1R21MH124073-01 Mobile Mental Health in Community Based Organizations

Study Protocol with SAP and ICF

NCT number: NCT04480021

Date: 7-16-2024

The Human Subjects Division (HSD) strives to ensure that people with disabilities have access to all services and content. **If you experience any accessibility-related issues with this form or any aspect of the application process, email hsdinfo@uw.edu for assistance.**

INSTRUCTIONS

- **This form is only for studies that will be reviewed by the UW IRB**. Before completing this form, check HSD's website to confirm that this should not be reviewed by an external (non-UW) IRB.
- **If you are requesting a determination** about whether the planned 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 the 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.
- For collaborative or multi-site research, describe only the UW activities unless you are requesting that the UW IRB provide the review and oversight for non-UW collaborators or co-investigators 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.

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1 OVERVIEW

Study Title: Mobile Mental Health in Community-Based Organizations: A Stepped Care Approach to Women's Mental Health

1.1 Home institution. Identify the institution through which the lead researcher listed on the IRB application will conduct the research. 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 **SOP: Use of the UW IRB**.*

University of Washington

1.2 Consultation history. Has there been any consultation with someone at HSD about this study?

It is not necessary to obtain advance consultation. However, if advance consultation was obtained, answering this question will help ensure that the IRB is aware of and considers the advice and guidance provided in that consultation.

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

Amritha Bhat communicated via phone with Jeffrey Love at HSD on 5/14/2020 about need for IRB review for JIT of NIH grant.

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 the 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.

The funder has requested that we provide IRB approval for the project as part of a Just in Time grant submission due by close of business on 5/25/2020.

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. You will be asked to describe the specific procedures in a later section.

If this 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).

Background: Undiagnosed and untreated depression is a significant cause of morbidity and mortality in low-middle-income countries (LMIC) such as India. The rates of diagnosis and treatment of depression among women in rural India are disproportionately low despite a primary care based task-sharing model of mental-health treatment. Stepped care approaches support appropriate treatment of symptoms while reducing the burden on healthcare systems and mobile technology can reduce the mental health treatment gap given its reach and easy access. However, as our preliminary study at a task-sharing care model in rural south India (Maanasi clinic, situated 60 miles from Bangalore city) revealed: illiteracy and the practice of sharing mobile phones as a family resource present hurdles to the adoption of mobile mental health (mHealth) based interventions. *To date, the feasibility of an mHealth application to screen depression, track symptom severity and support the delivery of stepped care treatment has not been tested in LMIC.*

Specific Aim 1: In phase I of this exploratory study, we will adopt a user centered participatory approach to design and develop a multiple-user, voice-response, mobile application ("MITHRA"), to be used in community-based organizations for screening, tracking and supporting stepped care treatment for depression, including select modules of the Healthy Activity Program, a brief psychological intervention based on behavioral activation. The application will include audio, video and enhanced touchscreen capabilities, to overcome the barrier of illiteracy and lack of access.

Specific Aim 2: In phase II, using a randomized-control design, we will examine feasibility and utility of "MITHRA" deployed at community-based organizations (n=3) vs enhanced usual care (n=3) in different villages supported by the Maanasi program (enrolling approximately 60 women).

Specific aim 3: Throughout the duration of the funding period we will arrange for mentored participation of Psychiatry and Community Medicine residents from India in the research project. Community Health workers will benefit from regular videoconference didactic and case presentation (ECHO) sessions such as symptoms of and treatment for common mental disorders.

The grant will accomplish the goals of developing a unique mobile application that is scalable, examining its feasibility and building research capacity at the research site in India.

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.

Participatory design of an app and randomized controlled trial of the app.

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.
X	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. 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.
☐	6. 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.
☐	7. 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.
☐	8. Preliminary, exploratory, or research development activities (such as pilot and feasibility studies, or reliability/validation testing of a questionnaire)
☐	9. Expanded access use of a drug or device not yet approved for this purpose
☐	10. Use of a Humanitarian Use Device

☐ 11. Other. Explain:

N/A

1.8 Background, experience, and preliminary work. Answer this question **only** if the 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 the proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that the project is intended to address.

This should be a plain language description. 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.

Untreated depression is a significant cause of morbidity and mortality in low and middle-income countries (LMIC) such as India. The vast majority (75-85%) of people with depression in LMIC receive little or no treatment, resulting in a large 'treatment gap' of over 90%, which is greater in rural populations, especially among women. The alarmingly high treatment gap persists despite attempts to improve access by integrating mental health care with primary care as outlined in India's Mental Health Policy. Mild to moderate depression can lead to significant health and economic burden, and self-management can be used effectively to manage mild and moderate depression. There is therefore an urgent need and opportunity to identify and treat mild to moderate depression without increasing burden on the strained healthcare system. Within a stepped care approach, self-administered treatments are an evidence based approach to mild to moderate depressive symptom when combined with regular monitoring of symptoms. This approach is especially useful in leveraging the available workforce in resource constrained settings.

Mobile health (mHealth) has been recommended as a means to improve access to care due to ease of access and availability even in resource poor settings. Mobile apps have demonstrated high usability and feasibility, and mild to moderate effect sizes in the treatment of depression. This is particularly relevant to the Indian context - in India, most people have access to a mobile phone and network coverage. However, there are differences in usage patterns that need to be considered in developing mHealth strategies. For e.g., in rural India, while 87% of people own a cell phone, only 14% of them use text messaging perhaps because of the high rate of illiteracy. Furthermore, as we found in our qualitative work in rural India with women with depression, although women do report owning a mobile phone, this is often a shared family phone that is with the husband for most of the day. Therefore, to ensure adequate uptake, any mHealth program needs to account for barriers such as illiteracy and lack of access to a personal mobile device. It is also critical to obtain end user or consumer feedback at every stage of development of mHealth solutions, as our work illustrates the need to contextualize mHealth by obtaining key stakeholder feedback to increase cultural relevance and acceptability.

Community-based organizations (CBOs) for women (called "mahila mandals" or "sthree shakthi" – women power) are instrumental in increasing women's empowerment and participation in microfinancing systems in rural India. They are self-help groups launched by the Department of Women and Child Development in the year 2000, implemented throughout India to empower rural women and make them self-reliant. Each group

consists of about 15 to 20 women members who are from below poverty line families, or landless agricultural labourers who meet regularly (weekly, biweekly or monthly). CBOs are used as platforms to deliver public health interventions including first aid training and prenatal education, and provide a unique opportunity for depression screening and intervention. In CBOs, using a stepped care approach to depression treatment that begins with offering education and self-administered treatments and allows for treatment intensification as required can provide invaluable opportunities to maximize treatment resources. This could also help address an important barrier to mental health treatment delivery, i.e., transportation, as many women would then receive depression screening, tracking and treatment support in their own village. In previous studies, women cite travel times and inability to take time off from work as a significant barrier to seeking mental health care in the PHC, and as a reason for treatment discontinuation. This barrier is relevant throughout the country, as although India's District Mental Health Program aims to provide community based accessible mental health care, 40% of patients still travel more than 10 km to access mental health services.
We propose, with user centered design methodology, to develop and test the feasibility of deploying a mobile based app (MITHRA) in CBOs in rural India to screen, track and treat depression using a stepped care algorithm in order to address the treatment-gap in LMIC, especially focusing on mild to moderate depression.[30-32,44,52] The stepped care approach will include education about depression and activity scheduling, based on the Healthy Activity Program (HAP), which is an evidence-based intervention that is acceptable, efficacious and cost effective in the treatment of depression and has been tested in rural India. It is effective in the treatment of moderate to severe depression and can also benefit mildly depressed individuals who may not require involvement of a mental health professional. Based on key stakeholder input, depression screening and education can be included with a general health survey, or independently. The app will be a Multi user Interactive Health Response Application (MITHRA = "friend" in Kannada, the regional language) deployed in CBOs in rural south India. Considering the culture and context of LMIC, education and advice about behavioral activation delivered via the app as part of stepped care treatment of depression, is an appropriate, initial effective and cost-effective treatment.[5]

b. Experience and preliminary work. Briefly describe experience or preliminary work or data (if any) that you, your team, or your collaborators/co-investigators 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: Your team has already conducted a Phase 1 study of an experimental drug which supports the Phase 2 study being proposed in this application; your team has already done a small pilot study showing that the reading skills intervention described in this application is feasible in an after-school program with classroom aides; your team has experience with the type of surgery that is required to implant the study device; the study coordinator is experienced in working with subjects who have significant cognitive impairment.

Our multidisciplinary research team has a long working relationship and has carried out formative research underlying the current proposal. Our qualitative analysis in the same population proposed for study in the current project helped understand some of the barriers to mental health care access and attitudes to mobile mental health. The study team will consist of Dr. Bhat and Dr. Srinivasan as Principal Investigators, and Drs. Collins Tony Raj, Goud and Pradeep as co – Investigators. In addition, in each year of the project, Psychiatry or Community Medicine residents will be selected from the St. John's Medical College training program for mentored participation in our team. Members of this team have collaborated on previous projects and in the development of this proposal and will continue to meet at regular intervals across the funding period for periodic review of progress and for problem solving.
Dr. Bhat is the overall contact PI owing to her experience in integrated mental health care, task sharing, and women's mental health. She has trained in both India and the US and has collaborated with Drs. Srinivasan, Goud and Pradeep in the past. She will coordinate activities between University of Washington and St. John's Medical College. Together with Dr. Srinivasan she will ensure that participating sites receive the necessary logistic and administrative support to implement the research plan. Dr. Srinivasan is the ideal India PI due to his understanding of the barriers and facilitators to community based mental health and because of his extensive experience on multiple studies examining the treatment of common mental disorders in India.

