. Which users will participate in the in the DISCOVER phase evaluation(s) selected above? *(see Participant Identification handout [pasted below] for additional guidance*)

Table 1. EBPI Usability Test Participant Identification Process

1. Generate preliminary user list	• Generate an overly-inclusive list • Consider individuals in different roles
2. Articulate most relevant user characteristics	• Personal characteristics • Task-related characteristics • Geographic/social/setting characteristics
3. Describe and prioritize main user groups	• Articulate primary, secondary, and negative (i.e., non-) users
4. Select typical and representative users for testing	• Sample into user subtype strata • Recruit ~6-20 users per test

DESIGN/BUILD

The Design/Build phase of the DDBT framework is dedicated to the iterative development and small-scale testing of the program, practice, or strategy to improve its usability and contextual appropriateness in the destination context.

12. Is the project focusing (in part or in full) on the **DESIGN/BUILD** phase of the DDBT framework?
    - No (skip to #21)
    - Yes (continue below)

13. **If your proposed project STARTS at the Design/Build phase**, we assume you have completed the necessary Discovery work. Please describe here (a) what methods you used for your Discovery work, (b) the outcomes of the work, and (c) the degree to which Discovery findings were driven by observations and interactions with end-users and the destination context.

14. If your proposed project **includes BOTH the Discovery and Design/Build phases**, we encourage you to think through how some hypothetical outcomes of the Discovery phase would influence the design choices you will make in the Design/Build phase. This activity can help ensure that Discovery phase activities are designed to answer the most critical questions.

15. Are there any a priori redesign decisions / modifications planned for the DESIGN/BUILD phase, based on existing knowledge / research findings?
    - No (skip to #18)
    - Yes (continue below)

16. Which aspects of the **content, structures, or artifacts** of the program, practice, or strategy do you anticipate redesigning during the DESIGN/BUILD phase (see Stirman et al., 2013)?
    - Tailoring/tweaking/refining
    - Adding elements
    - Removing/skipping elements
    - Shortening/condensing/simplifying
    - Lengthening/extending
    - Substituting
    - Reordering models or segments
    - Integrating the program, practice, strategy into another framework
    - Integrating another intervention or strategy into the selected program practice or strategy
    - Repeating elements or modules
    - Loosening structure
    - Departing from the program, practice, or strategy ("drift")
    - Other: _____

17. Which aspects of the **parameters** of the program, practice, or strategy do you anticipate redesigning during the DESIGN/BUILD phase (see Stirman et al., 2013)? *(Recall that parameters are static properties that define and constrain the program, practice, or strategy intervention or service "space," such as content sequencing, modality, language, dosage)*
    - Format (including digitization)
    - Setting
    - Personnel
    - Other: _____

18. Which methods will be used to evaluate iterative versions of the program, practice, or strategy in the DESIGN/BUILD phase? (check all that apply) *(see Lyon et al., in prep for more info)*
    - Quantitative instruments (e.g., Intervention Usability Scale)
    - Heuristic evaluation checklist (e.g., Heuristic Evaluation Rubric for EBPIs) – completed by design team
    - Cognitive Walkthroughs (with anticipated success ratings, qualitative feedback and anticipated errors)
    - Task-based, scenario-driven testing
    - Other: _____

    Please list any standardized measures or scales you plan to collect as part of the methods in the DESIGN/BUILD stage: _____

19. Which users will participate in the in the DESIGN/BUILD evaluation(s) selected above? *(see Participant Identification handout [pasted below] for additional guidance*)

Table 1. EBPI Usability Test Participant Identification Process

1. Generate preliminary user list	• Generate an overly-inclusive list • Consider individuals in different roles
2. Articulate most relevant user characteristics	• Personal characteristics • Task-related characteristics • Geographic/social/setting characteristics
3. Describe and prioritize main user groups	• Articulate primary, secondary, and negative (i.e., non-) users
4. Select typical and representative users for testing	• Sample into user subtype strata • Recruit ~6-20 users per test

20. Who is your development team for your redesigned innovation? What skills do you anticipate will be necessary to build your redesigned innovation? Redesign teams may need expertise in design processes, development (e.g., of curriculia, technologies, etc.), as well as the destination context.

TEST

The Test phase is focused on evaluating the feasibility ("actual fit") of the redesigned, program, practice, or strategy in the intended destination context. Although patient outcomes may be collected, the intent of Test phase evaluation is not to determine clinical efficacy but rather the match of the tools to the intended environment and problem(s) that it seeks to address.

21. Is the project focusing (in part or in full) on the **TEST** phase of the DDBT framework?
    - No (your intake form is complete)
    - Yes (continue below)

22. **Projects that START at the TEST phase** typically will have completed the necessary Discovery and/or Design/Build work. Please describe here (a) what methods you used for your Discovery and Design/Build work, (b) the outcomes of the work, and (c) the degree to which Discovery and Design/Build findings were driven by observations and interactions with end-users and the destination context.

23. If your proposed project **includes the Discovery and/or Design/Build phases**, we encourage you to think through how some hypothetical outcomes of the those phases would help you determine whether you are ready to proceed to the TEST phase or influence the redesign choices you will make in the TEST phase. This activity can help ensure that earlier phase activities are designed to answer the most critical questions.

