IRB CONTINUING REVIEW APPROVAL

October 7, 2024

Dear Dror Ben-Zeev:

On 10/7/2024, University of Washington IRB Committee J reviewed the following application:

Type of Review:	Continuing Review
Title of Study:	Implementing mHealth for Schizophrenia in Community Mental Health Settings
Investigator:	Dror Ben-Zeev
STUDY ID	STUDY00006141
CR ID:	CR00008895
Funding:	Name: National Institute of Mental Health (NIMH), Grant Office ID: A132489, Funding Source ID: R01MH116057-01A1
IND, IDE, or HDE:	None
Relying Sites:	

IRB Approval

Under FWA #00006878, the IRB renewed approval for your activity from 10/7/2024 to 10/6/2025.

- Your application qualified for expedited review ("minimal risk"; Category 5 and 7).
- Tracking IRB approval periods and preventing a lapse is the researcher's responsibility. However, the Zipline system sends automated courtesy reminders prior to expiration of approval. If a renewal application or study closure is not received within 90 days of expiration, HSD may administratively close the study. In some circumstances, HSD may refuse to review additional submissions from the researcher until a status report is received, lapsed IRB approval may be considered continuing non-compliance, and the study may be "terminated" by the IRB.
- Your study has a federal Certificate of Confidentiality (CoC). See this INFORMATION SHEET for a description of the CoC protections and responsibilities.
- If you plan to continue data collection past the expiration of the CoC, contact the Human Subjects Division prior to expiration. We will help you determine whether you need to apply for a CoC extension.

Thank you for your commitment to ethical and responsible research. We wish you great success!

Sincerely,

Kelly McPherson
IRB Administrator, Team J
206-221-6422
Kellymc3@uw.edu

INSTRUCTIONS

- If you are requesting a determination about whether your activity is human subjects research or qualifies for exempt status, you may skip all questions except those marked with a . For example **1.1** must be answered.
- Answer all questions. If a question is not applicable to your research or if you believe you have already answered a question elsewhere in the application, state "NA" (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary "back and forth" for clarification. Use non-technical language as much as possible.
- To check a box, place an "X" in the box. To fill in a text box, make sure your cursor is within the gray text box bar before typing or pasting text.
- The word "you" refers to the researcher and all members of the research team, unless otherwise specified.
- For collaborative research, describe only the information that is relevant to you unless you are requesting that the UW IRB provide the review and oversight for your collaborators as well.
- You may reference other documents (such as a grant application) if they provide the requested information in non-technical language. Be sure to provide the document name, page(s), and specific sections, and upload it to **Zipline**. Also, describe any changes that may have occurred since the document was written (for example, changes that you've made during or after the grant review process). In some cases, you may need to provide additional details in the answer space as well as referencing a document.
- If you are using this form on paper, attach the PAPER SUPPLEMENT: IRB Protocol on Paper

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1 OVERVIEW

Study Title: Implementing mHealth for Schizophrenia in Community Mental Health Settings

1.1 Home institution. Identify the home institution of the lead researcher as listed on the IRB application. Provide any helpful explanatory information.

In general, the home institution is the institution (1) that provides the researcher's paycheck and that considers him/her to be a paid employee, or (2) at which the researcher is a matriculated student. Scholars, faculty, fellows, and students who are visiting the UW and who are the lead researcher: identify your home institution and describe the purpose and duration of your UW visit, as well as the UW department/center with which you are affiliated while at the UW.

Note that many UW clinical faculty members are paid employees of non-UW institutions.

The UW IRB provides IRB review and oversight for only those researchers who meet the criteria described in the **POLICY: Use of the UW IRB**.

The University of Washington

1.2 Consultation history. Have you consulted with anyone at HSD about this study?

It is not necessary to obtain advance consultation. If you have: answering this question will help ensure that the IRB is aware of and considers the advice and guidance you were provided.

[ ] **No**
[x] **Yes** → If yes, briefly describe the consultation: approximate date, with whom, and method (e.g., by email, phone call, in-person meeting).

I have consulted with Amanda Guyton on Nov 5th and 8th, 2018.

1.3 Similar and/or related studies. Are there any related IRB applications that provide context for the proposed activities?

Examples of studies for which there is likely to be a related IRB application: Using samples or data collected by another study; recruiting subjects from a registry established by a colleague's research activity; conducting Phase 2 of a multi-part project, or conducting a continuation of another study; serving as the data coordinating center for a multi-site study that includes a UW site.

Providing this information (if relevant) may significantly improve the efficiency and consistency of the IRB's review.

[x] **No**
[ ] **Yes** → If yes, briefly describe the other studies or applications and how they relate to the proposed activities. If the other applications were reviewed by the UW IRB, please also provide: the UW IRB number, the study title, and the lead researcher's name.

1.4 Externally-imposed urgency or time deadlines. Are there any externally-imposed deadlines or urgency that affect your proposed activity?

HSD recognizes that everyone would like their IRB applications to be reviewed as quickly as possible. To ensure fairness, it is HSD policy to review applications in the order in which they are received. However, HSD will assign a higher priority to research with externally-imposed urgency that is beyond the control of the researcher. Researchers are encouraged to communicate as soon as possible with their HSD staff contact person when there is an urgent situation (in other words, before submitting the IRB application). Examples: a researcher plans to test an experimental vaccine that has just been developed for a newly emerging epidemic; a researcher has an unexpected opportunity to collect data from students when the end of the school year is only four weeks away.

HSD may ask for documentation of the externally-imposed urgency. A higher priority should not be requested to compensate for a researcher's failure to prepare an IRB application in a timely manner. Note that IRB review requires a certain minimum amount of time; without sufficient time, the IRB may not be able to review and approve an application by a deadline.

	No
x	**Yes**

→ If yes, briefly describe the urgency or deadline as well as the reason for it.

IRB approval is required for this study prior to the National Institutes of Health issuing the notice of award (NOA). IRB review is requested as soon as possible to avoid delays in funding.

Regarding our modification submission on 2.10.20: We plan to start enrolling participants in early March. If this could be a prioritized review we would be very grateful. Thank you!

1.5 Objectives Using lay language, describe the purpose, specific aims, or objectives that will be met by this specific project. If hypotheses are being tested, describe them.

If your application involves the use of a HUD "humanitarian" device: describe whether the use is for "on-label" clinical patient care, "off-label" clinical patient care, and/or research (collecting safety and/or effectiveness data).

The proposed study: We propose to conduct a multi-site site hybrid type III effectiveness/implementation study in Washington State. The study involves a systematic head-to-head comparison between EF and IF implementation models applied to the FOCUS mHealth intervention. Specifically, we aim to:

Aim 1. Evaluate and compare implementation outcomes. We will measure and compare FOCUS penetration among providers, acceptability within agencies, cost and cost effectiveness associated with FOCUS within CMHCs using EF or IF implementation approaches.
Aim 2. Examine moderators and mediators of implementation effects. We will examine the extent to which CMHC characteristics (i.e., readiness for change, organizational culture, urban vs. rural setting) moderate implementation outcomes. Consistent with the NIMH experimental therapeutics approach, we will evaluate mechanisms of action and examine whether absorptive capacity (practitioner–level target) mediates the effect of EF and IF on implementation outcomes.
Aim 3. Evaluate and compare patient outcomes. We will measure and compare whether the

implementation strategies differentially affect FOCUS patients' psychiatric symptom severity, recovery, and illness management capacity. We will also examine whether mHealth engagement (patient-level target) mediates the effects of EF and IF on patient outcomes.

1.6 Study design. Provide a one-sentence description of the general study design and/or type of methodology.

Your answer will help HSD in assigning applications to reviewers and in managing workload. Examples: a longitudinal observational study; a double-blind, placebo-controlled randomized study; ethnographic interviews; web scraping from a convenience sample of blogs; medical record review; coordinating center for a multi-site study.

multi-site site hybrid type III effectiveness/implementation study

1.7 Intent. Check all the descriptors that apply to your activity. You must place an "X" in at least one box.

This question is essential for ensuring that your application is correctly reviewed. Please read each option carefully.

	Descriptor
☐	1. Class project or other activity whose purpose is to provide an educational experience for the researcher (for example, to learn about the process or methods of doing research).
☐	2. Part of an institution, organization, or program's own internal operational monitoring.
☐	3. Improve the quality of service provided by a specific institution, organization, or program.
☒	4. Designed to expand the knowledge base of a scientific discipline or other scholarly field of study, and produce results that: • Are expected to be applicable to a larger population beyond the site of data collection or the specific subjects studied, or • Are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.
☐	5. Develop information about a drug or device through its prospective use and assignment to subjects, which will then be submitted to the Food and Drug Administration (FDA) in support of a marketing or research application for an investigational drug or device, or for changes to the purpose, population, or dose for an already-approved drug or device.
☐	6. Focus directly on the specific individuals about whom the information or biospecimens are collected through oral history, journalism, biography, or historical scholarship activities, to provide an accurate and evidence-based portrayal of the individuals.
☒	7. A quality improvement or program improvement activity conducted to improve the implementation (delivery or quality) of an accepted practice, or to collect data about the implementation of the practice for clinical, practical, or administrative purposes. This does not include the evaluation of the efficacy of different accepted practices, or a comparison of their efficacy.

☐ 8. Public health surveillance activities conducted, requested, or authorized by a public health authority for the sole purpose of identifying or investigating potential public health signals or timely awareness and priority setting during a situation that threatens public health.

☐ 9. Preliminary, exploratory, or research development activities (such as pilot and feasibility studies, or reliability/validation testing of a questionnaire)

☐ 10. Expanded access use of a drug or device not yet approved for this purpose

☐ 11. Use of a Humanitarian Use Device

☐ 12. Other. Explain:

1.8 Background, experience, and preliminary work. Answer this question **only** if your proposed activity has one or more of the following characteristics. The purpose of this question is to provide the IRB with information that is relevant to its risk/benefit analysis.

- Involves more than minimal risk (physical or non-physical)
- Is a clinical trial, or
- Involves having the subjects use a drug, biological, botanical, nutritional supplement, or medical device.

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

a. Background. Provide the rationale and the scientific or scholarly background for your proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that your project is intended to address.

Do not provide scholarly citations. Limit your answer to less than one page, or refer to an attached document with background information that is no more than three pages long.

Poorly managed, schizophrenia-spectrum disorders (SSD) are a major public health concern. SSD develop in approximately 1.5% of the world's population and are ranked as one of the leading causes of disability and government expenditure on healthcare. 1 In the U.S. direct treatment costs associated with SSD are estimated at approximately $25 billion annually. 2 Poor management of SSD leads to symptom exacerbation and functional deterioration which often result in devastating outcomes including psychiatric hospitalizations, profound social isolation, unemployment, homelessness, victimization, self-injury, and suicide. 3-5 There are several evidence-based illness management interventions that have been shown to prolong the recovery periods and improve the outcomes of people with SSD. 6-8 Unfortunately, because they are time intensive and require the skills of trained providers who are often in short-supply, these interventions are seldom available at community mental health clinics (CMHCs) where many individuals with SSD receive care. 9-11