Many of these studies are collaborations with the United States and he is well versed in multiple PI projects such as the one we propose. He will provide oversight and supervision to the Community Health Workers (CHWs) and residents working on the project and arrange for psychiatrist back up for the CHWs in case of study related emergencies. Dr. Collins has several years' experience in global mental health projects and in mixed methods analysis. She is also experienced in modification of evidence-based treatments for delivery by lay health workers. She will provide input on mixed methods analysis, CHW training and overall study conduct. She is the director of the Global Mental Health program in the Department of Psychiatry and Behavioral Sciences at the University of Washington and in this capacity meets monthly with Dr. Bhat. She will meet with Dr. Bhat additionally as outline in the proposal. Dr. Tony Raj will lead the informatics team and oversee the process of iterative app development with end user input, and usability and pilot testing Dr. Goud will supervise CBO and CHW activities in his capacity as the Head of the Department for Community Medicine at St. John's Medical College. Dr. Johnson will ensure the smooth running of the day-to-day activities of the trial included recruitment, conduct of focus groups and supervision of CHWs. He will coordinate the local IRB submission at the study site.

1.9 Supplements. Check all boxes that apply, to identify relevant Supplements that should be completed and uploaded to ***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
☐	**Department of Energy** The research involves Department of Energy funding, facilities, data, or personnel.	*ZIPLINE* 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 the proposed research	*ZIPLINE* 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, and the UW is being asked to provide the required certification or to ensure that the consent forms can be certified	*ZIPLINE* SUPPLEMENT: Genomic Data Sharing
☐	**Medical device** Procedures involve the use of any medical device, even if the device is not the focus of the proposed 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
☐		SUPPLEMENT: Multi-site or Collaborative Research

	Multi-site or collaborative study The UW IRB is being asked to review on behalf of one or more non-UW institutions in a multi-site or collaborative study.	
☐	**Non-UW Individual Investigators** The UW IRB is being asked to review on behalf of one or more non-UW individuals who are not affiliated with another organization for the purpose of the research.	SUPPLEMENT: Non-UW Individual Investigators
x	None of the above	

2 PARTICIPANTS

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

For women's focus group:
- Women
- Age ≥ 18 years
- Resident of the village (i.e. not a guest attendee at the CBO)

For provider focus groups:
- CHWs who have been in the community for at least 6 months and interact regularly with members of the CBO.
- Administrators of the CBO who have been in the role for at least 6 months.
- Mental health and primary care providers who have treated women with depression.

For pilot RCT:
- Age ≥ 18 years
- Resident of the village (i.e. not a guest attendee)
- Plans to attend CBO meetings regularly.

2.2 Inclusion and exclusion criteria.

a. Inclusion criteria. Describe the specific criteria that will be used to decide who will be included in the research from among interested or potential subjects. Define any technical terms in lay language.

Inclusion for women's focus group:
- Age ≥ 18 years
- Resident of the village (i.e. not a guest attendee at the CBO)

Inclusion for provider focus groups:
- CHWs who have been in the community for at least 6 months and interact regularly with members of the CBO.
- Administrators of the CBO who have been in the role for at least 6 months.
- Mental health and primary care providers who have treated women with depression.

- Age ≥ 18 years
- Resident of the village (i.e. not a guest attendee)
- Plans to attend CBO meetings regularly.

b. Exclusion criteria. Describe the specific criteria that will be used to decide who will be excluded from the research from subjects who meet the inclusion criteria listed above. Define any technical terms in lay language.

Exclusion criteria for focus groups:
Unable to participate in informed consent discussion and did not complete PHQ-9.

Exclusion criteria for RCT:
- Diagnosed with severe mental illness such as bipolar disorder or schizophrenia
- Suicide attempt or severe alcohol or substance use in the past 6 months
- Unable to participate in informed consent discussion.

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

a. Will the proposed research recruit or obtain data from individuals that are known to be prisoners?

For records reviews: if the records do not indicate prisoner status and prisoners are not a target population, select "No". See the WORKSHEET: Prisoners for the definition of "prisoner".

[x] **No** → If no, skip the rest of part a. and continue to 2.3.b
[ ] **Yes** → If yes, answer the following questions (i – iv).

i. Describe the type of prisoners, and which prisons/jails:

ii. One concern about prisoner research is whether the effect of participation on prisoners' general living conditions, medical care, quality of food, amenities, and/or opportunity for earnings in prison will be so great that it will make it difficult for prisoners to adequately consider the research risks. How will the chances of this be reduced?

iii. Describe what will be done to make sure that (a) recruitment and subject selection procedures will be fair to all eligible prisoners and (b) prison authorities or other prisoners will not be able to arbitrarily prevent or require particular prisoners from participating.

iv. If the research will involve prisoners in federal facilities or in state/local facilities outside of Washington State: check the box below to provide assurance that study team members will (a) not encourage or facilitate the use of a prisoner's participation in the research to influence parole decisions, and (b) clearly inform each prisoner in advance (for example, in a consent form) that participation in the research will have no effect on his or her parole.

[ ] **Confirmed**

b. Is the research likely to have subjects who become prisoners while participating in the 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 the study, will any study procedures and/or data collection related to the subject be continued while the subject is a prisoner?

☐ **No**

☐ **Yes** → If yes, describe the procedures and/or data collection that 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 will be purposefully included. (In other words, being a part of the population is an inclusion criterion for the study.)

The WORKSHEETS describe the criteria for approval but do not need to be completed and should not be submitted.

Population	Worksheet
☐ Fetuses in utero	WORKSHEET: Pregnant Women
☐ Neonates of uncertain viability	WORKSHEET: Neonates
☐ Non-viable neonates	WORKSHEET: Neonates
☐ Pregnant women	WORKSHEET: Pregnant Women

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

N/A

2.5 Native Americans or non-U.S. indigenous populations. Will Native American or non-U.S. indigenous populations be actively recruited 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

☒ **No**

☐ **Yes** → If yes, name the tribe, tribal-focused organization, or similar community-based organization. The UW IRB expects that tribal/indigenous approval will be obtained before beginning the research. This may or may not involve approval from a tribal IRB. The study team and any collaborators/investigators are also responsible for identifying any tribal laws that may affect the research.

2.6 Third party subjects. Will the research collect private identifiable information about *other individuals* from the study 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 the research team to readily identify the person. For example, suppose that the research is about immigration history. If subjects are asked questions about their grandparents but are not asked for names or other information that would allow easy identification of the grandparents, then private identifiable information is not being collected about the grandparents and the grandparents are not subjects.

[x] **No**

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

2.7 Number of subjects. Is it possible to predict or describe the maximum number of subjects (or subject units) needed to complete the 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 the specific study. 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 in the context of risks and benefits. Unless otherwise specified, if the IRB determines that the research involves no more than minimal risk: there are no restrictions on the total number of subjects that may be enrolled. If the research involves more than minimal risk: The number of enrolled subjects must be limited to the number described in this application. If it is necessary later to increase the number of subjects, submit a Modification. Exceeding the IRB-approved number (over-enrollment) will be considered non-compliance.

[ ] **No** → If no, provide the rationale in the box below. Also, provide any other available information about the scope/size of the research. You do not need to complete the table.

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

[x] **Yes** → If yes, for each subject group, use the table below to provide the 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

	Provide numbers for the site(s) reviewed by the UW IRB and for the study-wide total number; example: 20/100
Community health workers	3
Community based organization (CBO) administrators	3
Primary care and mental health providers	3
CBO participants for focus group	6
CBO participants for RCT	60

3 NON-UW RESEARCH SETTING

Complete this section only if UW investigators and people named in the SUPPLEMENT: Non-UW Individual Investigators will conduct research procedures outside of UW and Harborview

3.1 Reason for locations. Describe the reason(s) for choosing the locations.

This is especially important when the research will occur in locations or with populations that may be vulnerable to exploitation. One of the three ethical principles the IRB must consider is justice: ensuring that reasonable, non-exploitative, and well-considered procedures are administered fairly, with a fair distribution of costs and potential benefits.

This research is aimed at examining the feasibility of app-based screening and treatment of depression in women in rural settings with a high treatment gap such as at our India site.

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 the research, how it is conducted, or how consent is obtained or documented.

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. In some distinct cultural groups, signing forms may not be the norm.

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

Research will be conducted within CBOs, and consent will be obtained by community health workers who are known to the women. This approach has been used in previous studies in the same location and is acceptable to women and culturally appropriate.
Study procedures will be explained in detail before obtaining informed consent with the option of using thumb impression instead of signature if illiteracy is a barrier.

3.3 Location-specific laws. Describe any local laws that may affect the 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 Location-specific administrative or ethical requirements. Describe local administrative or ethical requirements that affect the research.

Example: A school district may require researchers to obtain permission from the head district office as well as school principals before approaching teachers or students; a factory in China may allow researchers to interview factory workers but not allow the workers to be paid for their participation.

N/A

3.5 If the PI is a student: Does the research involve traveling outside of the US? N/A

☐ **No**

☐ **Yes** → If yes, confirm by checking the box that (1) you will register with the **UW Office of Global Affairs** before traveling; (2) you will notify your advisor when the registration is complete; and (3) you will request a UW Travel Waiver if the research involves travel to the list of countries requiring a UW Travel Waiver.

☐ **Confirmed**

4 RECRUITING and SCREENING PARTICIPANTS

4.1 Recruiting and Screening. Describe how subjects will be identified, recruited, and screened. 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.

End user focus group: Women for the end user focus group will be recruited from via i) advertisements ii) flyers iii) word of mouth and iv) community health workers (CHWs). We will oversample for women with depressive symptoms such that we have an equal number of women with Patient Health Questionnaire -9 (PHQ-9) score above 5 and PHQ-9 score below 5. For prescreening, to identify women with a PHQ-9 above 5, community health workers located in the Community Based Organization (CBO) will use the PHQ-9 questionnaire, introduced with talking points which have been uploaded.