24. Which methods will be used to evaluate the redesigned program, practice, or strategy in the TEST phase? (check all that apply) *(see Lyon et al., in prep for more info)*
    - Quantitative instruments *(e.g., Intervention Usability Scale)*
    - Heuristic evaluation checklist (*e.g., Heuristic Evaluation Rubric for EBPIs)* – completed by design team
    - Cognitive Walkthroughs *(with anticipated success ratings, qualitative feedback and anticipated errors)*
    - Task-based, scenario-driven testing
    - Extended/in vivo user testing or observation
    - Other: _____

25. Which implementation outcomes will you assess in the TEST phase, and which instruments or data will you use? *(see Proctor et al., 2011 for more info; note: it is unlikely that a DDBT study will collect penetration, sustainment, or cost data)*
    - Acceptability. *Instrument or data:* _____
    - Appropriateness. *Instrument or data:* _____

- Feasibility. *Instrument or data:* _____
- Adoption. *Instrument or data:* _____
- Fidelity. *Instrument or data:* _____
- Penetration. *Instrument or data:* _____
- Sustainment. *Instrument or data:* _____
- Cost. *Instrument or data:* _____
- Other: _____

26. Which users will participate in the in the TEST phase evaluation(s) selected above? *(see Participant Identification handout for additional guidance*)

Table 1. EBPI Usability Test Participant Identification Process

1. Generate preliminary user list	• Generate an overly-inclusive list • Consider individuals in different roles
2. Articulate most relevant user characteristics	• Personal characteristics • Task-related characteristics • Geographic/social/setting characteristics
3. Describe and prioritize main user groups	• Articulate primary, secondary, and negative (i.e., non-) users
4. Select typical and representative users for testing	• Sample into user subtype strata • Recruit ~6-20 users per test

27. Do you have committed partners who represent the destination context for the TEST phase?

Appendix D

UW Alacrity Center Pilot Funding Agreement

The undersigned investigators agree to the following obligations:

(1) The investigators will submit monthly progress reports months after the funding date; and
(2) The investigators will acknowledge the UW Alacrity Center on all abstracts, presentations and publications resulting from the pilot funding.

Failure to comply with this agreement may result in loss of current pilot funding and/or eligibility to apply for future pilot studies.

Co-Principal Investigator #1

Printed Name_____

Signature_____

Date_____

Co-Principal Investigator #2

Printed Name_____

Signature_____

Date_____

Appendix E

UW Alacrity Center Required Measures

Participant Demographics
Required for all study populations
ALACRITY standardized demographics form – to be collected from all participant groups in the study.

Perceptual Implementation Outcomes
All 3 required
Acceptability of Intervention Measure (AIM) –to be taken by Clinicians (end users) to measure how receptive they are to adopting the new intervention.

Feasibility of Intervention Measure (FIM) – to be taken by Clinicians (end users) to measure how possible and likely they are adopt the new intervention.

Intervention Appropriateness Measure (IAM) – to be taken by Clinicians (end users) to measure how suitable the intervention is for the circumstances.

Each of these measures contain 4 questions, and can all be found here.

Patient-Reported Outcomes
Both measures required for studies with a test phase and that engage patients with specific mental health challenges.
Sheehan Disability Scale (SDS) – to be taken by patients to measure the severity of symptoms (any type) and their impact on functioning.

Symptom Tracker – to be taken by patients to measure the severity of symptoms of specific disorders/challenges. Whichever scale is deemed most appropriate for the study. Examples are the Patient Health Questionnaire (PHQ-9) and/or Generalized Anxiety Disorder-7 (GAD-7).

Usability Metrics
One of the following 3 is required
System Usability Scale (SUS) – This measures how easy the intervention/system is to use and learn. Used for digital interventions (e.g. apps or computer programs).

Intervention Usability Scale (IUS) – This measures how easy the intervention/system is to use and learn. Used for interventions (e.g. therapeutic modalities).

Implementation Strategy User Scale – This measures how easy the intervention/system is to use and learn. Used for system-level interventions.

Required for studies evaluating or testing a digital tool
User Burden Scale – This measures the mental/emotional/economic challenges of using a digital tool as part of an intervention and is completed by anyone directly interacting with the tool.

Suggested for studies involving an EBPI

Heuristic Evaluation Rubric for EBPI's (HERE) – This multi-faceted evaluation of efficiency/quality/usability of EBPI's involves experts in both design and the relevant subject matter (at least 2 people) filling out the rubric independently and the comparing answers and negotiating a final score together.

**We are developing a system to receive and categorize information and qualitative data on usability issues.*

Behavioral Implementation Outcomes

As appropriate/feasible

Fidelity – Measured through original fidelity instrument, modified fidelity instrument, or documentation of changes in how fidelity is evaluated

Cost – Can include overall costs before and after redesign

- Time invested – hours to train/certify; hours spent on feedback/supervision
- Training costs – total training hours x salary level

Adoption – Defined as the intention, initial decision, or action to try or employ an innovation or evidence-based practice (aka uptake). Include baseline adoption when possible.

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