Widely available technologies can help overcome the capacity constraints of brick-and mortar CMHCs, expand the reach of evidence-based mental healthcare, and provide much needed illness management skills and resources for people with SSD, wherever they may be. 12-14 People with SSD use smartphones and are interested in mHealth. Access and use of mobile technology is one of the few areas where gaps between people with SSD and the general population are narrow. In part due to the Federal Lifeline Assistance Program and the perpetually dropping costs of mobile phones and data plans, people with SSD in the U.S. now have broad access to mobile devices. 15 A recent meta-analysis found mobile phone penetration rates of 82% among people with SSD over the last three years with over a third owning smartphones.16 Survey research shows that the majority of people with SSD are open to receiving services and illness management support via their personal mobile devices and to sharing the information captured by technologies with their providers to support their care. 17-19 Evidence-based mobile health (mHealth) for SSD. mHealth interventions have emerged in all areas of healthcare including treatment and rehabilitation of people with severe psychiatric conditions. 20-22 Recent studies have demonstrated that a range of mHealth approaches, including clinical texting support, 23-25 behavioral sensing, 26, 27 and illness self-management apps, 28-30 are feasible, acceptable, and clinically promising for people with SSD. With funding from the NIMH, PCORI, and CMMI, our group developed and tested FOCUS--a multi-modal smartphone illness self-management system for people with SSD. A series of studies conducted with over 500 participants across ten US states has shown that FOCUS is feasible, usable, highly engaging, and effective among people with SSD 28, 31-37 (see Pilot Work for more details). Independent reviews of mHealth in Psychiatry have identified FOCUS to be one of the most carefully designed, optimized, comprehensive, and patient-centered mobile interventions for a defined clinical population. 37 FOCUS is ready for deployment in community mental health centers, however, optimal methods for providing mHealth treatment of SSD in real world practice settings are largely unexplored. Merely making digital health tools accessible (i.e., passive diffusion) will produce limited uptake and reach.Using targeted implementation strategies to engage CMHC providers will be crucial to integration of FOCUS in standard practice.38,39 Practice facilitation is an evidence-based implementation strategy, but one that has not yet been applied systematically to mHealth in CMHC settings. Practice Facilitation refers to the use of an individual (internal or external to a clinical setting) who carries out a specific role aimed at helping integrate evidence based interventions into practice. Practice facilitators work with providers and clinical organizations to make changes designed to improve patient outcomes. 40-42 A meta-analysis of 23 studies provides strong support for practice facilitation in primary care settings. 43 The Agency for Healthcare Research and Quality (AHRQ) has endorsed practice facilitation as an evidence-based approach. AHRQ notes that practice facilitators serve as key assets for innovation implementation in “Safety Net Practices” providing services to patients with chronic illness (defined by the Institute of Medicine as clinics that deliver healthcare and other services to uninsured, Medicaid and other vulnerable patients). 44 Safety Net Practices and CMHCs have multiple commonalities. We adapted core practice facilitation functions outlined in AHRQ’s comprehensive practice facilitation curriculum 45 to develop two mHealth implementation models for CMHCs: External Facilitation (EF) (i.e., led by specialists who are not members of CMHC treatment teams), and Internal Facilitation (IF) (i.e., led by CMHC-embedded facilitators). Early versions of these models for implementation of FOCUS were shown to be feasible and acceptable to patients (see pilot work). The real-world implementation viability of these strategies to change the behavior of providers who work in CMHCs has not been evaluated. On the one hand, a few highly-trained and well-supervised external facilitators may be sufficient to engage many sites, creating opportunities for lowcost implementation on a large scale (e.g., hub-and-spoke model). On the other hand, there may be

return on investment considerations that would make the addition of an internal facilitator more appealing and contextually appropriate. There may be benefits in using recognized members of the clinical setting who can capitalize on existing relationships and awareness of workflows and practice processes, have legitimacy and trust, have access to patient records, engage in clinical team meetings, and conduct facilitation activities with CMHC staff in person, thus enhancing penetration. We propose to use IF and EF to engage providers and compare the effects of both models on patient and implementation outcomes. Key implementation variables. A host of implementation research outcomes have been articulated for studies focused on improving the quality of health services. 46 The promise of mHealth rests largely in its ability to efficiently transform contemporary healthcare at a large scale. 47, 48 Therefore, examining the impact of the implementation strategy on penetration of a practice within a service setting, acceptability (perception that an innovation is agreeable, palatable, or satisfactory), cost-effectiveness (value for money of alternative approaches) and affordability (i.e., the expense of the particular intervention) are particularly critical. Organizational factors are critical to effective implementation: With growing recognition that "bad systems trump good programs," 49 the role of organizational influences on implementation has become widely recognized. 50-52 Critical factors influencing implementation success include the extent to which an organization is ready to engage in a change effort. 53 Organizational readiness for change varies depending on how much members of an organization determine task demands, resource availability, and situational factors to be favorable. A strong organizational culture (i.e., shared assumptions, values, and beliefs that govern how people behave in an organization) has repeatedly been found to predict positive implementation and service quality outcomes.52, 54, 55 We will directly examine whether our implementation strategies have a differential impact on implementation outcomes depending on an organization's culture and readiness for change.

b. Experience and preliminary work. Briefly describe experience or preliminary work or data (if any) that you or your team have that supports the feasibility and/or safety of this study.

It is not necessary to summarize all discussion that has led to the development of the study protocol. The IRB is interested only in short summaries about experiences or preliminary work that suggest the study is feasible and that risks are reasonable relative to the benefits. Examples: You have already conducted a Phase 1 study of an experimental drug which supports the Phase 2 study you are now proposing to do; you have already done a small pilot study showing that the reading skills intervention you plan to use is feasible in an after-school program with classroom aides; you have experience with the type of surgery that is required to implant the study device; you have a study coordinator who is experienced in working with subjects who have significant cognitive impairment.

The FOCUS mHealth intervention has undergone an extensive process of development and evaluation in partnership with CMHC patients with SSD and provider stakeholders.
A. FOCUS: Design and usability. The intervention was developed to provide automated real-time/realplace illness management support to individuals with SSD (R34MH100195). Patients provided ongoing feedback on the look, feel, and content of the intervention throughout the development process. 28 Through a series of focus groups and individual interviews, patient and CMHC providers helped determine treatment targets and even selected the intervention name. To maximize usability, FOCUS was developed in accordance with design principles for electronic resources for people with serious mental illness and cognitive impairment. 56 Several iterative cycles of usability testing with patients helped inform improvements and hone the system so that it would be appropriate for people who may have cognitive deficits, low literacy levels, and limited experience with technology. Once installed, FOCUS can be semi-tailored to each user (e.g., name, preferred treatment targets, prompting schedule).

Description of the mHealth intervention. FOCUS has three elements:28, 33 1) FOCUS application (app): The system includes pre-programmed daily self-assessment prompts as well as on-demand functions that can be accessed 24 hours a day. Self-management content was adapted from psychosocial intervention strategies targeting five broad domains: 28 Voices (i.e., coping with auditory hallucinations via cognitive restructuring, distraction, guided hypothesis testing), Mood (i.e., anaging depression and anxiety via behavioral activation, relaxation techniques, supportive content), Sleep (i.e., sleep hygiene, relaxation, health and wellness psychoeducation), Social (i.e., cognitive restructuring of persecutory ideation, anger management, activity scheduling, skills training), and Medication (i.e., behavioral tailoring, reminders, psychoeducation). The system uses audio prompts, video content, cartoons, and written text to deliver coping strategies in the form of interactive questions, suggestions, and guided demonstrations. Content can be accessed as either brief video or audio clips or sequences of digital screens with written material coupled with visual displays; 2) Clinician dashboard: FOCUS users' responses to daily self-assessments are securely transmitted to a remote server. The information is processed and displayed on an online dashboard with a real-time summary of engagement, module selection, and reported symptom severity over the last 7 days, that is accessible to authorized staff who use it to inform and enhance their clinical services. If, dashboard data suggest a patient requires additional assistance, staff call to assess further and provide consultation ; 3) mHealth support personnel: FOCUS patients are engaged throughout the treatment period by trained individuals to encourage their adherence to FOCUS by assisting them in all technical and clinical aspects of the intervention.

B. FOCUS: Feasibility, acceptability, and efficacy. FOCUS was deployed among individuals with SSD (n=43) receiving services from CMHCs in Illinois 33 and Vermont. 31 FOCUS feasibility, acceptability, satisfaction, and efficacy outcomes were very promising. Results: Participants learned to use the intervention with ease. On average, participants used FOCUS 4.8 times a day, 6 days a week. Across both trials, approximately 60% of FOCUS use was self-initiated by patients ("on-demand" functions). This finding is important, given that participants were not incentivized to engage, and their access to other smartphone resources was not dependent on their use of FOCUS. Approximately 90% of participants rated the intervention as highly acceptable, usable, and engaging. The smartphone multi-media elements proved to be highly engaging to participants (e.g., as reported in qualitative interviews: "[The intervention] was like having a friend check in with you. When I watched the videos it made it feel more personal]".31 Baseline levels of cognitive functioning, negative symptoms, and persecutory ideation did not impede participants' use of FOCUS. Efficacy:
FOCUS use led to statistically significant and clinically meaningful reductions in psychotic symptoms (PANSS positive symptom scale, Cohen's d=.70), depression (BDI-II Cohen's d=.50), and general psychopathology (PANSS psychopathology scale, Cohen's d=.73). Relevance for implementation: Although FOCUS demonstrated strong usability, feasibility, and efficacy in trials where our research staff identified, recruited, and monitored (via the clinician dashboard) study participants from CMHCs, there are substantial opportunities to increase reach and impact of the intervention by helping CMHC clinical staff and administrators integrate FOCUS into their routine care regimen for patients with SSD. In our field trials FOCUS was a siloed research activity—CMHC clinicians did not have access to their patients' data and were not "in the loop" of intervention activity. Engaging CMHC providers in the mHealth intervention would create opportunities to integrate FOCUS into practice and make meaningful use of their patients' data (i.e. inform in person services, better understand their illness profile and needs, encourage FOCUS engagement), which in turn may enhance mHealth implementation. 57

C. FOCUS: Effectiveness and readiness for implementation (pilot EF). We conducted a comparative effectiveness trial (RCT) 35 comparing FOCUS to a widely used an evidence-based group intervention (WRAP) in community mental health settings (n=163) (PCORI CER140311403). Results: FOCUS participants had better treatment commencement (90% vs. 58%), better continuous full engagement in treatment, equivalent (high) treatment satisfaction, and equivalent significant improvement in clinical outcomes: general psychopathology (SCL-9 Cohen's d=.44) depression (BDI-2 Cohen's d=.31), and recovery (RAS Cohen's d=.38). These moderate/large effects are clinically meaningful and comparable to more time/labor/resource intensive clinic based interventions.36 Patients rated the FOCUS intervention supported by EF as highly acceptable. Dropout in the FOCUS arm was very low (3.5%). Engagement was associated with clinical outcomes: more weeks of full engagement (defined as 5+ days of weekly use) were significantly associated with larger increases in recovery scores post-treatment. Patients who completed at least 8+ "fully engaged" weeks showed greater improvements in general psychopathology, depression, and recovery than those who did not. Relevance for implementation: CMHC providers and organizational leaders indicated a strong acceptability and interest in adoption and integration of mHealth in their programs. These findings were supported by responses to implementation survey items (rated 1-"Not at all" to 5-"Very Much"): I would be supportive of incorporating FOCUS into standard practice at my agency: M= 4.9; Connecting with clients through their smartphones would improve their quality of care: M=3.9; Connecting with clients through smartphone intervention would make me more effective in my job: M=4.25). Relevance for implementation: The FOCUS intervention required training and supervision of a single external facilitator who engaged with
patients and supported and trained CMHC providers from a centralized location. The EF was not part of the CMHC clinical staff but hired and trained specifically for this role. 58 The clinical training materials and supervision structure was adapted and refined over the course of the 3-year study. The EF served as the point of contact, FOCUS trainer, and mHealth supporter for patients and staff. The facilitator met with participants at the beginning of the intervention to build rapport and to provide smartphone and FOCUS training. All other interactions were conducted remotely, successfully.

D. FOCUS: Multi-site deployment (pilot IF). With funding from the Center for Medicare and Medicaid Innovation (C1MS331052) FOCUS was used in conjunction with a treatment offered to people with SSD who were recently discharged from a psychiatric hospitalization. 59 This effort was conducted in partnership with CMHCs in eight states and constitutes the largest deployment of an mHealth intervention for people with SSD to date (n=342). 33 Clinical staff members at each site were selected and trained as internal practice facilitators to serve as the primary point of contact for patients, provided technical troubleshooting and smartphone configuration services, and served as the local mHealth champion and resource for treatment teams. 59, 60

Results were promising: Participants engaged with FOCUS on 82% of the weeks they had the smartphone and 44% used the intervention over 5-6 months, on average 4.3 days a week. Relevance for implementation: All study sites were able to identify personnel to serve as internal facilitators, all facilitators successfully completed training with our study team before commencing IF activities at their agencies, CMHC staff were able to log on, understand, and use the FOCUS clinical dashboard successfully. Notably, on-site CMHC personnel identified FOCUS candidates, and the vast majority of patients in the relapse prevention program who were offered FOCUS agreed to use it (92%). While the uptake and patient engagement findings were encouraging in terms of feasibility of the IF model, it was not structured as a controlled experimental study; there was no implementation comparator arm, it was impossible to isolate the mHealth-specific facilitator costs,

or to determine the relative impact of more resource-intensive internal facilitation on patient outcomes relative to EF.

1.9 Supplements. Check all boxes that apply, to identify Supplements you should complete and upload to the **Supporting Documents** SmartForm in **Zipline**.

This section is here instead of at the end of the form to reduce the risk of duplicating information in this IRB Protocol form that you will need to provide in these Supplements.