Provider focus group: Primary care and mental health providers will be recruited from Anekal Primary Health Center and CHWs will be recruited from the Community Based Organizations (CBOs) and by contacting them through the parent Mahila Mandal Organization.

All advertisements and flyers will be reviewed and approved before use by the Human Subjects division at University of Washington.

For the RCT, participants will be recruited from community-based organizations (CBOs) via i) advertisements ii) flyers iii) word of mouth and iv) community health workers (CHWs). Our recruitment strategies will enable us to recruit women with varying degrees of depression and to be representative of women in the villages covered by the CBO.

All advertisements and flyers will be reviewed and approved before use by the Human Subjects division at University of Washington.

4.2 Recruitment materials.

a. What materials (if any) will be used 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.

Talking points for CHWs attached as appendix.

b. Upload descriptions of each type of material (or the materials themselves) to ***Zipline***. If letters or emails will be sent to any subjects, these should include a statement about how the subject's name and contact information were obtained. No sensitive information about the person (such as a diagnosis of a medical condition) should be included 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:

- *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, 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). This means that a Modification would not be necessary if/when the study phone number or contact person changes. Also, instead of listing the inclusion/exclusion criteria, the description below 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, 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 that will be provided, 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.

Subjects will be compensated for their time spent on participating in the focus groups and individual interviews. All women (including CHWs and CBO attendees) will receive Rs. 200 (approx. $3) each time they participate. This amount represents a payment for the time and potential stress associated with the study procedures and is comparable with other similar studies at this location. This amount of compensation is commensurate with the average income in this region and ensures that consent is not unduly influenced by financial consideration

4.5 Non-monetary compensation. Describe any non-monetary compensation that will be provided. Example: extra credit for students; a toy for a child. If class credit will be offered to students, there must be an alternate way for the students to earn the extra credit without participating in the research.

None

4.6 Will data or specimens be accessed or obtained for recruiting and screening procedures prior to enrollment?

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.

[ ] **No** → If no, skip the rest of this section; go to question **5.1**.

[x] **Yes** → If yes, describe the data and/or specimens (including PHI) and whether it will be retained as part of the study data.

For the CBO participant focus groups in Aim 1, potential participants will receive a paper based PHQ-9 to enable recruitment of up to 3 women with PHQ-9 scored of more than 5. The paper PHQ-9s will not have identifying information and will be shredded immediately after the CHW has determined the total scores. We will however maintain a count of how many women were prescreened and how many of them had a score of more than 5. For the RCT we will administer PHQ-9 to all attendees of the CBO using the same talking points, to identify CBOs with more than one woman who scores positive on the PHQ-9.

4.7 Consent for recruiting and screening. Will consent be obtained 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, skip the rest of this section; go to question **5.1**.

[x] **Yes** → If yes, describe the consent process.

CHWs will administer the PHQ9, if more than one woman PHQ9 positive then CHW will proceed with informed consent for all members of SHG. The CHW will use the attached talking points to obtain verbal consent from participants.

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

[x] **No** → If no, describe the information that will be provided during the consent process and for which procedures.

[ ] **Yes** → If yes, upload the consent form to ***Zipline***.

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), drug dosing information (if any), use of records, time required, and setting/location. If it is available: Upload a study flow sheet or table to ***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.*

App development: Using a qualitative, user-centered design approach we will: (1) develop consensus on the desired features, content, and design of the MITHRA app; (2) develop an initial working prototype of MITHRA and conduct technical feasibility testing (3) iteratively refine and evaluate the app prototype based on usability testing. In parallel, Drs. Bhat, Johnson, and Srinivasan will use the HAP manual to develop the depression education and treatment modules that will be embedded in the MITHRA app. We will explore with the design group the desirability of features such as including physical health questionnaires to improve user buy in and reduce stigma and include the validated Kannada version of the Patient Health Questionnaire – 9 (PHQ-9) depression screening questionnaire. The standard life cycle of software development, configuration and testing will be followed. The study team will train members of the CBO to use the app and the tablet devices. We will obtain end user and stakeholder input as follows:

We will form three groups – 1 group with 3 CHWs and with CBO leadership, 1 group with 2 -3 primary and mental health care providers and 1 group with 6 – 7 CBO participants (2 -3 with PHQ-9 score of 5 or more). We will conduct 1 focus group interview with each of the 3 groups and triangulate these to inform step (1) of developing consensus on desired features of the app. In addition to the current plan, we will conduct one to two focus groups with participants at conclusion of the trial. Using a semi-structured interview guide, we will obtain inputs on design of the proposed app, keeping in mind the specifications of audio enabled, simplified touchscreen and follow up decision algorithm. We will include questions about introducing the PHQ-9 screen (as a depression screen on its own or as part of a more general health questionnaire), acceptable user interfaces, length of modules to be viewed, and women's preferences regarding viewing HAP modules (for e.g. do they prefer viewing in the CBO or would they prefer an option to check out the tablet to their home for viewing). We will record and transcribe focus group content and analyze it using qualitative analysis software Nvivo. Using a thematic content analysis approach, we will identify common themes to help guide app development. The informatics team will complete step (2) in consultation with Dr. Raj using the information obtained during step (1). For step (3) of iterative refinement of the app, we will conduct 2 Participatory Design Group meetings alternating with modification of the prototype until saturation of issues raised in PDG meetings is reached.

Randomized trial: We will randomize CBOs to use MITHRA (n=3) or enhanced usual care (EUC) (n=3) for 12 weeks. Randomization will be clustered to account for distance from the PHC. The MITHRA CBOs will each have 2 -3 tablets for use by all attendees. A CHW will be present at meetings and encourage women to use the MITHRA app. During their time at the meeting, women will complete the PHQ-9 screening and modules based on their individual depression score. Privacy will be ensured. They will also have the option to take turns checking out the tablet for viewing at home (if this is reported by the design group to be a desirable feature). In the EUC CBOs, CHWs will offer monthly group education (45 min) regarding the symptoms of depression, informed by training webinars led by study Investigators. We have the support of the CBO and PHC leadership for this project (see attached letters of support). In both MITHRA and EUC CBOs CHWs will conduct community outreach to encourage women to attend meetings, as depression can lead to amotivation and women with depression may be less likely to attend CBO meetings. All CHWs will receive training in depression, screening and common treatments, resources and referrals.

Outcome Measures: CHWs will maintain rosters of CBO attendees at MITHRA CBOs and EUC CBOs. In monthly review sessions with the study investigators, the CHWs will review questionnaire completion and scores, and directly contact the woman (by phone or home visit or at a CBO meeting) if there is a need to step up care beyond that advised by the app. Women typically attend CBO meetings 2 -3 times a month and use at every attendance will be encouraged.

MITHRA is an app which will be available on 2 -3 tablets placed in Community Based Organizations (CBOs). Women can log in to MITHRA using a unique password protected secure single user sign on (fingerprint sign in to account for varying levels of literacy) to complete the physical health questionnaire and the PHQ -9 (validated Kannada version of the PHQ-9) in an assigned private place in the CBO. On completion of the PHQ-9, each woman will receive a prompt based on her total score (see Fig). Women who score < 5 will watch general information on depression; women who score 5 – 10 will watch modules 1 and 2 (case descriptions, What is Depression? and Introduction to PHQ-9) Women who score 10 – 15 will watch modules 1, 2, and 3 (Connection between activity and mood).

On repeat sign in, they will also receive questions on completion of behavioral activation homework. Women who score more than 15 will receive a prompt to view modules 1 through 4 which includes additional content on strategies for specific problems, and information on medications. They will receive information on how to seek mental health care. This ensures that women with mild to moderate depression receive initial treatment without having to overcome transportation barriers. The app will track, and graph PHQ-9 score change over time to inform need to step up care. Any woman who scores anything other than 0 on question 9 of the PHQ 9 (suicidal ideation item) will be asked to call the CHW associated with that CBO. For these women, the app will also trigger an alert to the CHW who will immediately call the patient to complete a risk assessment based on the study SI protocol. CHWs will be trained in the study safety protocol and a chain of contact will be established for each type of scenario. The woman will be escorted to the PHC if needed. Modules described above will follow the content of the Healthy Activity Program manual and will be delivered in

short (10-15 min) interactive multimediabased modules. Depending on their PHQ-9 score, women will watch 4 to 8 modules over the course of 1 to 3 months.

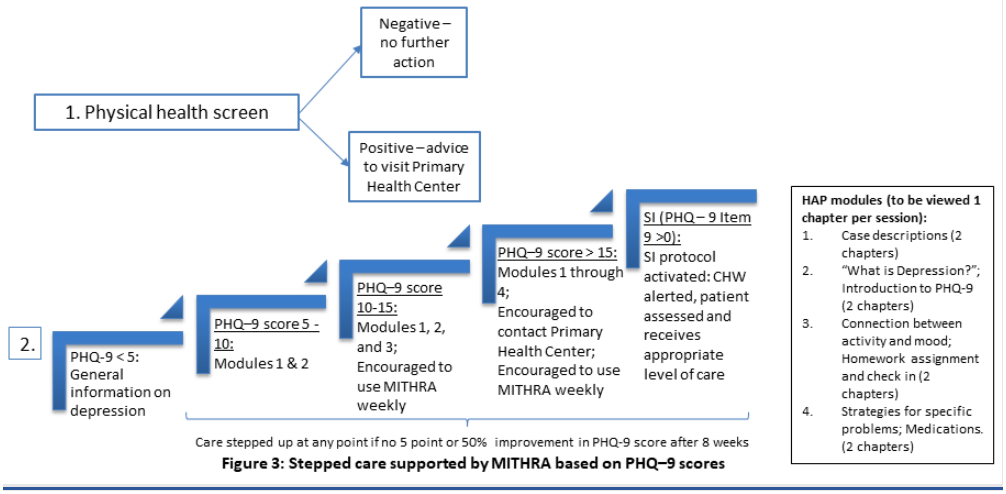

Figure 3: Stepped care supported by MITHRA based on PHQ–9 scores

Enhanced Usual Care (EUC): For EUC, CHWs will offer standardized monthly group education (45 min) regarding the symptoms of depression, informed by training from study Investigators. All CHWs will receive education on depression symptoms and referrals.