Check all That Apply	Type of Research	Supplement Name
☐	**Department of Defense** The research involves Department of Defense funding, facilities, data, or personnel.	ZIPLINE SUPPLEMENT: Department of Defense PAPER SUPPLEMENT Department of Defense
☐	**Department of Energy** The research involves Department of Energy funding, facilities, data, or personnel.	ZIPLINE and PAPER SUPPLEMENT: Department of Energy
☐	**Drug, biologic, botanical, supplement** Procedures involve the use of any drug, biologic, botanical or supplement, even if the item is not the focus of your research	ZIPLINE SUPPLEMENT: Drugs PAPER SUPPLEMENT: Drugs
☐	**Emergency exception to informed consent** Research that requires this special consent waiver for research involving more than minimal risk	ZIPLINE SUPPLEMENT: Exception from Informed Consent for Emergency Research (EFIC)
☐	**Genomic data sharing** Genomic data are being collected and will be deposited in an external database (such as the NIH dbGaP database) for sharing with other researchers	ZIPLINE SUPPLEMENT: Genomic Data Sharing PAPER SUPPLEMENT: Genomic Data Sharing
☐	**Medical device** Procedures involve the use of any medical device, even if the device is not the focus of your research, except when the device is FDA-approved and is being used through a clinical facility in the manner for which it is approved	ZIPLINE SUPPLEMENT: Devices PAPER SUPPLEMENT: Devices

☐	**Multi-site study** (You are asking the UW IRB to review one or more sites in a multi-site study.)	ZIPLINE SUPPLEMENT: Participating Site in Multi-Site Research
☐	**Participant results sharing** Individual research results will be shared with subjects.	ZIPLINE SUPPLEMENT: Participant Results Sharing
☒	None of the above	

2 PARTICIPANTS

2.1 Participants. Describe the characteristics of the subject populations or groups, including age range, gender, health status, and any other relevant characteristics.

Patient participants will all be over the age of 18, include all genders, use English, own a smartphone with data plan has a diagnosis of schizophrenia-spectrum disorders and receive services from a participating clinic.

2.2 Inclusion and exclusion criteria. Describe the criteria you will use to decide who will be included in your study from among interested or potential subjects. Define any technical terms in lay language.

Patient inclusion criteria: a) Chart diagnosis of SSD (i.e., schizophrenia, schizoaffective disorder, schizotypal disorder, delusional disorder, or schizophreniform disorder; b) 18 years or older; c) English-speaking; d) Own a smartphone that can support FOCUS and active data plan.

Patient exclusion criteria: 1) Used FOCUS in the past; 2) Plan to move or discontinue CMHC services in the upcoming 6 months.

CMHC staff will be asked to complete an online survey evaluating implementation outcomes and clinic characteristics. Staff from CMHC administration/budget/finance offices will also help inform costing through the use of de-identified data.

Staff inclusion criteria: a) Staff members at a participating study site; b) 18 years or older.

2.3 Prisoners. IRB approval is required in order to include prisoners in research, even when prisoners are not an intended target population.

a. Do you intend to deliberately recruit prisoners or obtain prisoner data/specimens?

See the WORKSHEET: Prisoners for the definition of "prisoner".

☒ **No**
☐ **Yes** → If yes, describe the type of prisoners, and which prisons/jails.

b. Is your research likely to have subjects who become prisoners while participating in your study?

For example, a longitudinal study of youth with drug problems is likely to have subjects who will be prisoners at some point during the study.

[x] **No**
[ ] **Yes** → If yes, if a subject becomes a prisoner while participating in your study, will you continue the study procedures and/or data collection while the subject is a prisoner?

[ ] **No**
[ ] **Yes** → If yes, describe the procedures and/or data collection you will continue with prisoner subjects

2.4 Protected populations. IRB approval is required for the use of the subject populations listed here. Check the boxes for any of these populations that you will purposefully include in your research. (In other words, being a part of the population is an inclusion criterion for your study.)

The WORKSHEETS describe the criteria for approval.

Population	Worksheet
[ ] Children	WORKSHEET: Children
[ ] Children who are wards	WORKSHEET: Children
[ ] Cognitively impaired adults	
[ ] Fetuses in utero	WORKSHEET: Pregnant Women
[ ] Neonates of uncertain viability	WORKSHEET: Neonates
[ ] Non-viable neonates	WORKSHEET: Neonates
[ ] Pregnant women	WORKSHEET: Pregnant Women

"Children" are defined as individuals who have not attained the legal age for consent to treatments or procedures involved in the research and its specific setting. This will vary according to the location of the research (that is, for different states and countries).

a. If you check any of the boxes above, use this space to provide any information you think may be relevant for the IRB to consider.

2.5 Native Americans or non U.S. indigenous populations. Will you actively recruit from Native American or non-U.S. indigenous populations through a tribe, tribe-focused organization, or similar community-based organization?

Indigenous people are defined in international or national legislation as having a set of specific rights based on their historical ties to a particular territory and their cultural or historical distinctiveness from other populations that are often politically dominant.

Examples: a reservation school or health clinic; recruiting during a tribal community gathering

[x] **No**

[ ] **Yes** → If yes, name the tribe, tribal-focused organization, or similar community based organization. The UW IRB expects that you will obtain tribal/indigenous approval before beginning your research.

2.6 Third party subjects. Will you collect private identifiable information about other individuals from your subjects? Common examples include: collecting medical history information or contact information about family members, friends, co-workers.

"Identifiable" means any direct or indirect identifier that, alone or in combination, would allow you or another member of your research team to readily identify the person. For example, suppose that you are studying immigration history. If you ask your subjects several questions about their grandparents but you do not obtain names or other information that would allow you to readily identify the grandparents, then you are not collecting private identifiable information about the grandparents.

[x] **No**

[ ] **Yes** → If yes, these individuals are considered human subjects in your study. Describe them and what data you will collect about them.

2.7 Number of subjects. Can you predict or describe the maximum number of subjects (or subject units) you need to complete your study, for each subject group?

Subject units mean units within a group. For most research studies, a group will consist of individuals. However, the unit of interest in some research is not the individual. Examples:

- Dyads such as caregiver-and-Alzheimer's patient, or parent and child
- Families
- Other units, such as student-parent-teacher

Subject group means categories of subjects that are meaningful for your research. Some research has only one subject group – for example, all UW students taking Introductory Psychology. Some common ways in which subjects are grouped include:

- By intervention – for example, an intervention group and a control group.
- By subject population or setting – for example, urban versus rural families
- By age – for example, children who are 6, 10, or 14 years old.

The IRB reviews the number of subjects you plan to study in the context of risks and benefits. You may submit a Modification to increase this number at any time after you receive IRB approval. If the IRB determines that your research involves no more than minimal risk: you may exceed the approved number and it will not be considered non-compliance. If your research involves more than minimal risk: exceeding the approved number will be considered non-compliance.

☐ **No** → If no, provide your rationale in the box below. Also, provide any information you can about the scope/size of the research. You do not need to complete the table.

Example: you may not be able to predict the number of subjects who will complete an online survey advertised through Craigslist, but you can state that you will post your survey for two weeks and the number who respond is the number who will be in your study.

☒ **Yes** → If yes, for each subject group, use the table below to provide your estimate of the maximum desired number of individuals (or other subject unit, such as families) who will complete the research.

Group name/description	Maximum desired number of individuals (or other subject unit, such as families) who will complete the research *For clinical trials: provide numbers for your site and for the study-wide total number
Patients with SSD	300
Staff	200

3 INTERNATIONAL RESEARCH SETTING

Answer the questions in this section ONLY if your research will occur at sites outside of the United States

3.1 Reason for sites. Describe the reason(s) why you selected the sites where you will conduct the research.

N/A

3.2 Local context. Culturally-appropriate procedures and an understanding of local context are an important part of protecting subjects. Describe any site-specific cultural issues, customs, beliefs, or values that may affect your research or how it is conducted.

Examples: It would be culturally inappropriate in some international settings for a woman to be directly contacted by a male researcher; instead, the researcher may need to ask a male family member for permission before the woman can be approached. It may be appropriate to obtain permission from community leaders prior to obtaining consent from individual members of a group.

This federal site maintains an international list of human research standards and requirements: http://www.hhs.gov/ohrp/international/index.html

N/A

3.3 Site-specific laws. Describe any local laws that may affect your research (especially the research design and consent procedures). The most common examples are laws about:

- **Specimens** – for example, some countries will not allow biospecimens to be taken out of the country.
- **Age of consent** – laws about when an individual is considered old enough to be able to provide consent vary across states, and across countries.
- **Legally authorized representative** – laws about who can serve as a legally authorized representative (and who has priority when more than one person is available) vary across states and countries.
- **Use of healthcare records** – many states (including Washington State) have laws that are similar to the federal HIPAA law but that have additional requirements.

N/A

3.4 Site-specific administrative or ethical requirements. Describe local administrative or ethical requirements that affect your research.

Example: A school district may require you to obtain permission from the head district office as well as school principals before approaching teachers or students; a factory in China may allow you to interview factory workers but not allow you to pay them.

N/A

4 RECRUITING and SCREENING PARTICIPANTS

4.1 Procedures. Describe how you will identify, recruit, and screen subjects. Include information about: how, when, where, and in what setting. Identify who (by position or role, not name) will approach and recruit subjects, and who will screen them for eligibility.

Mental health providers will describe the study to their patients to gauge interest- clinicians will obtain interest and will pass along contact information to the research team from interested patients or will provide the study URL (hosted by Qualtrics) for patient's to enter their contact, express interest and assess eligibility.

Patient Participants will be identified based on a protocol previously used by the Washington State CMHC implementation effort.

The protocol entails coordinating with middle managers and IT staff at each agency to audit Electronic Health Records (EHRs) by diagnosis. This procedure generates a list of active patients who meet diagnostic inclusion criteria. "Active status" is defined by the research team as seen in the CMHC for services within the several months. For agencies that lack the capability to execute a search by diagnosis among active patients, caseload audits are delegated to the treatment teams.

Once the "active status" list has been generated, it will then be given to care coordinators or treatment team leaders along with a script to introduce the study to eligible individuals, provide a brief verbal introduction to the study along with a 1-page handout prepared by the research team.

Patients can indicate their interest through accessing a secure study webpage (hosted by Qualtrics) or by giving permission to their clinician to pass along their contact information to the research team. On the study webpage they will be asked for their first and last name, phone number, the clinic they currently receive care from and to answer 3 inclusion questions + interest in future studies; 1. If they have a smartphone with data plan that can support the FOCUS app, 2. If they have ever used FOCUS before, and 3. If they plan to leave treatment in the next 6 months. 4. If they are interested in being informed about future research studies.

Consent forms will be available to potential participants in one of three ways; 1. They can pick up a printed form at the participating clinic, and/or 2. A copy can be downloaded from the study webpage, and/or 3. Emailed/texted to the potential participant before research staff reach out via phone.

After receiving interest of a potential participant and consent form has been received researchers would then reach out via phone call to provide a more comprehensive description of the project, screening, and informed consent. Participants will be fully informed that they are free to stop their participation at any time. Candidates will need to pass a brief quiz testing their understanding that participation is completely voluntary. Participants will be required to answer questions demonstrating that they understand what type of data will and will not be collected from them over the upcoming months (self-report and FOCUS use data). Each question will need to be answered correctly before individuals can proceed to provide consent. Individuals who commence the study will be assigned to their sites practice facilitator (external or internal). Randomization will occur at the site level with equal representation of urban and rural settings in each implementation arm.

Staff Participants who will participate in on-site data collection evaluating implementation outcomes and clinic characteristics will be purposively selected from CMHC (both study arms) and from CMHC

administration/budget/finance offices (for costing). The assessment evaluating implementation outcomes will be fully explained to staff participants via webpage (hosted by Qualtrics), where staff can check a box to indicate they are willing to participate. Assessments time points will be at 0M (prior to their patient beginning treatment), then at roughly 3M (time-point after the patient completes treatment). The confidential survey takes 20-30 minutes to complete (questions are included in the supportive documents) and staff will be compensated $20 in the form of an Amazon gift card for their time. Staff key informants will complete interviews with a trained member of the research team related to costing, including questions about services and effort put towards the study. Key informant interviews will last approximately 60 minutes and be audio-recorded, and later transcribed. Numbers will be provided at aggregate levels, or if treatments were specified, would not identify the individual.

4.2 Recruitment materials.

a. What materials (if any) will you use to recruit and screen subjects?

Examples: talking points for phone or in-person conversations; video or audio presentations; websites; social media messages; written materials such as letters, flyers for posting, brochures, or printed advertisements; questionnaires filled out by potential subjects.