5.2 Recordings. Does the research involve creating audio or video recordings?

[ ] **No** → If no, go to question **5.3**.
[x] **Yes** → If yes, describe what will be recorded (if not already described in 5.1) and answer question **a**.

a. Before recording, will consent for being recorded be obtained from subjects and any other individuals who may be recorded?

[ ] **No** → If no, email hsdinfo@uw.edu before submitting this application in Zipline. In the email, include a brief description of the research and a note that individuals will be recorded without their advance consent.

[x] **Yes**

5.3 MRI scans. Will any subjects have a Magnetic Resonance Imaging (MRI) scan as part of the study procedures?

This means scans that are performed solely for research purposes or clinical scans that are modified for research purposes (for example, using a gadolinium-based contrast agent when it is not required for clinical reasons).

[x] **No** → If no, go to question **5.4**.
[ ] **Yes** → If yes, answer questions **a** through **c**.

a. Describe the MRI scan(s). Specifically:

- What is the purpose of the scan(s)? *Examples: obtain research data; safety assessment associated with a research procedure.*
- Which subjects will receive an MRI scan?
- Describe the minimum and maximum number of scans per subject, and over what time period the scans will occur. *For example: all subjects will undergo two MRI scans, six months apart.*

b. Use of gadolinium. Will any of the MRI scans involve the use of a gadolinium-based contrast agent (GBCA?)

☐ **No**

☐ **Yes** → If yes, which agents will be used? *Check all that apply.*

	Brand Name	Generic Name	Chemical Structure
☐	Dotarem	Gadoterate meglumine	Macrocylic
☐	Eovist / Primovist	Gadoxetate disodium	Linear
☐	Gadavist	Gadobutro	Macrocyclic
☐	Magnevist	Gadpentetate dimeglumine	Linear
☐	MultiHance	Gadobenate dimeglumine	Linear
☐	Omniscan	Gadodiamide	Linear
☐	OptiMARK	Gadoversetamide	Linear
☐	ProHance	Gadoteridol	Macrocyclic
☐	Other, provide name:		

1.) The FDA has concluded that gadolinium is retained in the body and brain for a significantly longer time than previously recognized, especially for linear GBCAs. The health-related risks of this longer retention are not yet clearly established. However, the UW IRB expects researchers to provide a compelling justification for using a linear GBCA instead of a macrocyclic GBCA, to manage the risks associated with GBCAs.

Describe why it is important to use a GBCA with the MRI scan(s). Describe the dose that will be used and (if it is more than the standard clinical dose recommended by the manufacturer) why it is necessary to use a higher dose. If a linear GBCA will be used, explain why a macrocyclic GBCA cannot be used.

2.) Information for subjects. Confirm by checking this box that subjects will be provided with the FDA-approved Patient Medication Guide for the GBCA being used in the research or that the same information will be inserted into the consent form.

☐ **Confirmed**

c. MRI facility. At which facility(ies) will the MRI scans occur? Check all that apply.

☐ UWMC Radiology/Imaging Services (the UWMC clinical facility)

	DISC Diagnostic Imaging Sciences Center (UWMC research facility)
	BMIC Biomolecular Imaging Center (South Lake Union research facility)
	Harborview Radiology/Imaging Services (the Harborview clinical facility)
	SCCA Imaging Services
	Northwest Diagnostic Imaging
	Other: identify in the text box below:

Personnel. For MRI scans that will be conducted at the DISC or BMIC research facilities: The role, qualifications, and training of individuals who will operate the scanner, administer the GBCA (if applicable), and/or insert and remove the IV catheter should be described in question **12.3**.

5.4 Data variables. Describe the specific data that will be obtained (including a description of the most sensitive items). Alternatively, a list of the data variables may be uploaded to ***Zipline***.

1. App usage rates – measured at baseline and 3 months. We will obtain data on women's rates of use of the MITHRA app - this data will be obtained from the app, enabled by the single user sign on.
2. Depression measured by Quick Inventory of Depressive Symptoms (QIDS SR) at baseline 3 months and 6 months. QIDS SR will be collected by a blinded / masked research assistant. Research assessments will be conducted over the phone or in the Primary Health Center to avoid unblinding of CBO randomization status (presence of tablets in the CBOs)
3. Behavioral Activation – Behavioral Activation Depression Scale (BADS). We will administer the BADS to all women to calculate adherence to behavioral activation recommendations (for intervention women) and to measure degree of behavioral activation (for Enhanced Usual Care women).
4. Mental health services utilization – At baseline, 3 months and 6 months. We will obtain information on rates of utilization of mental health services including number of contacts with mental health providers and details of medications taken.

Depression – clinical outcome (not research measure)- Patient Health Questionnaire – 9. We will obtain information on rates of utilization of mental health services including the number of contacts with mental health providers and details of medications taken.

5.5 Data sources. For all types of data that will be accessed or collected for this research: Identify whether the data are being obtained from the subjects (or subjects' specimens) or whether they are being obtained 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.

All research measures will be obtained from subjects by research coordinators in person or by phone.

5.6 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 the 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 identity 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 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.

India research team members will have access to design group member names and contact information. The UW research team will have access to the design group member names as part of the meeting attendance. India research team members will have access to the audio recordings and transcripts of the focus group meetings and notes from design team meetings. India research team members will have access to the participant informed consents. India team will have access to the app data. India and UW research teams will have access to the de-identified data set.

[ ] **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 access.
- [ ] There is an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to study team members under any circumstances.

  This agreement should be available upon request from the IRB. 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. Describe them below.

b. Will you or any study team members obtain any direct or indirect identifiers?

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

India research team members will obtain contact information for the design group members. India research team members will obtain notes from the design group meetings and a recording and transcript of the design group meetings. India research team members will obtain the clinician and patient focus group consents.
India research team members will obtain qualitative data from the focus group participants.
India research team will obtain and create a data set of patient app data.

UW research team - NA

[ ] **No** → If no, select the reason(s) why you (and all members of your team) will not obtain direct or indirect identifiers.

- [ ] There will be no identifiers.
- [ ] Identifiers or the key have been (or will have been) destroyed before access.
- [ ] There will be an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) under any circumstances.

  This agreement should be available upon request from the IRB. 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. Describe them below.

c. If any identifiers will be obtained, indicate how the identifiers will be stored (and for which data). NOTE: Do not describe the data security plan here – that information is requested in section 9.6.

- [ ] Identifiers will be stored with the data. Describe the data to which this applies:
- [x] Identifiers and study data will be stored separately but a link will be maintained between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

Qualitative data: Audio recordings of the focus group sessions will be collected by UW study staff. Audio recordings will be transmitted to the transcriptionist via a HIPAA-compliant FTP server and recordings will be transcribed with removal of as much personally identifiable information as possible. Once the transcriptions are confirmed to be accurate, the audio recordings will be destroyed. Electronic copies of the transcriptions

will only be available to members of the study team, and will be stored on a password-protected computer server that is housed in a locked facility with restricted access. The India team will translate the transcriptions.

No identifying information will be attached to study data. Study data will be labeled with a unique study identification number. Only the relevant project staff will have access to the master list linking subject names to study identification numbers. The master list will be kept separate from the de-identified study data.

All identifying information collected as part of the study will be stored in a database on a secure server and will be password protected with limited access by the study team. Access will be limited to the research staff.

App data: Patient data will be a limited data set (dates of service and date of birth). The de-identified limited data sets will be created by the India UW team and shared with the UW research team. We will adhere to all requirements imposed by the Institutional Review Board and legal requirements such as HIPAA.

Participant consents: The India team will collect and manage participant consents. The consents will be stored in a secure locked drawer, separate from the de-identified data.

☐ Identifiers and study data will be stored separately, 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 the 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.

Qualitative Data: Audio recordings of the focus group sessions will be collected by India study staff . Audio recordings will be transmitted to the transcriptionist via a HIPAA-compliant FTP server and recordings will be transcribed with removal of as much personally identifiable information as possible. Once the transcriptions are confirmed to be accurate, the audio recordings will be destroyed. Electronic copies of the transcriptions will only be available to members of the study team and will be stored on a password-protected computer server that is housed in a locked facility with restricted access.

No identifying information will be attached to study data. Study data will be labeled with a unique study identification number. Only the relevant project staff will have access to the master list linking subject names to study identification numbers. The master list will be kept separate from the de-identified study data.

All identifying information collected as part of the study will be stored in a database on a secure server and will be password protected with limited access by the study team. Access will be limited to the research staff.

Patient data will be a limited data set (dates of service and date of birth). The de-identified limited data sets will be created by the India team and shared with the UW research team. We will adhere to all requirements imposed by the Institutional Review Board and legal requirements such as HIPAA

The India investigators are listed below and have completed human subjects training.

Srinivasan K, MD
Ramakrishna Goud, MD
Johnson Pradeep, MD
Tony Raj, MD
Dhinagaran Devadass MBBS
Abhijeet Wagmare MBBS

5.7 Protected Health Information (PHI). Will participants' identifiable PHI be accessed, obtained, used, or disclosed 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?