1-page handout summarizing the study (included)

b. Upload descriptions of each type of material (or the materials themselves) to the **Consent Forms and Recruitment Materials** SmartForm of **Zipline**. If you will send letters to the subjects, the letter should include a statement about how you obtained the subject's name, contact information, and any other subject-specific information (such as a health condition) that is mentioned in the letter.

HSD encourages researchers to consider uploading descriptions of most recruitment and screening materials instead of the materials themselves. The goal is to provide the researchers with the flexibility to change some information on the materials without submitting a Modification for IRB approval of the changes. Examples:

- You could provide a list of talking points that will be used for phone or in-person conversations instead of a script.
- For the description of a flyer, you might include the information that it will provide the study phone number and the name of a study contact person (without providing the actual phone number or name). In doing so, you would not need to submit a Modification if/when the study phone number or contact person changes. Also, instead of listing the inclusion/exclusion criteria, you might state that the flyer will list one or a few of the major inclusion/exclusion criteria.
- For the description of a video or a website, you might include a description of the possible visual elements and a list of the content (e.g., study phone number; study contact person; top three inclusion/exclusion criteria; payment of $50; study name; UW researcher).

4.3 Relationship with participant population. Do any members of the study team have an existing relationship with the study population(s)?

Examples: a study team member may have a dual role with the study population (for example, being their clinical care provider, teacher, laboratory directory or tribal leader in addition to recruiting them for his/her research).

[x] **No**

☐ **Yes** → If yes, describe the nature of the relationship.

4.4 Payment to participants. Describe any payment you will provide, including:

- The total amount/value
- Whether payment will be "pro-rated" so that participants who are unable to complete the research may still receive some part of the payment

The IRB expects the consent process or study information provided to the subjects to include information about the number and amount of payments, and especially the time when subjects can expect to receive payment. One of the most frequent complaints received by HSD is from subjects who expected to receive cash or a check on the day that they completed a study and who were angry or disappointed when payment took 6-8 weeks to reach them.

Do not include a description of any expenses that will be reimbursed.

Patient baseline assessment $30+$10 travel or data plan
Patient post-trial assessment $30+ $10 travel or data plan
Patient follow-up assessment $30+ $10 travel or data plan
Staff assessment: $20

4.5 Non-monetary compensation. Describe any non-monetary compensation you will provide. Example: extra credit for students; a toy for a child. If you will be offering class credit to students, you must provide (and describe) an alternate way for the students to earn the extra credit without participating in your research.

N/A.

4.6 Consent for recruiting and screening. Will you obtain consent for any of the recruiting and screening procedures? (Section 8: Consent of Adults asks about consent for the main study procedures).

"Consent" includes: consent from individuals for their own participation; parental permission; assent from children; consent from a legally authorized representative for adult individuals who are unable to provide consent.

Examples:

- For a study in which names and contact information will be obtained from a registry: the registry should have consent from the registry participants to release their names and contact information to researchers.
- For a study in which possible subjects are identified by screening records: there will be no consent process.
- For a study in which individuals respond to an announcement and call into a study phone line: the study team person talking to the individual may obtain non-written consent to ask eligibility questions over the phone.

☐ **No** → If no, you must still answer question **4.7** below.

☒ **Yes** → If yes, describe the consent process.

Eligibility criteria may be obtained over the phone by a study staff member, referred to the research team from clinical staff or through the online webpage after the potential

participant has been referred to the study. Information includes: name, contact information, age, if they own a smartphone / data plan, used FOCUS in the past, or plan to discontinue services over the next 6 months. For staff: age, confirmation they work for a participating study site.

a. Documentation of consent. Will you obtain a written or verifiable electronic signature from the subject on a consent form to document consent for the **recruiting and screening procedures**?

[x] **No** → If no, describe the information you will provide during the consent process

It would be impossible to obtain written screening consent with potential participants over the phone. We request a waiver of consent for the screening process.

[ ] **Yes** → If yes, upload the consent form to the **Consent Forms and Recruitment Materials** page of **Zipline**.

4.7 Data and specimens. For studies where you will obtain consent, describe any data and/or specimens (including any PHI) you will obtain prior to obtaining consent and whether you will retain it as part of the study.

Obtain means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time.

Examples: names and contact information; the information gathered from records that were screened; results of screening questionnaires or screening blood tests; Protected Health Information (PHI) from screening medical records to identify possible subjects.

A list of active participants will be generated either through culling EMR data or talking with clinical teams that will serve as the primary list for their clinical teams to approach to describe the study and gauge interest.

5 PROCEDURES

5.1 Study procedures. Using lay language, provide a complete description of the study procedures, including the sequence, intervention or manipulation (if any), time required, and setting/location. If it is available and you think it would be helpful to the IRB: Upload a study flow sheet or table to the **Supporting Documents** SmartForm in **Zipline**.

For studies comparing standards of care: It is important to accurately identify the research procedures. See UW IRB **POLICY: Risks of Harm from Standard Care** and the draft guidance from the federal Office of Human Research Protections, **"Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care";** October 20, 2014.

About the study:
This study is a multi-site site hybrid type III effectiveness/implementation study. The intention of this study is to examine the delivery of FOCUS within two treatment models. One, where the app is delivered through an internal facilitator embedded within a mental health clinic (study site), the other, involves an external facilitator delivering the intervention (staff at UW). Both facilitators help participants install, use, and incorporate the app's strategies into their own coping skillset.

The project will involve recruiting outpatients with schizophrenia spectrum disorder who receive mental health services at CMHCs in WA for participation in a randomized controlled trial (15 at each CMHC; n=300). Patient participants will engage in a 3-month long mHealth intervention called FOCUS which involves use of a smartphone system in their own environment and weekly phones calls with a practice facilitator that is based at the UW (EF model) or the CMHC where they receive care (IF model). Participants enrolled in the IF arm may also have in-person meetings with their agency-facilitator at their CMHC or in the community.

Arm I: All the same research procedures as ARM II, FOCUS delivery to participants is through an Internal Facilitator (staff member of study site who is identified and trained to serve as a navigator to the FOCUS app (technology, program use and application of strategies to their treatment plan)).

Arm II: All the same research procedures as ARM I, FOCUS delivery to participants is through an External Facilitator (UW staff who will be trained to serve as a navigator to the FOCUS app (technology, program use and application of strategies to their treatment plan)).

Description of the mHealth intervention:
FOCUS has three elements: 1) FOCUS application (app): The system includes pre-programmed daily self-assessment prompts as well as on-demand functions that can be accessed 24 hours a day. Self-management content was adapted from psychosocial intervention strategies targeting five broad domains: Voices (i.e., coping with auditory hallucinations via cognitive restructuring, distraction, guided hypothesis testing), Mood (i.e., anaging depression and anxiety via behavioral activation, relaxation techniques, supportive content), Sleep (i.e., sleep hygiene, relaxation, health and wellness psychoeducation), Social (i.e., cognitive restructuring of persecutory ideation, anger management, activity scheduling, skills training), and Medication (i.e., behavioral tailoring, reminders, psychoeducation). The system uses audio prompts, video content, cartoons, and written text to deliver coping strategies in the form of interactive questions, suggestions, and guided demonstrations. Content can be accessed as either brief video or audio clips or sequences of digital screens with written material coupled with visual displays; 2) Clinician dashboard: FOCUS users' responses to daily self-assessments are securely transmitted to a remote server. The information is processed and displayed on an online dashboard with a real-time summary of engagement, module selection, and reported symptom severity over the last 30 days, that is accessible to authorized staff who use it to inform and enhance their clinical services. If, dashboard data suggest a patient requires additional assistance, staff call to assess further and provide consultation ; 3) mHealth support personnel: FOCUS patients are engaged throughout the treatment period by trained individuals to encourage their adherence to FOCUS by assisting them in all technical and clinical aspects of the intervention.

FOCUS data will be used directly by the IF / EF to inform their weekly calls with participants. A summary of FOCUS data use may also be shared with their clinicians to inform their care / treatment plans. Weekly phone calls will be used to assess if there are any technical issues experienced by the participant, along with resolving that issue. IF/EF's will also talk about the FOCUS app use over the previous week and how they can use the tips/ strategies to support their goals. Each weekly call should last approx. 10-15 minutes.

Study Sites
Randomization will occur at the level of the clinic and will be balanced within study arm by number of patients served and rural/urban designation. Study sites (k=20) will vary in staffing and services capacity. Sites will either be randomized to have an internal facilitator (IF) or external facilitator (EF). The internal and external facilitators will work to engage participating organizations, practitioners, and patients throughout the study which includes sending email and placing phone calls with participating organizations, practitioners and patients in order to conduct the study (i.e., schedule appointments, request materials, etc.). They will provide updates about study progress and will maintain and request data from the study sites.

Patient Participants

After consenting into the study, patient participants will receive a phone call prior to each assessment (0M, 3M, 6M) letting them know they will receive a text or email (for those who have identified trouble receiving text messages) with the assessment URL and to provide instructions for how to complete the assessment (ensure they are in a private place, have reliable data for transmission, will take aprox. 20-30 minutes to complete, etc). Participants will then receive the web-based baseline assessment via text and will be asked to complete it in a private and quiet space. For those who have expressed difficulty completing the assessment through the web-based assessment, a phone call can be conducted with trained assessor to ask questions directly over the phone. Afterward, they will be asked to meet with their assigned facilitator (IF/ EF) to install the FOCUS app on their phone, describe how to use it and set up a time for their weekly calls. This may be done via phone call, or video call, whichever is preferred by the participant. Participants will continue to use the program for 3 months in their own environments, along with participating in weekly calls to discuss what they've learned in the FOCUS app and how those strategies can help support their symptom coping strategies.

The FOCUS application uninstalls at 3 months and then the 3 month web-based outcome assessment will be sent via text and will ask participants to complete it in a private and quiet space. Once again those who express difficulty completing the assessment through the web-based platform can request a call with an assessor on the research team. Participants who complete treatment will be mailed out a certificate of completion to their home address or clinic (based on participant's choice). They will no longer have access to the app, nor will participate in weekly calls for the next 3 months. They would then be sent another assessment at 6 months to complete.

Patient Participant Assessment:
Patient participants will receive a text from researchers just before their assessment date providing instructions on how to complete the online assessment. They will then be invited to conduct assessments at 0, 3, and 6 months via embedded link to a secure study portal (Qualtrics). For participants who need additional assistance, they can come into the participating clinic to complete on a tablet provided by the research team. Patient participants will receive $30 compensation for each completed assessment (estimated completion time < 45 minutes) for a maximum of $90 compensation (Plus additional $10 each assessment to compensate data transmission or travel to site if more assistance is necessary). All participants will be paid for each assessment, but they will not be compensated for engagement in the intervention; assessments are administered to everyone enrolled in the study regardless of how/whether they engaged in FOCUS (note: all patient participants own working smartphones as part of inclusion criteria).

Assessments include questions about psychiatric treatment and hospitalizations, along with other measures of mental health including depression, anxiety, hearing voices, and recovery:

- Demographics and other characteristics
- PhQ9
- GAD-7
- Hospitalization- days hospitalized, no identifiers will be captured.
- ISI: Insomnia Severity Index
- Green Paranoid Thoughts Scale
- Symptom Checklist SCL-9Hamilton Program for Schizophrenia Voices Questionnaire (HPSVQ)
- Recovery Assessment Scale (RAS)
- Illness Management Recovery Scale (IMRS)
- Working Alliance Inventory (3M only)
- mHealth Mastery Measure (3M only)
- AIM
- Satisfaction

Information we plan to collect from EMR data:

- A list of active participants will be generated either through culling EMR data or talking with clinical teams that will serve as the primary list for their clinical teams to approach to describe the study and gauge interest.
- Services billed- no identifiers will be shared with the research team

Mental Health Provider Participants:
Select mental health providers will be invited to complete an online assessment with the research team. Staff participants will be invited to complete a confidential online survey. This includes exposure to the FOCUS app, if strategies or the program was incorporated into their treatment plans, and perceptions of how the program was adopted and implemented at their clinic.

Mental Health Provider Assessment:

Providers who receive FOCUS data

- Offered mHealth, i.e., the percent of each practitioner's eligible patients who are offered FOCUS
- Treatment Initiation, i.e., percent of consenting patients who followed their practitioner's guidance and went on to download FOCUS onto their smartphone and interact with the system at least once. Dashboard Use, i.e., the average number of times each practitioner logs on to the online FOCUS dashboard to view their individual patients' uploaded FOCUS data

The following will be captured via online confidential survey (Qualtrics):**

- The perception among practitioners that an innovation is agreeable, palatable, or satisfactory. (Measured via AIM / IAM / FIM).
- ORIC: Organizational Readiness for Implementing Change

Providers at the clinic who may not have been directly involved with the FOCUS Intervention (to provide contextual factors) through online confidential survey (Qualtrics):

- Organizational Readiness to Change Assessment (ORCA)
    - CMHC staff participants will complete 23 items using a 5-point bipolar rating scale (1-Strongly agree to 5-Strongly disagree). Constructs evaluated include clinical cooperation within the practice, clarity in patient care goals and process, level of support (e.g., training, budget, staffing) and typical receptivity to guidance (staff) and feedback (leadership).
- Absorptive capacity will be measured among CMHC practitioners who were engaged in IF or EF implementation at 0, 3, and 6 months using the 14-item ACAP Scale.
    - The ACAP Scale evaluates dimensions of absorptive capacity including
        - Acquiring (e.g., searching for new information, motivation to use information)
        - Assimilating (e.g., communication of new ideas and concepts across stakeholders, cross departmental sharing of information)
        - Transforming (e.g. ability to structure and use collected information, linking existing knowledge with new insights, applying new knowledge to practical work), and
        - Exploiting new knowledge in practice (e.g., adapting practices according to new knowledge, working more effectively by adopting new technologies)
- IF/EF self-report: Clinicians will report the number of access points to the clinician dashboard, distribution of weekly reports to the clinical team, and correspondence of data derived from the dashboard to treatment targets.

- **IP addresses are collected by Qualtrics which may or may not be potentially identifiable, but will not be used by the research team as data.

Key informant interviews related to costing procedures will also be completed at a select number of study locations. Interviews will be conducted remotely by a trained research team member. Questions will be related to time, effort, and resources dedicated to the study. Interviews will last approximately 60 minutes, and be audio-recorded and later transcribed.

5.2 Data sources. For all types of data that you will access or collect for this research: Identify whether you are obtaining the data from the subjects (or subjects' specimens) or whether you are obtaining the data from some other source (and identify the source).

If you have already provided this information in Question 5.1, you do not need to repeat the information here.

1) Self-report and interview-based measures obtained directly from CMHC staff participants by trained evaluators about services billed for and time allocation (for costing only).
2) mHealth engagement data recorded by the FOCUS system and uploaded to a secure server.

3) Self report symptom and self-management ratings obtained via Qualtrics survey.
4) Confidential staff questionnaire responses via Qualtrics.
- **IP addresses are collected by Qualtrics which may or may not be potentially identifiable, but will not be used by the research team as data.

5.3 Retrospective/prospective. For all types of data and specimens that you will access or collect for this research: Describe which data are:
- Retrospecitve (i.e., exist at the time this application is sent to HSD)
- Prospective (do not yet exist)
- Both retrospective and prospective (for example, past and future school records)

Retrospective Only:
- patient care status (still receiving services at study site).

Prospective Only:
- Assessment measures
- FOCUS app use data

5.4 Identifiability of data and specimens. Answer these questions carefully and completely. This will allow HSD to accurately determine the type of review that is required and to assist you in identifying relevant compliance requirements. Review the following definitions before answering the questions:

Access means to view or perceive data, but not to possess or record it. See, in contrast, the definition of "obtain".
Identifiable means that the identify of an individual is or may be readily (1) ascertained by the researcher or any other member of the study team from specific data variables or from a combination of data variables, or (2) associated with the information.
Direct identifiers are direct links between a subject and data/specimens. Examples include (but are not limited to): name, date of birth, medical record number, email or IP address, pathology or surgery accession number, student number, or a collection of your data that is (when taken together) identifiable.
Indirect identifiers are information that links between direct identifiers and data/specimens. Examples: a subject code or pseudonym.
Key refers to a single place where direct identifiers and indirect identifiers are linked together so that, for example, coded data can be identified as relating to a specific person. Example: a master list that contains the data code and the identifiers linked to the codes.
Obtain means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time. This is different from **accessing**, which means to view or perceive data.

a. Will you or any members of your team have <u>access</u> to any direct or indirect identifiers?

[x] **Yes** → If yes, describe which identifiers and for which data/specimens.

The research team will have access to the following direct identifiers: participant names, contact information (phone number, address, email), emergency family

member contact information. The research team will also have access to the key and study identifiers.

We will collect audio recordings of costing interviews with key informants (select study site staff). The recordings will include the voice of the key informant and may contain their name and place of work in the course of the interview. After transcribing the audio recordings, the recordings will be destroyed.

☐ **No** → If no, select the reason(s) why you (and all members of your team) will not have access to direct or indirect identifiers.

☐ There will be no identifiers.

☐ Identifiers or the key have been (or will have been) destroyed before you have access.

☐ You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

b. Will you <u>obtain</u> any direct or indirect identifiers?

☒ **Yes** → If yes, describe which identifiers and for which data/specimens.

The research team will obtain the following direct identifiers: participant names, contact information (phone number, address, email), emergency family member contact information, . The research team will also have access to the key and study identifiers.

☐ **No** → If no, select the reason(s) why you (and all members of your team) will not have access to direct or indirect identifiers.

☐ There will be no identifiers.

☐ Identifiers or the key have been (or will have been) destroyed before you have access.

☐ You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

c. If you obtain any identifiers, indicate how the identifiers will be stored (and for which data).

☒ You will store the identifiers with the data. Describe the data to which this applies:

Identifiers (First and last name, phone number, email address and IP address) will be obtained through the study eligibility page (hosted by Qualtrics). Here, identifiers will be captured and stored with eligibility criteria (1. If over 18, 2. Has a phone with data plan that can support FOCUS, 3. Has never used FOCUS before, 4. Confirmation of location they receive services (to verify if a participating clinic). The eligibility screener data will be stored separately from assessment data (0M, 3M, 6M data).

☒ You will store identifiers and study data separately but you will maintain a link between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

Contact information; including name, phone number, family contact information, mailing and email addresses will be collected at the time of screening and will be stored in a key with study identifiers.

These will be stored on secured servers behind firewalls in encrypted documents on secured University of Washington computers.

Unidentifiable data collected through the FOCUS app and Qualtrics assessment (0M, 3M, 6M) will be stored separately from identifiable data and will be identified by study ID or other ID.

☐ You will store identifiers separately from the study data, with no link between the identifiers and the study data. Describe the data to which this applies:

d. Research collaboration. Will individuals who provide coded information or specimens for your research also collaborate on other activities for this research? If yes, identify the activities and provide the name of the collaborator's institution/organization.

Examples include but are not limited to: (1) study, interpretation, or analysis of the data that results from the coded information or specimens; and (2) authorship on presentations or manuscripts related to this work.

No

5.5 Newborn dried blood spots. Will you use newborn dried bloodspots collected in the United States on or after March 18, 2015?

[x] **No**
[ ] **Yes** → If yes, is this research supported by any federal funding (including any fellowship or career development award that provides salary support)?

[ ] **No**
[ ] **Yes** → If yes, describe how you will ensure that the bloodspots were collected with parental permission (in compliance with a 2015 law that applies to federal-funded research).

5.6 Protected Health Information (PHI). Will you access, obtain, use, or disclose a participant's identifiable PHI for any reason (for example, to identify or screen potential subjects, to obtain study data or specimens, for study follow-up) that does not involve the creation or obtaining of a Limited Data Set?

[ ] **No** → If no, skip the rest of this question; go to question **5.7**
[X] **Yes** → If yes, answer all of the questions below.

a. Describe the PHI you will access or obtain, and the reason for obtaining it. Be specific.

We will collect participant names, contact information (mailing address, phone number, email), and family member contact information (if available- or other emergency contact),

b. Is any of the PHI located in Washington State?

[ ] **No**
[x] **Yes**

c. Describe how you will access or obtain the PHI. Be specific.

We will obtain PHI via study site through phone or video conference, or encrypted documents.

d. For which PHI will you obtain HIPAA authorization from the subjects by having them sign a HIPAA Authorization form, before obtaining and using the PHI?

We no longer plan to capture PHI that would require a signed HIPAA authorization form.

Confirm by checking the box that you will use the UW Medicine HIPAA Authorization form maintained on the HSD website if you will access, obtain, use, or disclose UW Medicine PHI.

[x] **Confirmed**

e. For which PHI will you NOT obtain HIPAA authorization from the subjects?

Name, contact information (mailing address, phone number, email), family emergency contact, and if they're still actively receiving services at the study site.

Provide the following assurances by checking the boxes.

[x] The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

[ ] You will fulfill the HIPAA "accounting for disclosures" requirement. See UW Medicine Privacy Policy #25. THIS IS ONLY FOR UW RECORDS.

[x] There will be reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research.

5.7 Genomic data sharing. Will you obtain or generate genomic data, as defined by the National Institutes of Health (NIH)? See https://gds.nih.gov/13faqs_gds.html.

[x] **No**

[ ] **Yes** → If yes, answer the question below.

a. Is this research funded by NIH through a grant or contract application submitted to NIH on or after January 25, 2015?

[ ] **No**

[ ] **Yes** → If yes, you must comply with the NIH Genomic Data Sharing policy. Complete the **ZIPLINE SUPPLEMENT Genomic Data Sharing** and upload it to the **Supporting Documents** SmartForm of **Zipline**.

5.8 Data and specimen sharing/banking. Do you plan to share some or all of the data, specimens, or subject contact information with other researchers or a repository/database, or to bank them for your own future unspecified research uses? **You are strongly encouraged to consider the broadest possible future plans you might have, and whether you will obtain consent now from the subjects for future sharing or unspecified uses.** Answer **NO** if your only sharing will be through the NIH Genomic Data Sharing described in question 5.7.

Many federal grants and contracts now require data or specimen sharing as a condition of funding, and many journals require data sharing as a condition of publication. "Sharing" may include: informal arrangements to share your banked data/specimens with other investigators; establishing a repository from which you formally share with others through written agreements; or sending your data/specimens

to a third party repository/archive/entity such as the NIH dbGaP database, the Social Science Open Access Repository (SSOAR), or the UCLA Ethnomusicology Archive.

[ ] **No**
[x] **Yes** → If yes, answer all of the questions below.

a. Describe <u>what will be stored</u>, including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

We will bank all unidentifiable data on UW secured computers. A list of potential participants who want to participate in future research studies will be stored in a password protected file on secured computers along with participant contact information and a few screening variables (age, previous phone use, gender, etc- a copy of this information is attached with this submission: "future contact for research").

b. Describe <u>what will be shared</u>, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens.

Direct identifiers will not be shared with anyone outside of the research team. Unidentifiable data may be shared with the research community.

c. Describe <u>the possible future uses</u>, including limitations or restrictions (if any) on future uses or users. As stated above, consider the broadest possible uses.

Examples: data will be used only for cardiovascular research; data will not be used for research on population origins.

Potential future uses of de-identified data:
- Data that could inform future interventions
- Recruitment for future studies
- Data to support grant proposals for future research

d. <u>Consent</u>. Will you obtain consent now from subjects for the banking and/or future sharing?

[ ] **No**
[x] **Yes** → If yes, be sure to include the information about this consent process in the consent form (if there is one) and in your answers to the consent questions in Section 6.

e. <u>Withdrawal</u>. Will subjects be able to withdraw their data/specimens from banking or sharing?

[x] **No**
[ ] **Yes** → If yes, describe how, and whether there are any limitations on withdrawal.

Example: data can be withdrawn from the repository but cannot be retrieved after they are released.

f. Agreements for sharing or release. Confirm by checking the box that you will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement between you and the recipient for release of data or specimens to individuals or entities other than federal databases.

Data Use Agreements or Gatekeeping forms are used for data; Material Transfer Agreements are used for specimens (or specimens plus data. Do not attach your template agreement forms; the IRB neither reviews nor approves them

[x] **Confirmed**

5.9 Communication with subjects during the study. Describe the types of communication (if any) you will have with already-enrolled subjects during the study. Provide a description instead of the actual materials themselves.

Examples: email, texts, phone, or letter reminders about appointments or about returning study materials such as a questionnaire; requests to confirm contact information.

If technical issues are identified or if participants have gone 'dark' (missing data over a period of time) we will provide a text message or call checking in with the participant. Based on their response (i.e. express needing technical support, or non-response), an RA will contact the participant to ensure their phone is working and to assess if they are still interested in participating. If a participant has gone dark for in extended period of time and are unable to be reached by phone, a letter will be sent to their mailing address (email or physical mailing address: copy of letter attached). PHI will not be transmitted in text messages or emails.