PHI is individually identifiable healthcare record information or clinical specimens from an organization considered a "covered entity" by federal HIPAA regulations, in any form or media, whether electronic, paper, or oral. ***You must answer yes to this question if the research involves identifiable health care records (e.g., medical, dental, pharmacy, nursing, billing, etc.), identifiable healthcare information from a clinical department repository, or observations or recordings of clinical interactions.***

☒ **No** → If no, skip the rest of this question; go to question **5.8**

☐ **Yes** → If yes, answer all of the questions below.

a. Describe the PHI and the reason for using it. *Be specific. For example, will any "free text" fields (such as physician notes) be accessed, obtained, or used?*

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

☐ **No**
☐ **Yes**

c. Describe the pathway of how the PHI will be accessed or obtained, starting with the source/location and then describing the system/path/mechanism by which it will be identified, accessed, and copied for the research. *Be specific. For example: directly view records; search through a department's clinical database; submit a request to Leaf.*

d. For which PHI will subjects provide HIPAA authorization before the PHI is accessed, obtained and/or used?

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

☐ **Confirmed**

e. For which PHI will HIPAA authorization NOT be obtained from the subjects?

Provide the following assurances by checking the boxes.

☐ The minimum necessary amount of PHI to accomplish the purposes described in this application will be accessed, obtained and/or used.

☐ 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.

☐ The HIPAA "accounting for disclosures" requirement will be fulfilled, if applicable. See UW Medicine Compliance Policy #104.

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

5.8 Genomic data sharing. Will the research obtain or generate genomic data?

☒ **No**
☐ **Yes** → If yes, answer the question below.

a. Will genomic data from this research be sent to a national database (for example, NIH's dbGaP database)?

☐ **No**
☐ **Yes** → If yes, complete the ***ZIPLINE* SUPPLEMENT Genomic Data Sharing** and upload it to ***Zipline***.

5.9 Whole genome sequencing. For research involving biospecimens: Will the research include whole genome sequencing?

Whole genome sequencing is sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.

☒ **No**
☐ **Yes**

5.10 Possible secondary use or sharing of information, specimens, or subject contact information. Is it likely that the obtained or collected information, specimens, or subject contact information will be used for any of the following:

- Future research not described in this application (in other words, secondary research)
- Submission to a repository, registry, or database managed by the study team, colleagues, or others for research purposes
- Sharing with others for their own research

Please consider the broadest possible future plans and whether consent will be obtained now from the subjects for future sharing or research uses (which it may not be possible to describe in detail at this time). Answer **YES** even if future sharing or uses will use de-identified information or specimens. Answer **NO** if sharing is unlikely or if the only sharing will be through the NIH Genomic Data Sharing described in question 5.8.

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 (for example): informal arrangements to share banked data/specimens with other investigators; establishing a repository that will formally share with other researchers through written agreements; or sending data/specimens to a third party repository/archive/entity such as 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 what will be stored for future use, including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

De-identified data will be stored for future use.

b. Describe what will be shared with other researchers or with a repository/database/registry, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens.

The award is subject to the data sharing guidance outlined in NOT-MH-14-015 and use of the NIMH Data Archive. No direct identifiers will be shared.

c. Who will oversee and/or manage the sharing?

The UW research team will manage the sharing.

d. Describe the possible future uses, 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.

Future uses might include other women's mental health research projects.

e. Consent. Will consent be obtained now from subjects for the secondary use, banking and/or future sharing?

[x] **No**

[ ] **Yes** → If yes, be sure to include the information about this consent process in the consent form (if there is one) and in the answers to the consent questions in Section 8.

f. Withdrawal. Will subjects be able to withdraw their data/specimens from secondary use, 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.

g. Agreements for sharing or release. Confirm by checking the box that the sharing or release will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement with 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 any template agreement forms; the IRB neither reviews nor approves them

[x] **Confirmed**

5.11 Communication with subjects during the study. Describe the types of communication (if any) the research team 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.

The India research team will have contact with the design team and focus group participants during the course of the study by phone, email and/or in person. No contact will occur between the research study team and the patients receiving care.

The India and UW team will have contact with the design team participants during the course of the study during the design meetings, via the phone and in person.
The India team will have contact with the RCT participants during the course of the trial by phone email or postal letters and in person.

5.12 Future contact with subjects. Is there a plan to retain any contact information for 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 the study team; if not, describe who else could be provided with the contact information. Describe the 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.

We will retain contact information to be able to inform subjects about future related studies.

5.13 Alternatives to participation. Are there any alternative procedures or treatments <u>that might be advantageous</u> 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.

5.14 Upload to *Zipline* all data collection forms (if any) that will be directly used by or with the subjects, and any scripts/talking points that will be used 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.*
- ***NOTE:** Sometimes the IRB can approve the general content of surveys and other data collection instruments rather than the specific form itself. This prevents the need to submit a modification request for future minor changes that do not add new topics or increase the sensitivity of the questions. To request this general approval, use the text box below to identify the questionnaires/surveys/ etc. for which you are seeking this more general approval. Then briefly describe the scope of the topics that will be covered and the most personal and sensitive questions. The HSD staff person who screens this application will let you know whether this is sufficient or whether you will need to provide more information.*
- ***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 the proposed research, provide a description of the process by which the data collection/questions will be established during the interactions with subjects, how the data collection/questions will be documented, the topics likely to be addressed, the most sensitive type of information likely to be gathered, and the limitations (if any) on topics that will be raised or pursued.*

Use this text box (if desired) to provide:

- Short written descriptions of materials that cannot be uploaded, such as URLs
- A description of the process that will be used for data that will be gathered in an evolving way.
- The general content of questionnaires, surveys and similar instruments for which general approval is being sought. (See the **NOTE** bullet point in the instructions above.)

All relevant materials have been uploaded

6 CHILDREN (MINORS) and PARENTAL PERMISSION

6.1 Involvement of minors. Does the 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.
- The generic age of consent may be different in other states, and in other countries.

☐ **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 the study population(s). If there is more than one answer, explain.

☐ **Don't know** →This means is it not possible to know the age of the subjects. For example, this may be true for some research involving social media, the Internet, or a dataset that is obtained 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 parental permission be obtained for:

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

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

☐ Some of the research procedures → Use the table below to identify the procedures for which parental permission will not be obtained.

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[2]	Reason why parental permission will not be obtained	Will parents be informed about the research?[3] YES	NO
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Table footnotes

1. *If the answer is the same for all children groups or all procedures: collapse the answer across the groups and/or procedures.*
2. *If identifiable information or biospecimens will be obtained without parent permission, any waiver granted by the IRB does not override parents' refusal to provide broad consent (for example, through the Northwest Biotrust).*
3. *Will parents be informed about the research beforehand even though active permission is not being obtained?*

b. Indicate the plan for obtaining parental permission. One or both boxes must be checked.

☐ 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 both boxes are checked, 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 may need to 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). The description 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 assent be obtained for:

☐ All research procedures and child groups	→ Go to question **7.2.**
☐ None of the research procedures and child groups	→ Use the table below to provide justification, then skip to question **7.6**
☐ Some of your research procedures and child groups	→ Use the table below to identify the procedures for which assent will not be obtained.

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 assent will not be obtained

Table footnotes

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

7.2 Assent process. Describe how assent will be obtained, for each child group. If the research involves children of different ages, answer separately for each group. If the children are non-English speakers, include a description of how their comprehension of the information will be evaluated.

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

7.4 E-consent. Will any electronic processes (email, websites, electronic signatures, etc.) be used to present assent information to subjects/and or to obtain documentation (signatures) of assent? If yes, describe how this will be done.

7.5 Documentation of assent. Which of the following statements describes whether documentation of assent will be obtained?

☐ None of the research procedures and child groups	→ Use the table below to provide justification, then go to question **7.5.b**
☐ All of the research procedures and child groups	→ Go to question **7.5.a**, do not complete the table
☐ Some of the research procedures and/or child groups	→ Complete the table below and then to go question **7.5.a**

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

Table footnotes

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

a. Describe how assent will be documented. If the children are functionally illiterate or are not fluent in English, include a description of the documentation process for them.

b. Upload all assent materials (talking points, videos, forms, etc.) to ***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. The documents should be in Word, if possible.

7.6 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 it was not obtained at the beginning of their participation).
Children who reach the legal age of consent: Informed consent must be obtained 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 the plans (if any) to re-obtain assent from children.

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

- If adult consent will be obtained from them, describe what will happen regarding now-adult subjects who cannot be contacted.
- If consent will not obtained or will not be possible: explain why.

7.7 Other regulatory requirements. (This is for 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 does not necessarily include the signing of a consent form.
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.

CHARACTERISTICS OF CONSENT	are the qualities of the consent process as a whole. These are:
	• Consent must be legally effective.
	• The process minimizes the possibility of coercion or undue influence.
	• Subjects or their representatives must be given sufficient opportunity to discuss and consider participation.
	• The information provided must:
	  ○ Begin with presentation of key information (for consent materials over 2,000 words)
	  ○ Be what a reasonable person would want to have
	  ○ Be organized and presented so as to facilitate understanding
	  ○ Be provided in sufficient detail
	  ○ Not ask or appear to ask subjects to waive their rights

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. **NOTE**: If you plan to obtain identifiable information or identifiable biospecimens without consent, any waiver granted by the IRB does not override a subject's refusal to provide broad consent (for example, the Northwest Biotrust).
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 the 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 and characteristics. This series of questions is about whether consent will be obtained for all procedures except recruiting and screening and, if yes, how.

The issue of consent for recruiting and screening activities is addressed in question 4.7. You do not need to repeat your answer to question 4.6.

a. Are there any procedures for which consent will not be obtained?