5.10 Future contact with subjects. Do you plan to retain contact information for your subjects so that they can be contacted in the future?

[ ] **No**

[x] **Yes** → If yes, describe the purpose of the future contact, and whether use of the contact information will be limited to your team; if not, describe who else could be provided with the contact information. Describe your criteria for approving requests for the information.

Examples: inform subjects about other studies; ask subjects for additional information or medical record access that is not currently part of the study proposed in this application; obtain another sample.

Future contact would be limited to our research team and would be for the purpose of recruitment in new studies our team would be conducting.

5.11 Alternatives to participation. Are there any alternative procedures or treatments that might be advantageous to the subjects?

If there are no alternative procedures or treatments, select "No". Examples of advantageous alternatives: earning extra class credit in some time-equivalent way other than research participation; obtaining supportive care or a standard clinical treatment from a health care provider instead of participating in research with an experimental drug.

[x] **No**

[ ] **Yes** → If yes, describe the alternatives.

5.12 Upload to the Supporting Documents SmartForm of **Zipline** all data collection forms that will be directly used by or with the subjects, and any scripts/talking points you will use to collect the data. Do not include data collection forms that will be used to abstract data from other sources (such as medical or academic records, or video recordings.

- **Examples**: survey, questionnaires, subject logs or diaries, focus group questions.
- **Translations must be included**. However, you may wait to provide them until you know that the IRB will approve the English versions, especially if the translations will cost money.
- **For materials that cannot be uploaded**: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.
- **For data that will be gathered in an evolving way**: This refers to data collection/questions that are not pre-determined but rather are shaped during interactions with participants in response to observations and responses made during those interactions. If this applies to your research, provide a description of the process by which you will establish the data collection/questions as you interact with subjects, how you will document your data collection/questions, the topics you plan to address, the most sensitive type of information you will plan to gather, and the limitations (if any) on topics you will raise or pursue.

Use this text box (if desired) to provide short written descriptions of materials that cannot be uploaded, such as URLs, and/or a description of the process you will use for data that will be gathered in an evolving way.

5.13 Send HSD a Confidentiality Agreement if you will obtain or use any private identifiable UW records without subject consent (for example, screening medical records or class grades to identify possible subjects).

The Confidentiality Agreement form must be completed, printed, signed, and mailed to the Human Subjects Division at Box 359470. Your IRB application cannot be approved until we receive the Confidentiality Agreement.

6 CHILDREN (MINORS) and PARENTAL PERMISSION

6.1 Involvement of minors. Does your research include minors (children)?

Minor or child means someone who has not yet attained the legal age for consent for the research procedures, as described in the applicable laws of the jurisdiction in which the research will be conducted. This may or may not be the same as the definition used by funding agencies such as the National Institutes of Health.

- In Washington State the generic age of consent is 18, meaning that anyone under the age of 18 is considered a child.
- There are some procedures for which the age of consent is much lower in Washington State. See the **WORKSHEET: Children** for details.
- The generic age of consent may be different in other states, and in other countries.

[x] **No** → If no, go to Section 8.

☐ **Yes** → If yes, provide the age range of the minor subjects for this study and the legal age for consent in your population(s). If there is more than one answer, explain.

☐ **Don't know** →This means is it not possible to know the age of your subjects. For example, this may be true for some research involving social media, the Internet, or a dataset that you obtain from another researcher or from a government agency. Go to Section 8.

6.2 Parental permission. Parental permission means actively obtaining the permission of the parents. This is not the same as "passive" or "opt out" permission where it is assumed that parents are allowing their children to participate because they have been provided with information about the research and have not objected or returned a form indicating they don't want their children to participate.

a. Will you obtain parental permission for:

☐ All of your research procedures → Go to question **6.2b.**

☐ None of your research procedures → Use the table below to provide your justification, and skip question 6.2b.

☐ Some of your research procedures → Use the table below to identify the procedures for which you will not obtain written documentation of consent from your adult subjects. "All" is an acceptable answer for some studies.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO parental permission	Reason why you will not obtain parental permissions	Will you inform them about the research?[2]	
			YES	NO
			☐	☐
			☐	☐
			☐	☐
			☐	☐

	☐	☐
	☐	☐

Table footnotes

1. If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.
2. Will you inform them about the research beforehand even though you are not obtaining active permission?

b. Indicate by checking the appropriate box(es) your plan for obtaining parental permission

☐ Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available; or when only one parent has legal responsibility for the care and custody of the child

☐ One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

This is all that is required for minimal risk research.

If you checked both boxes, explain:

6.3 Children who are wards. Will any of the children be wards of the State or any other agency, institution, or entity?

☐ **No**
☐ **Yes** → If yes, an advocate must be appointed for each child who is a ward. The advocate must be in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The same individual can serve as advocate for all children who are wards.

Describe who will be the advocate(s). Your answer must address the following points:

- Background and experience
- Willingness to act in the best interests of the child for the duration of the research
- Independence of the research, research team, and any guardian organization

7 ASSENT OF CHILDREN (MINORS)

Go to Section 8 if your research does not involve children (minors).

7.1 Assent of children (minors). Though children do not have the legal capacity to "consent" to participate in research, they should be involved in the process if they are able to "assent" by having a study explained to them and/or by reading a simple form about the study, and then giving their verbal choice about whether they want to participate. They may also provide a written assent if they are older. See **WORKSHEET: Children** for circumstances in which a child's assent may be unnecessary or inappropriate.

a. Will you obtain assent for:

☐ All of your research procedures and child groups → Go to question **7.2.**

☐ None of your research procedures and child groups → Use the table below to provide your justification, then skip to question 7.5.

☐ Some of your research procedures and child groups → Use the table below to identify the procedures for which you will not obtain assent. "All" is an acceptable answer for some studies.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be obtained	Reason why you will not obtain assent

Table footnotes

1. If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.

7.2 Assent process. Describe how you will obtain assent, for each child group. If your research involves children of different ages, answer separately for each group. If the children are non-English speakers, include a description of how you will ensure that they comprehend the information you provide.

7.3 Dissent or resistance. Describe how you will identify a child's objection or resistance to participation (including non-verbal indications) during the research, and what you will do in response.

7.4 Documentation of assent. Which of the following statements describes whether you will obtain documentation of assent?

☐ None of your research procedures and child groups → Use the table below to provide your justification, then go to question 7.4.a.

☐ All of your research procedures and child groups → Go to question **7.4.a**, do not complete the table

☐ Some of your research procedures and/or child groups → Complete the table below and then to go question 7.4.a

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be documented	Reason why you will not document assent

Table footnotes

1. If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.

a. Describe how you will document assent. If the children are functionally illiterate or are not fluent in English, include a description of what you will do.

b. Upload all assent materials (talking points, videos, forms, etc.) to the **Consent Form and Recruitment Materials** SmartForm of **Zipline**. Assent materials are not required to provide all of the standard elements of adult consent; the information should be appropriate to the age, population, and research procedures.

7.5 Children who reach the legal age of consent during participation in longitudinal research.

Children who were enrolled at a young age and continue for many years: It is best practice to re-obtain assent (or to obtain it for the first time, if you did not at the beginning of their participation).
Children who reach the legal age of consent: You must obtain informed consent from the now-adult subject for (1) any ongoing interactions or interventions with the subjects, or (2) the continued analysis of specimens or data for which the subject's identify is readily identifiable to the researcher, unless the IRB waives this requirement.

a. Describe your plans (if any) to re-obtain assent from children.

b. Describe your plans (if any) to obtain consent for children who reach the legal age of consent.

- If you plan to obtain consent, describe what you will do about now-adult subjects whom you are unable to contact.
- If you do not plan to obtain consent or think that you will be unable to do so, explain why.

7.6 Other regulatory requirements. (This is for your information only; no answer or response is required.) Researchers are responsible for determining whether their research conducted in schools, with student records, or over the Internet comply with permission, consent, and inspection requirements of the following federal regulations:

- PPRA – Protection of Pupil Rights Amendment
- FERPA – Family Education Rights and Privacy Act

- COPPA – Children's Online Privacy Protection Act

8 CONSENT OF ADULTS

Review the following definitions before answering the questions in this section.

CONSENT	is the process of informing potential subjects about the research and asking them whether they want to participate. It usually (but not always) includes an opportunity for subjects to ask questions. It does not necessarily include the signing of a consent form. This question is about the consent process.
CONSENT DOCUMENTATION	refers to how a subject's decision to participate in the research is documented. This is typically obtained by having the subject sign a consent form.
CONSENT FORM	is a document signed by subjects, by which they agree to participate in the research as described in the consent form and in the consent process.
ELEMENTS OF CONSENT	are specific information that is required to be provided to subjects.
PARENTAL PERMISSION	is the parent's active permission for the child to participate in the research. Parental permission is subject to the same requirements as consent, including written documentation of permission and required elements.
SHORT FORM CONSENT	is an alternative way of obtaining written documentation of consent that is most commonly used with individuals who are illiterate or whose language is one for which translated consent forms are not available.
WAIVER OF CONSENT	means there is IRB approval for not obtaining consent or for not including some of the elements of consent in the consent process.
WAIVER OF DOCUMENTATION OF CONSENT	means that there is IRB approval for not obtaining written documentation of consent.

8.1 Groups Identify the groups to which your answers in this section apply.

- [x] Adult subjects
- [ ] Parents who are providing permission for their children to participate in research

→ If you selected **PARENTS**, the word "consent" below should also be interpreted as applying to parental permission and "subjects" should also be interpreted as applying to the parents.

8.2 The consent process. This series of questions is about whether you will obtain consent for all procedures except recruiting and screening and, if yes, how.

The issue of consent for recruiting and screening activities is addressed in question 4.6. You do not need to repeat your answer to question 4.6.

a. Are there any procedures for which you will not obtain consent?

[x] **No**
[ ] **Yes** → If yes, use the table below to identify the procedures for which you will not obtain consent. "All" is an acceptable answer for some studies.

Be sure to consider all research procedures and plans, including future contact, and sharing/banking of data and specimens for future work.

Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO consent process	Reason why you will not obtain consent	Will you provide them with info about the research after they finish? YES	NO
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Table footnotes

1. If your answer is the same for all groups you can collapse your answer across the groups and/or procedures.

b. Describe the consent process**,** if you will obtain consent for any or all procedures, for any or all groups. Address groups and procedures separately if the consent processes are different.

Be sure to include:

- The location/setting where consent will be obtained
- Who will obtain consent (refer to positions, roles, or titles, not names).
- Whether/how you will provide an opportunity for questions
- How you will provide an adequate opportunity for the subjects to consider all options

CMHC staff will describe the study to patient participants and request permission to forward their name to research staff or will provide their patient's with the study URL to express their interest in participating and enter eligibility criteria.

Patient Participants:
A copy of the consent is available on the study website and can either be mailed (email or text) or picked up by the participant at their participating site. Research staff will then contact potential participants to describe informed consent and limitations to privacy. Participants will be fully informed that they are free to stop their participation at any time. Candidates will need to pass a brief quiz testing their understanding that participation is completely voluntary. Participants will be required to answer questions demonstrating that they understand what type of data will and will not be collected from them over the upcoming months (self-report and FOCUS use data). Each question will need to be answered correctly before individuals can proceed to provide consent verbally over the phone (we request a waiver of written consent).

Staff Participants:
Eligible staff from participating clinics will be asked to complete a confidential survey online prior to their patient starting treatment, then again after their participant completed the intervention (roughly 3 months later).

We would like to request a waiver for the stamp in order to make the form's contact information modifiable (highlighted text in both consent forms).

Costing Interview Key Informants:
Key informants will be selected from selected study sites to complete a costing interview via videoconferencing. Prior to initiating the audio-recorded interview, key informants will review the consent form and provide verbal consent which will be audio-recorded.

c. Comprehension**.** Describe how you will ensure or test the subjects' understanding of the information during the consent process.

Candidates will need to pass a brief quiz testing their understanding that participation is completely voluntary, how long the research study is and what confidentiality means. Participants will be required to answer questions demonstrating that they understand what type of data will and will not be collected from them.

d. Influence**.** Does your research involve any subject groups that might find it difficult to say "no" to your research because of the setting or their relationship with you, even if you don't pressure them to participate?

Examples: Student participants being recruited into their teacher's research; patients being recruited into their healthcare provider's research, study team members who are participants; outpatients recruited from an outpatient surgery waiting room just prior to their surgery.