- [x] **No**
- [ ] **Yes** → If yes, use the table below to identify the procedures for which consent will not be obtained. "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 consent will not be obtained	Will subjects be provided with info about the research after they finish? YES	NO
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Table footnotes

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

b. Describe the consent process**,** if consent will be obtained 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)*
- *How subjects will be provided sufficient opportunity to discuss the study with the research team and consider participation*

c

Participatory Design Team: Providers and CBO participants – India team research staff will approach community health workers, CBO administrators, primary care physicians, psychiatrists and CBO participants for consent to participate in focus group discussions of desirable features of an app and to provide feedback on iterative versions of the app.
Each potential member of the design group will be provided a copy of the consent form (English, or translated Kannada version as appropriate) to review at the time that they are approached about the study and have an opportunity to ask questions. Each will be instructed that their involvement in the design groups is voluntary and they may decline participation without any risk of negative effect on their work position or health care. Consent process will occur in the CBO or in the primary care clinic.

Randomized trial: CBO participants: Women who attend CBO meetings will be approached by community health workers to introduce the randomized trial . With their permission their contact information will be shared with the research coordinator who will then contact them to make an appointment for the informed consent discussion. They will be given the English or Kannada consent form to review and have the opportunity to ask questions. Each will be instructed that their involvement in the trial is voluntary and they may decline or discontinue participation without any risk of negative effect on their health care..
No non-English speaking subjects will be enrolled until the translated consent forms have been submitted as a modification to the UW IRB and they have approved them

c. Comprehension**.** Describe the methods that will be used to ensure or test the subjects' understanding of the information during the consent process.

If English is not the first language, a Kannada translated version of the consent will be used. The India research team speaks both English and Kannada and can answer any questions. The India research team will provide study information at point of consent and offer to answer questions. Research staff will offer to walk/talk them through the consent process and answer any questions. If the research team has concerns about a participant's comprehension, they will ask the participant to summarize their understanding of what they are consenting to do.

d. Influence**.** Does the research involve any subject groups that might find it difficult to say "no" to participation because of the setting or their relationship with someone on the study team, even if they aren't pressured 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 will be done to reduce any effect of the setting or relationship on the participation 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. Information provided is tailored to needs of subject population. Describe the basis for concluding that the information that will be provided to subjects (via written or oral methods) is what a *reasonable member of the subject population(s)* would want to know. If the research consent materials contain a key information section, also describe the basis for concluding that the information presented in that section is that which is *most likely* to assist the selected subject population with making a decision. See **GUIDANCE: Key Information for Consent Materials**.

For example: Consultation with publications about research subjects' preferences, disease-focused nonprofit groups, patient interest groups, or other researchers/study staff with experience with the specific population. It may also involve directly consulting selected members of the study population.

Information provided in the consent materials will be based on previous depression treatment studies conducted in the area and informed by questions participants have asked during these past studies.

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

Information provided in the consent materials will be based on previous depression treatment studies conducted in the area and informed by questions participants have asked during these past studies.

8.3 Electronic presentation of consent information. Will any part of the consent-related information be provided electronically for some or all of the subjects?

This refers to the use of electronic systems and processes instead of (or in addition to) a paper consent form. For example, an emailed consent form, a passive or an interactive website, graphics, audio, video podcasts. See GUIDANCE: Electronic Informed Consent for information about electronic consent requirements at UW.

x	**No**	→ If no, skip to question 8.4
	Yes	→ If yes, answer questions **a** through **e**

a. Describe the electronic consent methodology and the information that will be provided.

All informational materials must be made available to the IRB. Website content should be provided as a Word document. It is considered best practice to give subjects information about multi-page/multi-screen information that will help them assess how long it will take them to complete the process. For example, telling them that it will take about 15 minutes, or that it involves reading six screens or pages.

b. Describe how the information can be navigated (if relevant). *For example, will the subject be able to proceed forward or backward within the system, or to stop and continue at a later time?*

c. In a standard paper-based consent process, the subjects generally have the opportunity to go through the consent form with study staff and/or to ask study staff about any question they may have after reading the consent form. Describe what will be done, if anything, to facilitate the subject's comprehension and opportunity to ask questions when consent information is presented electronically. Include a description of any provisions to help ensure privacy and confidentiality during this process.

Examples: hyperlinks, help text, telephone calls, text messages or other type of electronic messaging, video conference, live chat with remotely located study team members.

d. What will happen if there are individuals who wish to participate but who do not have access to the consent methodology being used, or who do not wish to use it? Are there alternative ways in which they can obtain the information, or will there be some assistance available? If this is a clinical trial, these individuals cannot be excluded from the research unless there is a compelling rationale.

For example, consider individuals who lack familiarity with electronic systems, have poor eyesight or impaired motor skills, or who do not have easy email or internet access.

e. How will additional information be provided to subjects during the research, including any significant new findings (such as new risk information) If this is not an issue, explain why.

8.4 Written documentation of consent. Which of the statements below describe whether documentation of consent will be obtained? NOTE: This question does not apply to screening and recruiting procedures which have already been addressed in question 4.7.

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. Is written documentation of consent being obtained for:

☐ None of the research procedures	→ Use the table below to provide justification then go to question **8.5.**
☒ All of the research procedures	→ Do not complete the table; go to question **8.4.b.**
☐ Some of the research procedures	→ Use the table below to identify the procedures for which written documentation of consent will not be obtained from adult subjects.

Adult subject group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO documentation of consent	Will they be provided with a written statement describing the research (optional)? YES	NO
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐

Table footnotes

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

b. Electronic consent signature. For studies in which documentation of consent will be obtained: will subjects use an electronic method to provide their consent signature?

- *FDA-regulated studies must use a system that complies with the FDA's "Part 11" requirements about electronic systems and records. Note that the UW-IT supported DocuSign e-signature system does not meet this requirement.*
- *Having subjects check a box at the beginning of an emailed or web-based questionnaire is not considered legally effective documentation of consent.*

☒ **No**

☐ **Yes** → If yes, describe the methodology that will be used.

See the GUIDANCE: Electronic Informed Consent for information about options (including the DocuSign system available through UW-IT) and requirements.

b.1 Is this method legally valid in the jurisdiction where the research will occur?

☐ **No**

☐ **Yes** → If yes, what is the source of information about legal validity?

b.2 Will verification of the subject's identity be obtained if the signature is not personally witnessed by a member of the study team? Note that this is required for FDA-regulated studies.

See the GUIDANCE: Electronic Informed Consent for information and examples

☐ **No** →If no, provide the rationale for why this is appropriate. Also, what would be the risks to the actual subject if somebody other than the intended signer provides the consent signature?

☐ **Yes** →If yes, how?

b.3 How will the requirement be met to provide a copy of the consent information (consent form) to individuals who provide an e-signature?

The copy can be paper or electronic and may be provided on an electronic storage device or via email. If the electronic consent information uses hyperlinks or other websites or podcasts to convey information specifically related to the research, the information in these hyperlinks should be included in the copy provided to the subjects and the website must be maintained for the duration of the entire study.

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

☐ **No**

☒ **Yes** → If yes, describe the process that will be used 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.

For all the subjects, English is not the first language, and a Kannada translated version of the consent will be used. The India research team speaks both English and Kannada and can answer any questions. The India research team will provide study information at point of consent and offer to answer questions. Research staff will offer to walk/talk them through the consent process and answer any questions. If the research team has concerns about a participant's comprehension, they will ask the participant to summarize their understanding of what they are consenting to do.

All staff engaged in research will receive training regarding the appropriate procedures for recruitment and consent, including training in how to explain the study in easy to understand language.

a. Interpretation. Describe how interpretation will be provided, 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.

India research staff obtaining consent will be local to the area and fluent in Kannada, the local language, and so will not require an interpreter.

b. Translations. Describe how translations will be obtained for all study materials (not just consent forms). Also, describe the method for ensuring 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.

The questionnaires we propose to use have validated Kannada versions. For study specific demographic questionnaires we will collaborate with the India team to create study materials that are similarly appropriate to the patient population. English study forms will be translated by the India team then back translated for accuracy.

8.6 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.

a. Describe the 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 written documentation of consent is not being obtained for any part of the research.

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

See 8.5 for discussion of how consent will be obtained for participants who do not read English well.

8.7 Deception. Will information be deliberately withheld, or will false information be provided, to any of the subjects?
Note: "Blinding" subjects to their study group/condition/arm is not considered to be deception, but not telling them ahead of time that they will be subject to an intervention or about the purpose of the procedure(s) is deception.

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

Example: It may be necessary to deceive subjects about the purpose of the study (describe why).

a. Will subjects be informed beforehand that they will be unaware of or misled regarding the nature or purposes of the research? (Note: this is not necessarily required.)

☐ **No**
☐ **Yes**

b. Will subjects be debriefed later? (Note: this is not necessarily required.)

☐ **No**
☐ **Yes** → If yes, describe how and when this will occur. Upload any debriefing materials, including talking points or a script, to ***Zipline***.

8.8 Cognitively impaired adults, and other adults unable to consent. Will such individuals be included in the 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 **8.9**.
☐ **Yes** → If yes, answer the following questions.

a. Rationale. Provide the rationale for including this population.

b. Capacity for consent / decision making capacity. Describe the process that will be used to determine whether a cognitively impaired individual is capable of consent decision making with respect to the research protocol and setting.

b.1. If there will be repeated interactions with the impaired subjects over a time period when cognitive capacity could increase or diminish, also describe how (if at all) decision-making capacity will be re-assessed and (if appropriate) consent obtained during that time.

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

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

d. 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 that will be used to obtain and document assent from the subjects.

e. Dissent or resistance. Describe how a subject's objection or resistance to participation (including non-verbal) during the research will be identified, and what will occur in response.