[x] **No**

[ ] **Yes** → If yes, describe what you will do, for each of these subject groups, to reduce any effect of the setting or relationship on their decision.

Examples: a study coordinator will obtain consent instead of the subjects' physician; the researcher will not know which subjects agreed to participate; subjects will have two days to decide after hearing about the study.

e. Ongoing process. For research that involves multiple or continued interaction with subjects over time, describe the opportunities (if any) you will give subjects to ask questions or to change their minds about participating.

8.3 Written documentation of consent. Which of the statements below describe whether you will obtain documentation of consent? NOTE: This question does not apply to screening and recruiting procedures which have already been addressed in question 4.6.

Documentation of consent that is obtained electronically is not considered written consent unless it is obtained by a method that allows verification of the individual's signature. In other words, saying "yes" by email is rarely considered to be written documentation of consent

a. Are you obtaining written documentation of consent for:

[x] None of your research procedures	→ Use the table below to provide your justification then go to question **8.4.**
[ ] All of your research procedures	→ Do not complete the table; go to question **8.3.b.**
[ ] Some of your research procedures	→ Use the table below to identify the procedures for which you will not obtain written documentation of consent from your adult subjects. "All" is an acceptable answer for some studies.

Adult subject group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO documentation of consent	Reason why you will not obtain documentation of consent	Will you provide them with info about the research after they finish? YES	NO
Patient Participants	FOCUS Intervention	Due to logistical complexities of remotely enrolling participants across k=20 sites we are requesting a waiver to written documentation of consent. No trained research staff will be on site to obtain written documented consent.	☐	☒
Staff Participants	Online assessment	Written documentation of consent will be extremely difficult to obtain and due to the low-risk nature of the confidential survey, we are requesting this waiver.	☐	☒
Staff Key Informant Interviews	Interviews regarding costing	Interviews will be conducted via videoconference. Consent will be obtained verbally and recorded.	☐	☒
			☐	☐
			☐	☐

Table footnotes

1. If your answer is the same for all adult groups or all procedures, you can collapse your answer across the groups and/or procedures.

b. Barriers to written documentation of consent. There are many possible barriers to obtaining written documentation of consent. Consider, for example, individuals who are functionally illiterate; do not read English well; or have sensory or motor impairments that may impede the ability to read and sign a consent form.

b.1 Describe your plans (if any) for obtaining written documentation of consent from potential subjects who may have difficulty with the standard documentation process (that is, reading and signing a consent form). Skip this question if you are not obtaining written documentation of consent for any part of your research.

Examples of solutions: Translated consent forms; use of the Short Form consent process; reading the form to the person; excluding individuals who cannot read and understand the consent form.

We are requesting a waiver for signed documentation of consent for patient and staff participants.

8.4 Non-English-speaking or -reading adult subjects. Will you enroll adult subjects who do not speak English or who lack fluency or literacy in English?

[x] **No**
[ ] **Yes** → If yes, describe the process you will use to ensure that the oral and written information provided to them during the consent process and throughout the study will be in a language readily understandable to them and (for written materials such as consent forms or questionnaires) at an appropriate reading/comprehension level.

a. Interpretation. Describe how you will provide interpretation and when. Also, describe the qualifications of the interpreter(s) – for example, background, experience, language proficiency in English and in the other language, certification, other credentials, familiarity with the research-related vocabulary in English and the target language.

b. Translations. Describe how you will obtain translations of all study materials (not just consent forms) and how you will ensure that the translations meet the UW IRB's requirement that translated documents will be linguistically accurate, at an appropriate reading level for the participant population, and culturally sensitive for the locale in which they will be used.

8.5 Deception. Will you deliberately withhold information or provide false information to any of the subjects?

[x] **No**
[ ] **Yes** → If yes, describe what information and why.

Example: you may wish to deceive subjects about the purpose of the study.

a. Will you debrief the subjects later? (Note: this is not required.)

[ ] **No**
[ ] **Yes** → If yes, describe how you will debrief the subjects. Upload any debriefing materials, including talking points or a script, to the **Consent Form and Recruitment Materials** SmartForm of **Zipline**.

8.6 Cognitively impaired adults, and other adults unable to consent.

a. Target population. Do you plan to intentionally include cognitively impaired adults in your research?

Examples: individuals with Traumatic Brain Injury (TBI) or dementia; individuals who are unconscious, or who are significantly intoxicated.

[ ] **No** → If no, go to question **8.8**.
[x] **Yes** → If yes, answer the following questions.

a.1. Rationale. Provide your rationale for including this population in your research.

We would like to extend the opportunity to participate to those with legal guardians. Previous research we have conducted using this intervention has been found to be effective with those with more severe symptoms and the PI feels this could be also beneficial for those who fit criteria with legal guardians.

a.2. Capacity for consent / decision making capacity. Describe the process you will use to determine whether a cognitively impaired individual is capable of consent decision making with respect to your research protocol and setting. If you will have repeated interactions with the impaired subjects over a time period when cognitive capacity could increase or diminish, also describe how (if at all) you will re-assess decision-making capacity and consent during that time.

We will continue to implement our current protocol of providing a competency screener, which consists of summarizing the study in their own words (we probe about length of study, what the study involves (i.e., smartphone app, calls with mHSS, questionnaires), reciting back three content areas the questionnaires will cover (health, mood and symptoms), and to define what voluntary participation means. Any participant, legal guardian or not, will not be enrolled into the trial if they are unable to answer these questions correctly.

a.3. Permission (surrogate consent). If you will include adults who cannot consent for themselves, describe your process for obtaining permission ("surrogate consent") from a legally authorized representative (LAR).

For research conducted in Washington State, see the **SOP: Legally Authorized Representative** to learn which individuals meet the state definition of "legally authorized representative".

A researcher will make a call to the legal guardian and will outline the study just as the current protocol for patient-participants outlines. We will also administer the competency screener so we can confirm they understand the basic requirements for the study.

a.4. Assent. Describe whether assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not (and why not). Describe any process you will use to obtain and document assent from the subjects.

A researcher will make a call to the potential participant (with LAR) and will outline the study just as the current protocol for patient-participants outlines. We will also administer the competency screener so we can confirm they understand the basic requirements for the study.

a.5. Dissent or resistance. Describe how you will identify the subject's objection or resistance to participation (including non-verbal) during the research, and what you will do in response.

8.7 Consent-related materials. Upload to the **Consent Forms and Recruitment Materials** SmartForm of **Zipline** all consent scripts/talking points, consent forms, debriefing statements, Information Statements, Short Form consent forms, parental permission forms, and any other consent-related materials you will use.

- Translations must be included. However, you are strongly encouraged to wait to provide them until you know that the IRB will approve the English versions.
- Combination forms: It may be appropriate to combine parental permission with consent, if parents are subjects as well as providing permission for the participation of their children. Similarly, a consent form may be appropriately considered an assent form for older children.
- For materials that cannot be uploaded: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.

9 PRIVACY AND CONFIDENTIALITY

9.1 Privacy protections. Is this research likely to leave subjects with a concern that their privacy is being/has been invaded?

Privacy refers to the sense of being in control of access that others have to ourselves. This can be an issue with respect to recruiting, consenting, sensitivity of the data being collected, and the method of data collection.

Examples:

- Many subjects will feel a violation of privacy if they receive a letter asking them to participate in a study because they have ____ medical condition, when their name, contact information, and medical condition were drawn from medical records without their consent. Example: the IRB expects that "cold call" recruitment letters will inform the subject about how their information was obtained.
- Recruiting subjects immediately prior to a sensitive or invasive procedures (e.g., in an outpatient surgery waiting room) will feel like an invasion of privacy to some individuals.
- Asking subjects about sensitive topics (e.g. details about sexual behavior) may feel like an invasion of privacy to some individuals.

[ ] **No**

[x] **Yes** → If yes, describe the steps you will take, if any, to protect the privacy of subjects and potential subjects.

Participants may feel uncomfortable answering questions about their symptoms during assessments. Participants will be reminded that they are able to skip questions, take a break at any time, or let research staff know they no longer want to participate in the study. We can connect patient participants to their clinical staff if needed.

9.2 Identification of individuals in publications and presentations. Do you plan to use potentially identifiable information about subjects in publications and presentations, or is it possible that individual identities could be inferred from what you plan to publish or present?

[x] **No**
[ ] **Yes** → If yes, will you obtain subject consent for this use?

- [ ] **Yes**
- [ ] **No** → If no, describe the steps you will take to protect subjects (or small groups of subjects) from being identifiable.

9.3 State mandatory reporting. Each state has reporting laws that require some types of individuals to report some kinds of abuse, and medical conditions that are under public health surveillance. These include:

- Child abuse
- Abuse, abandonment, neglect, or financial exploitation of a vulnerable adult
- Sexual assault
- Serious physical assault
- Medical conditions subject to mandatory reporting (notification) for public health surveillance

Are you or a member of your research team likely to learn of any of the above events or circumstances while conducting your research **AND** feel obligated to report it to state authorities?

[x] **No**
[ ] **Yes** → If yes, the UW IRB expects you to inform subjects of this possibility in the consent form or during the consent process, unless you provide a rationale for not doing so:

9.4 Retention of identifiers. Check the box below to indicate your assurance that you will not destroy any identifiers (or links between identifiers and data/specimens) that are part of your research records until after the end of the applicable records retention requirements (e.g. Washington State; funding agency or sponsor; Food and Drug Administration) for your research.

See the "Research Data" sections of the following website for UW Records management for the Washington State research rectords retention schedules that apply in general to the UW (not involving UW Medicine data):
http://f2.washington.edu/fm/recmgt/retentionschedules/gs/general/uwgsResearch#R

See the "Research Data and Records" information in Section 8 of this document for the retention schedules for UW Medicine Records: **http://www.uwmedicine.org/about/Documents/UWMRRS-1.5.pdf**

[x] **Confirm**

9.5 Certificates of Confidentiality. Do you have or, are you planning to obtain, a federal Certificate of Confidentiality for your research data?

[x] **No**

☐ Yes

9.6 **Data and specimen security protections**. Identify your data classifications and the security protections you will provide, referring to the **ZIPLINE GUIDANCE: Data and Security Protections** for the minimum requirements for each data classification level.

"Risk of harm" refers to the risk of harm that would occur with a breach of the unprotected or breached data.

Level	Data Classification
1	Very low risk of harm if disclosed These data have very little or no sensitivity. Disclosure of these data would have very little or no risk of physical, psychological, social, economic, legal, or educational advancement harm to the subjects. Examples: De-identified, anonymous, or publicly available data, data for which subjects have consented to allow public access (e.g., a museum archive), opinions of individuals about non-sensitive issues or performance on non- sensitive tasks.
2	Some risk of minor harm to individuals if disclosed These data have relatively little sensitivity except possibly short-term embarrassment or psychological discomfort if the data were disclosed. Examples: Performance of individuals on non-sensitive tasks in a competitive situation, genetic information about individuals' metabolism of medical drugs such as statins.
3	Could cause risk of material harm to individuals if disclosed These data could result in harm that can have genuine impact, but the magnitude and/or duration are generally not serious, long-lasting, and/or irreversible. Examples: Non-sensitive Personal Health Information.
4	Would likely cause serious harm to individuals if disclosed These data could result in serious harm, if disclosed. Examples: Sensitive Personal Health Information, such as the history of cancer or other significant conditions which could (for example) affect employability or insurability.
5	Extremely sensitive; could cause severe harm to individuals if disclosed These data could result in serious and long-lasting harm, if disclosed. Examples: Information about subjects' illegal behavior, very sensitive Personal Health Information such as the diagnosis of HIV/AIDS in some cultures, or a diagnosis of leprosy.

a. Which level of protections will you apply to your data and specimens? If you will use more than one level, describe which level will apply to which data and which specimens.

3

b. Use this space to provide additional information, details, or to describe protections that do not fit into one of the levels.

10 RISK / BENEFIT ASSESSMENT

10.1 Anticipated risks. Describe the reasonably foreseeable risks of harm, discomforts, and hazards to the subjects and others of the research procedures. For each harm, discomfort, or hazard:

- Describe the magnitude, probability, duration, and/or reversibility of the harm, discomfort, or hazard, AND
- Describe how you will manage or reduce the risks.
- Consider physical, psychological, social, legal, and economic risks, including risks to financial standing, employability, insurability, educational advancement or reputation.
- Examples of "others": embryo, fetus, or nursing child; family members; a specific group.
- Do not include the risks of non-research procedures that are already being performed.
- If the study design specifies that subjects will be assigned to a specific condition or intervention, then the condition or intervention is a research procedure - even if it is a standard of care.
- Examples of mitigation strategies: inclusion/exclusion criteria; applying appropriate data security measures to prevent unauthorized access to individually identifiable data; coding data; taking blood samples to monitor something that indicates drug toxicity.
- As with all questions on this application, you may refer to uploaded documents.