8.9 Research use of human fetal tissue obtained from elective abortion. Federal and UW Policy specify some requirements for the consent process. If you are conducting this type of research, check the boxes to confirm these requirements will be followed. N/A

- ☐ Informed consent for the donation of fetal tissue for research use will be obtained by someone other than the person who obtained the informed consent for abortion.
- ☐ Informed consent for the donation of fetal tissue for research use will be obtained after the informed consent for abortion.
- ☐ Participation in the research will not affect the method of abortion.
- ☐ No enticements, benefits, or financial incentives will be used at any level of the process to incentivize abortion or the donation of human fetal tissue.
- ☐ The informed consent form for the donation of fetal tissue for use in research will be signed by both the woman and the person who obtains the informed consent.

8.10 Consent-related materials. Upload to ***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 that will be used. Materials that will be used by a specific site should be uploaded to that site's **Local Site Documents** page.

- *Translations must be submitted and approved before they can be used. However, we strongly encourage you to wait to provide them until the IRB has approved 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. URLs (website addresses) may also be provided, or written descriptions of websites. 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. Describe the steps that will be taken, if any, to address possible privacy concerns of subjects and potential subjects.

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 procedure (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.*

The consent form list steps to ensure privacy of information. We will talk with participants about any concerns or questions they have of privacy protections.

9.2 Identification of individuals in publications and presentations. Will potentially identifiable information about subjects be used in publications and presentations, or is it possible that individual identities could be inferred from what is planned to be published or presented?

[x] **No**
[ ] **Yes** → If yes, will subject consent be obtained for this use?
  [ ] **Yes**
  [ ] **No** → If no, describe the steps that will be taken 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 the research team likely to learn of any of the above events or circumstances while conducting the research **AND** feel obligated to report it to state authorities?

[x] **No**
[ ] **Yes** → If yes, the UW IRB expects subjects to be informed 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 and data. Check the box below to indicate assurance that any identifiers (or links between identifiers and data/specimens) and data that are part of the research records will not be destroyed until after the end of the applicable records retention requirements (e.g. Washington State; funding agency or sponsor; Food and Drug Administration). If it is important to say something about destruction of identifiers (or links to identifiers) in the consent form, state something like "the link between your identifier and the research data will be destroyed after the records retention period required by state and/or federal law."

This question can be left blank for conversion applications (existing paper applications that are being "converted" into a Zipline application.)

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/gs/research?title=R

See the "Research Records and Data" information in Section 8 of this document for the retention schedules for UW Medicine Records: ***https://www.uwmedicine.org/recordsmanagementuwm-records-retention-schedule.pdf***

[x] **Confirm**

9.5 Certificates of Confidentiality. Will a federal Certificate of Confidentiality be obtained for the research data? *NOTE: Answer "No" if the study is funded by NIH or the CDC, because all NIH-funded and CDC-funded studies automatically have a Certificate.*

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

9.6 Data and specimen security protections. Identify the data classifications and the security protections that will be provided for all sites where data will be collected, transmitted, or stored, referring to the ***ZIPLINE* GUIDANCE: Data and Security Protections** for the minimum requirements for each data classification level. ***It is not possible to answer this question without reading this document. Data security protections should not conflict with records retention requirements.***

a. Which level of protections will be applied to the data and specimens? If more than one level will be used, describe which level will apply to which data and which specimens and at which sites.

Level 4

b. Use this space to provide additional information, details, or to describe protections that do not fit into one of the levels. If there are any protections within the level listed in 9.6.a which will *not* be followed, list those here, including identifying the sites where this exception will apply.

N/A

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 the risks will be reduced or managed. Do not describe data security protections here, these are already described in Question 9.6.

- *Consider possible physical, psychological, social, legal, and economic harms, including possible negative effects on financial standing, employability, insurability, educational advancement or reputation. For example, a breach of confidentiality might have these effects.*
- *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.*

Participating in a depression research trial may lead to stigma within the subjects' community. We will attempt to mitigate this by providing depression education within the broader community. Additionally, screening and stepped care treatment for depression will be within an app designed to screen for physical health as well, ensuring that women with depression are not singled out.

10.2 Reproductive risks. Are there any risks of the study procedures to men and women (who are subjects, or partner of subjects) related to pregnancy, fertility, lactation or effects on a fetus or neonate?

Examples: direct teratogenic effects; possible germline effects; effects on fertility; effects on a woman's ability to continue a pregnancy; effects on future pregnancies.

[x] **No** → If no go to question 10.3

[ ] **Yes** → If yes, answer the following questions:

a. Risks. Describe the magnitude, probability, duration and/or reversibility of the risks.

b. Steps to minimize risk. Describe the specific steps that will be taken to minimize the magnitude, probability, or duration of these risks.

Examples: inform the subjects about the risks and how to minimize them; require a pregnancy test before and during the study; require subjects to use contraception; advise subjects about banking of sperm and ova.

If the use of contraception will be required: describe the allowable methods and the time period when contraception must be used.

c. Pregnancy. Describe what will be done if a subject (or a subject's partner) becomes pregnant

For example; will subjects be required to immediately notify study staff, so that the study procedures can be discontinue or modified, or for a discussion of risks, and/or referrals or counseling?

10.3 MRI risk management. *Answer this question only if the subjects will receive MRI scans*. A rare but serious adverse reaction called nephrogenic systemic fibrosis (NSF) has been observed in individuals with kidney disease who received gadolinium-based contrast agents (GBCAs) for the scans. Also, a few healthy individuals have a severe allergic reaction to GBCAs.

a. Describe how the renal function of subjects will be assessed prior to MRI scans and how that information will be used to exclude subjects at risk for NSF.

N/A

b. Describe the protocol for handling a severe allergic reaction to the GBCA or any other medical event/emergency during the MRI scan, including who will be responsible for which actions.

N/A

10.4 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.

10.5 Subjects who will be under regional or general anesthesiology. Will any research procedures occur while 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 any of the boxes are checked:
Provide the name and institutional affiliation of a physician anesthesiologist who is a member of the research team or who will serve as a safety consultant about the interactions between the research procedures and the general or regional anesthesia of the subject-patients. If the procedures will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member, and the Vice Chair of Clinical Research in the UW Department of Anesthesiology and Pain Medicine must be consulted in advance for feasibility, safety and billing.

*** If the box about radio-isotopes is checked: the study team is 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.*

10.6 Data and Safety Monitoring. A Data and Safety Monitoring Plan (DSMP) is required for clinical trials (as defined by NIH). If required for this research, or if there is a DSMP for the research regardless of whether it is required, upload the DSMP to ***Zipline***. If it is embedded in another document being uploading (for example, a Study Protocol) use the text box below to name the document that has the DSMP. Alternatively, provide a description of the DSMP in the text box below.

DSMP has been uploaded

10.7 Un-blinding. If this is a double-blinded or single-blinded study in which the participant and/or relevant study team members 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 – app based study – participants will know what intervention they are getting

10.8 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 from the trial in case of emergent suicidal ideation or new psychosis as they will be directed to a higher level of care.

10.9 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.

All participants will receive standardized depression education. Participants randomized to the intervention will receive the MITHRA intervention for the treatment of depression.

10.10 Return of individual research results.

In this section, provide your plans for the return of individual results. An "individual research result" is any information collected, generated or discovered in the course of a research study that is linked to the identity of a research participant. These may be results from screening procedures, results that are actively sought for purposes of the study, results that are discovered unintentionally, or after analysis of the collected data and/or results has been completed.

*See the **GUIDANCE Return of Individual Results** for information about results that should and should not be returned, validity of results, the Clinical Laboratory Improvement Amendment (CLIA), consent requirements and communicating results.*

a. Is it anticipated that the research will produce any individual research results that are clinically actionable?

"Clinically actionable" means that there are established therapeutic or preventive interventions or other available actions that have the potential to change the clinical course of the disease/condition, or lead to an improved health outcome.

In general, every effort should be made to offer results that are clinically actionable, valid and pose life-threatening or severe health consequences if not treated or addressed quickly. Other clinically actionable results should be offered if this can be accomplished without compromising the research.

[ ] **No**
[x] **Yes** → If yes, answer the following questions (a.1-a.3).

a.1. Describe the clinically actionable results that are anticipated and explain which results, if any, could be urgent (i.e. because they pose life-threatening or severe health consequences if not treated or addressed quickly).

Examples of urgent results include very high calcium levels, highly elevated liver function test results, positive results for reportable STDs.

Research assessments include measures of depression which may indicate depression which will need treatment. We will inform subjects who score above the clinical cut off the results of their questionnaire and advise them to share these results with their primary care provider and seek treatment for depression.
For all subjects, whether they score above the cut off or not, anyone who scores anything other than 0 on the 9th question of the PHQ-9 will be informed of this and will receive further assessment / intervention as outlined in the attached suicidality protocol.

a.2. Explain which of these results will be offered to subjects.

Depression scores
Suicidal ideation / thoughts of self-harm

a.3. Explain which results will not be offered to subjects and provide the rationale for not offering these results.

Reasons not to offer the results might include:

- *There are serious questions regarding validity or reliability*
- *Returning the results has the potential to cause bias*
- *There are insufficient resources to communicate the results effectively and appropriately*
- *Knowledge of the result could cause psychosocial harm to subjects*

N/A

b. What is the plan (if any) for offering subjects any results that are not clinically actionable?

Examples: non-actionable genetic results, clinical tests in the normal range, experimental and/or uncertain results.

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

→ If yes, explain which results will be offered to subjects and provide the rationale for offering these results.

c. Describe the validity and reliability of any results that will be offered to subjects.

The IRB will consider evidence of validity such as studies demonstrating diagnostic, prognostic, or predictive value, use of confirmatory testing, and quality management systems.