There are minimal risks associated with participation in this study. Any potential risks that might exist fall into three categories: (1) risks associated with the intervention; (2) risks associated with research assessments (3) risks associated with potential loss of confidentiality. We address each in turn below.

1. Risks of the intervention. mHealth interventions for people with SSD have not been shown to cause harm in any of our mHealth studies or in research reported in the published literature. Our extensive line of FOCUS research in similar CMHC settings suggests it is a highly acceptable and safe intervention in this environment. We have deployed FOCUS for periods ranging five days to seven months and have not had any adverse events reported. PI Ben-Zeev is currently conducting a separate smartphone intervention study with more high-risk participants who were recently discharged from the hospital as part of a relapse prevention program for schizophrenia (R01MH103148). The four-year study is concluding in July 2017; participants with SSD have been using a smartphone system (CrossCheck) that is deployed for a period that is four times longer than what is proposed for the current study. The CrossCheck platform is much more elaborate and technologically complex than the FOCUS intervention we propose to use here. Similar to the FOUCS line of research, we have not had any adverse events reported.

Participants in FOCUS research choose if/ when to engage. The main risk is engaging in intervention content while engaged in other activities that require participants' full attention (e.g., driving, crossing streets, operating machinery or appliances, caring for a child). Participants will be instructed to use the smartphone only when it is completely safe to do so. Participants will be socialized to the intervention model and advised that research staff and project personnel (i.e., facilitators) will not see their intervention use content or messages in any time-sensitive manner and that these forms of communication should not be used for an emergency.

2. Risks associated with research assessments. Research assessments include questions about functioning, psychiatric symptoms, other emotional or social problems, and illness management and recovery skills (patients) as well as evaluation of FOCUS usefulness and assessment of its strengths and limitations in the context of CMHC workflow (for staff). Responding to these items may cause discomfort or distress in some. CMHC staff may feel apprehensive about offering feedback that may be viewed as critical of FOCUS intervention. Individuals may also endorse suicidal ideation when completing measures or bring this up during screenings or debriefings.

3. Risks associated with potential loss of confidentiality. Whenever healthcare information is relayed outside of the physical clinic it creates new patient privacy and data security challenges. Potential risks

include loss, theft, or inadequate disposal of a mobile phone that contains health information, unauthorized access to information while it is stored on the device or transmitted (intentionally or inadvertently). There is also the remote possibility that research records will be subpoenaed for civil or criminal proceedings. All of these potential losses of confidentiality will be disclosed in the informed consent documents

4. Risks associated with disclosure of harm to self or others. There is a possibility of participants disclosing harmful intentions. If participants disclose suicidal or homicidal intention, research staff will probe for more details (i.e. if they have a plan, date, person of interest), and will deliberate with the lead PI (a trained clinical psychologist) the level of risk and if there is a need for clinical response. Unless there is an overt need for immediate care (i.e., participant said they would immediately hurt themselves or others, admitted to overdosing prior to meeting with research staff, etc). If elevation is deemed necessary by the research team, a member of the research staff would then reach out to their clinical team to proceed with the outlined protocol procedures of the local site (mental health clinic serving as a study site). If participants indicate a 1 or higher on Q9 of the PhQ9 Scale ("Thoughts that you would be better off dead, or of hurting yourself"), will be sent an email providing additional resources (please see 'Email for PHQ9' attachment in this modification).

10.2 Unforeseeable risks. Are there any research procedures that may have risks that are currently unforeseeable?

Example: using a drug that hasn't been used before in this subject population.

[x] **No**
[ ] **Yes** → If yes, identify the procedures.

10.3 Subjects who will be under regional or general anesthesiology. Will any research procedures occur while subjects-patients are under general or regional anesthesia, or during the 3 hours preceding general or regional anesthesia (supplied for non-research reasons)?

[x] **No**
[ ] **Yes** → If yes, check all the boxes that apply.

- [ ] Administration of any drug for research purposes
- [ ] Inserting an intra-venous (central or peripheral) or intra-arterial line for research purposes
- [ ] Obtaining samples of blood, urine, bone marrow or cerebrospinal fluid for research purposes
- [ ] Obtaining a research sample from tissue or organs that would not otherwise be removed during surgery
- [ ] Administration of a radio-isotope for research purposes**
- [ ] Implantation of an experimental device

☐

☐ Other manipulations or procedures performed solely for research purposes (e.g., experimental liver dialysis, experimental brain stimulation)

If you checked any of the boxes:
You must provide the name and institutional affiliation of a physician anesthesiologist who is a member of your research team or who will serve as a safety consultant about the interactions between your research procedures and the general or regional anesthesia of the subject-patients. If your procedures will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member.

** If you checked the box about radio-isotopes: you are responsible for informing in advance all appropriate clinical personnel (e.g., nurses, technicians, anesthesiologists, surgeons) about the administration and use of the radio-isotope, to ensure that any personal safety issues (e.g., pregnancy) can be appropriately addressed. This is a condition of IRB approval.

10.4 Data and Safety Monitoring. A Data and Safety Monitoring Plan (DSMP) is required for clinical trials (as defined by NIH), and for studies funded by or involving the Department of Justice. If required for your research, upload your DSMP to the **Supporting Documents** SmartForm in **Zipline**. If it is embedded in another document you are uploading (for example, a Study Protocol, use the text box below to name the document that has the DSMP.

We plan to use a Data Safety and Monitoring Board (DSMB) to review problems when reported, and then in aggregate for this project on an annual basis. These procedures will protect the safety of our research participants and ensure that our study procedures are not harmful in any way. Serious, unexpected adverse events related to mHealth intervention research participation are very rare in studies that are conducted by our group. The PI, in consultation with co-investigators and others as needed, will review Adverse Event reports. They will gather other information to investigate the event and determine the need for subsequent action including reporting to the IRB and if determined an adverse event by the IRB, will then be reported to the DSMB.

10.5 Un-blinding. If this is a double-blinded or single-blinded study in which the participant and/or you do not know the group to which the participant is assigned: describe the circumstances under which un-blinding would be necessary, and to whom the un-blinded information would be provided.

N/A

10.6 Withdrawal of participants. If applicable, describe the anticipated circumstances under which participants will be withdrawn from the research without their consent. Also, describe any procedures for orderly withdrawal of a participant, regardless of the reason, including whether it will involve partial withdrawal from procedures and any intervention but continued data collection or long-term follow-up.

Participants will be withdrawn if we find they have previously enrolled in the study, used FOCUS or if they become unavailable for data collection over the 6 month participation (i.e. hospitalized or incarcerated).

10.7 Anticipated direct benefits to participants. If there are any direct research-related benefits that some or all individual participants are likely to experience from taking part in the research, describe them below:

Do not include benefits to society or others, and do not include subject payment (if any). Examples: medical benefits such as laboratory tests (if subjects receive the results); psychological resources made available to participants; training or education that is provided.

Participants may experience improvement in their illness management, psychosocial functioning, reduction in distress associated with psychiatric symptoms, and enhanced recovery. The potential benefit to future patients is that the study may provide data on effective implementation methods for improving outpatient illness management via mHealth. Community mental health stakeholders may benefit from the introduction of a new treatment approach that may improve patient outcomes, increase their access to timely and relevant information, and perhaps reduce the burden linked with in-person/clinic based care. Considering the minimal risks of the proposed research to outpatient and staff participants, and the potential benefit, the benefits of the research seem to far outweigh the risks.

10.8 Individual subjects findings.

a. Is it likely that your research will discover unintentionally discover a previously unknown condition such as a disease, suicidal intentions, or genetic predisposition?

	No
x	**Yes** → If yes, explain whether and how you would share the information with the subject.

There is a possibility of participants disclosing harmful intentions. If participants disclose suicidal or homicidal intention, research staff will probe for more details (i.e. if they have a plan, date, person of interest), and will deliberate with the lead PI (a trained clinical psychologist) the level of risk and if there is a need for clinical response. Unless there is an overt need for immediate care (i.e., participant said they would immediately hurt themselves or others, admitted to overdosing prior to meeting with research staff, etc). If elevation is deemed necessary by the research team, a member of the research staff would then reach out to their clinical team to proceed with the outlined protocol procedures of the local site (mental health clinic serving as a study site). If participants indicate a 1 or higher on Q9 of the PhQ9 Scale ("Thoughts that you would be better off dead, or of hurting yourself"), will be sent an email providing additional resources (please see 'Email for PHQ9' attachment in this modification).

b. Do you plan to routinely share the individual results of your study procedures with the subjects – such as genetic test results, laboratory tests, etc.?

x	**No**
	Yes → If yes, complete and upload the **SUPPLEMENT: Participant Results Sharing** to the **Supporting Documents** SmartForm of **Zipline**

10.9 Commercial products or patents. If a commercial product or patent could result from this study, describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined:

Participants would not receive any compensation if a commercial product or patent were created. This is clearly stated in the consent form.

11 ECONOMIC BURDEN TO PARTICIPANTS

11.1 Financial responsibility for research-related injuries. Answer this question only if the lead researcher is not a UW student, staff member, or faculty member whose primary paid appointment is at the UW.

Describe who will be financially responsible for research-related injuries experienced by subjects, and any limitations. Describe the process (if any) by which participants may obtain treatment/compensation.

The lead researcher is a UW faculty member

11.2 Costs to subjects. Describe any research-related costs for which subjects may be responsible (e.g., CT scan required for research eligibility screening; co-pays; cost of a device).

N/A

11.3 Reimbursement for costs. Describe any costs to subjects that will be reimbursed (such as travel expenses).

N/A

12 RESOURCES

12.1 Faculty Advisor. (For researchers who are students, fellows, or post-docs.) Provide the following information about your faculty advisor.

- Advisor's name
- Your relationship with your advisor (for example: graduate advisor; course instructor)
- Your plans for communication/consultation with your advisor about progress, problems, and changes.

N/A

12.2 Study team communication. Describe how you will ensure that each study team member is adequately trained and informed about the research procedures and requirements (including any changes) as well as their research-related duties and functions.

☐ **There is no study team.**

At the beginning of the study the team will meet to discuss the study, deliverables and implementation. Printed study protocols will outline study procedures in detail to ensure proper and consistent implementation. Trainings will be conducted with study staff to ensure they understand the protocols and provide the opportunity to ask questions / give feedback. Weekly team meetings will provide opportunities to discuss any changes in procedures or requirements. Audits of study materials, trackers and databases will take place monthly or quarterly basis with additional training provided if necessary.

13 OTHER APPROVALS, PERMISSIONS, and REGULATORY ISSUES

13.1 Other regulatory approvals. Identify any other regulatory approvals that are required for this research, by checking applicable boxes

Do not attach the approvals unless requested by the IRB.

Approval	Research for which this is required
☐ Radiation Safety	Procedures involving the use of radioactive materials or an ionizing radiation producing machine radiation, if they are conducted for research rather than clinical purposes. Approvals need to be attached to the Supporting Documents page in **Zipline**.
☐ Institutional Biosafety	Procedures involving the transfer/administration of recombinant DNA, DNA/RNA derived from recombinant DNA, or synthetic DNA.
☐ RDRC	Procedures involving a radioactive drug or biological product that is not approved by the FDA for the research purpose and that is being used without an IND, for basic science research (not to determine safety and effectiveness, or for immediate therapeutic or diagnostic purposes).
☐ ESCRO	Procedures involving the use of some types of human embryonic stem cells.

13.2 Approvals and permissions. Identify any other approvals or permissions that will be obtained. For example: from a school, external site/organization, funding agency, employee union, UW Medicine clinical unit.

Do not attach the approvals and permissions unless requested by the IRB.

We received approval from UW Medicine Harborview clinic leadership.

13.3 Financial Conflict of Interest. Does any member of the team have a Financial Conflict of Interest (FCOI) in this research, as defined by UW policy GIM 10?

☒ **No**

☐ **Yes** → If yes, upload the Conflict Management Plan for every team member who has a FCOI with respect to this research, to the **Supporting Documents** page of **Zipline**. If it is not yet available, use the text box to describe whether the Significant Financial Interest has been disclosed already to the UW Office of Research.