N/A

d. Describe the process for communicating results to subjects and facilitating understanding of the results. In the description, include who will approach the participant with regard to the offer of results, who will communicate the result (if different), the circumstances, timing, and communication methods that will be used.

N/A

e. Describe any plans to share results with family members (e.g. in the event a subject becomes incapacitated or deceased).

N/A

f. Check the box to indicate that any plans for return of individual research results have been described in the consent document. If there are no plans to provide results to participants, this should be stated in the consent form.

*See the **GUIDANCE Return of Individual Results** for information about consent requirements.*

[x] **Confirmed**

10.11 Commercial products or patents. Is it possible that a commercial product or patent could result from this study?

[x] **No**

[ ] **Yes** → If yes, describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined.

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.

For each institution involved in conducting the research: 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.

N/A

11.2 Costs to subjects. Describe any research-related costs for which subjects and/or their health insurance may be responsible (examples might include: CT scan required for research eligibility screening; co-pays; surgical costs when a subject is randomized to a specific procedure; cost of a device; travel and parking expenses that will not be reimbursed).

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 the 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 UW Principal Investigator Qualifications. Upload a current or recent Curriculum Vitae (CV), Biosketch (as provided to federal funding agencies), or similar document to the Local Site Documents page in Zipline. The purpose of this is to address the PI's qualifications to conduct the proposed research (education, experience, training, certifications, etc.).

For help with creating a CV, see http://adai.uw.edu/grants/nsf_biosketch_template.pdf and https://education.uwmedicine.org/student-affairs/career-advising/year-4/residency-applications/curriculum-vitae/

[x] **The CV will be uploaded.**

12.3 UW Study team qualifications. Describe the qualifications and/or training for each UW study team member to fulfill their role on the study and perform study procedures. (You may be asked about non-UW study team members during the review; they should not be described here.) You may list these individuals by name, however if you list an individual by name, you will need to modify this application if that individual is replaced. Alternatively, you can describe study roles and the qualifications and training the PI or study leadership will require for any individual who might fill that role. The IRB will use this information to assess whether risks to subjects are minimized because study activities are being conducted by properly qualified and trained individuals.

Describe: The role (or name of person), the study activities they will perform, and the qualifications or training that are relevant to performing those study activities.

Amritha Bhat, MD, MPH, PD/PI is Assistant Professor, Department of Psychiatry and Behavioral Sciences, University of Washington. She will oversee all aspects of the project along with the India PI. She will be responsible for data analyses and data interpretation. She has extensive experience in primary care based mental health care and women's mental health. She has also previously worked in India, in rural settings, and in the community mental health clinic identified in the application. She has trained care managers in Behavioral Activation in several integrated mental health implementations. She will serve as the UW PI. She will establish policy on project operations and budget management, supervise data analyses, and finalize all reports.

Throughout the study Dr. Bhat will provide project oversight and meet weekly with staff and team leaders about study implementation and clinical issues. Additionally, she will be available for guidance on content development for the Behavioral Activation intervention and will coordinate the ECHO learning sessions.

Pamela Collins, MD, Co I is Professor in the Departments of Psychiatry and Global Health and will serve as co Investogator on the study. She will provide support and oversight of the qualitative methodology in phase I of the app development. She has several years experience in global mental health, stigma reduction and competency-based training of lay health workers for delivery of psychological interventions. She will meet regularly with the UW and India teams and participate actively in study conduct and mixed methods and in ECHO learning sessions.

Research Coordinator TBD will be a bachelor's level individual with experience in the conduct of research studies. They will assist with the day to day grant related activities at UW and help schedule meetings and training sessions. They will assist with IRB applications and ensure data collection activities, manuscript preparation and dissemination activities are occurring as outlined in the grant proposal timeline.

12.4 Study team training and communication. Describe how it will be ensured 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.**

All study team members will have copies of the current UW IRB procedures and requirements. They will follow these guidelines in their related duties and functions.

13 OTHER APPROVALS, PERMISSIONS, and REGULATORY ISSUES

13.1 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.

Institutional Ethics Committee (IEC), St.John's Medical College & Hospital, St.John's National Academy of Health Sciences, Sarjapur road, Bangalore-34, Karnataka, India

13.2 Financial Conflict of Interest. Does any UW member of the team have ownership or other Significant Financial Interest (SFI) with this research as defined by UW policy GIM 10?

☒ **No**

☐ **Yes** → If yes, has the Office of Research made a determination regarding this SFI as it pertains to the proposed research?

- ☐ **No** → If no, contact the Office of Research (206.616.0804, research@uw.edu) for guidance on how to obtain the determination
- ☐ **Yes** → If yes, upload the Conflict Management Plan for every UW team member who has a FCOI with respect to the research, to ***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 and include the FIDS Disclosure ID if available.

Statistical Methods:

Assumptions of normality was assessed using Q-Q plot. Descriptive statistics, mean and standard deviation for normally distributed variables were used to describe the outcome parameters PHQ, QIDS. WHODAS and BADS. Chi-square test or Fisher's exact tests as appropriate, was used to test the association between baseline characteristics between study groups. At each time of assessment, outcome parameters were compared between study groups using independent t test or Mann Whitney U test as appropriate. Change in the outcome at 3 and 6 months from baseline was compared between the study groups using Wilcoxon signed rank test. McNemar Chi-square test was used to compare the change in the proportion of depression categories from baseline within each study group. In addition, RMANOVA was performed to compare the change in the outcome scores over time between study groups. A p-value of < 0.05 was considered statistically significant. All analyses were performed using SPSS version 26.0.

UNIVERSITY OF WASHINGTON
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

STUDY TITLE: Mobile Mental Health in Community-Based Organizations: A Stepped Care Approach to Women's Mental Health

This is a research study that aims to examine your experience and thoughts after using the app on the tablet in Community Based Organizations (CBO), (Multiuser Interactive Health Response Application (MITHRA) to help identify and provide information about treatment for common physical and mental problems. Srinivasan K, MD, St. John's Medical College, Bangalore, India, and Amritha Bhat, MD, MPH, Department of Psychiatry and Behavioral Sciences, University of Washington Seattle, Seattle, Washington, are the principal investigators leading the study team. This study is funded by the National Institute of Health.

RESEARCHER STATEMENT
We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY
The purpose of this study is to examine your expereince and thoughts after using the app on the tablet in Community Based Organizations (CBO), (Multiuser Interactive Health Response Application (MITHRA) This research is being done in order to improve apps that can be used to identify depression and provide information about treatment among women attending community based organization meetings.

NUMBER OF PARTICIPANTS
There will be approximately 60 women this project. 30 women will receive depression education during their CBO meetings from the community health worker, and 30 women will use the app provided in the CBO which will have information and questions on physical and mental health.

STUDY PROCEDURES
You are being asked to take part in the research study because you attend meetings at the CBO. If you agree to participate, the following procedures will occur:

- You can continue to attend your CBO meetings.
- In addition, you will receive education about depression by the community health worker in your CBO groups.
- If your CBO is randomly chosen to receive the app, you will use the app every time you come into the CBO for a meeting. You will spend 15 -20 minutes using the app in privacy, answering questions and watching videos. You may be asked to complete some simple activities at home, such as going for regular walks.

- If the app identifies depression of higher severity, the CHW will help connect you to a doctor at the primary care clinic.
- A research team member will call you or meet with you every 3 months and ask you questions about your mood and health – this will take approximately 15 minutes.
- After the study ends, you may be invited to participate in one of 1-2 focus groups, where you will be asked about your perceptions and experiences with the mobile app.

RISKS, STRESS, OR DISCOMFORT

The primary risk in participating in the study is loss of privacy. In order to reduce this risk, all data will be transmitted and stored securely. No individual-level information related to the study will be made available in any communications, oral reports, or publications.

ALTERNATIVES TO PARTICIPATION

You can choose to not participate in the study – the alternative is to not enroll in the study and instead continue to participate in the CBO meeting as usual.

RETURN OF RESULTS

Research assessments include measures of depression which may indicate depression which may need treatment. We will inform you if you score high on these questionnaires so that you may share these results with your primary care provider and seek treatment for depression.

BENEFITS OF THE STUDY

You will receive depression education free of charge. We anticipate that you will receive useful information on mental health, depression and on helpful treatments. There are no additional benefits to you related to the research project. The results of the proposed study will provide critical generalizable knowledge regarding the feasibility and acceptability of providing parenting intervention to women engaged in depression treatment.

USING YOUR DATA IN FUTURE RESEARCH

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that information and specimens may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

CONFIDENTIALITY OF RESEARCH INFORMATION

All of the information you provide will be confidential. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. However, if we learn that you intend to harm yourself or others, we must report that to the authorities. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. Our study team at the University of Washington, will have access to your data.

We have a Certificate of Confidentiality from the federal National Institute of Mental Health]. This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;
- Relevant authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the NIMH funding for this study ends. Currently this is 05/31/2023. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

All identifying information collected as part of the study will be stored in a database on a secure server and will be password protected with limited access. Study data and audio and video recordings will be labeled with a unique study identification numbers. The link between your identifying information and the research data will be destroyed after the study is complete and the records retention period required by state and/or federal law has been met.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

This study will result in the development of an app which we hope to disseminate for use. We will not provide individual participants with the results of the study. This study has been funded by the National Institute of Mental Health.

You will also receive compensation for your time participating in interviews (Rs.200 per interview). This payment may take 6 – 8 weeks after completion of interview, to reach you.

You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact the study coordinator, or the principal investigator of the study, Dr. Srinivasan K at St. John's Hospital +91 80 4946 6029.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the University of Washington Human Subjects Division at 206-543-0098.

CONSENT

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

_____

Printed name of subject Signature of subject Date

_____

Printed name of study staff obtaining consent Signature Date

Copies to: Researcher
Subject