ENHANCING ENGAGEMENT WITH DIGITAL MENTAL HEALTH CARE

STUDY00010958

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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: Enhancing Engagement with Digital Mental Health Care

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**
☒ **Yes** → If yes, briefly describe the consultation: approximate date, with whom, and method (e.g., by email, phone call, in-person meeting).

Emails during the grant proposal process with Elizabeth Falsberg
Emails with Reliance team during grant proposal process for letter of support for UW's IRB to serve as the single IRB on this project

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.

☒ **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.

We have received a JIT request from NIMH. Due to their funding year (ending in September), they've requested IRB approval (along with other JIT materials) prior to Council review.

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).

Digital mental health (DMH) is the use of technology to improve population well-being through rapid disease detection, outcome measurement, and care. DMH is a rapidly evolving sector, and it is estimated that the market share will reach $509.2 billion by 2025. Several randomized clinical trials have demonstrated that DMH tools are highly effective and capable of incredible reach with impressive return on investment. However, most consumers do not fully engage; the average length of engagement is only 2-4 weeks, with most consumers discontinuing use within hours of downloading. Studies on the impact that limited DMH engagement has on consumer outcomes are mixed. For instance, our work found that DMH engagement may be cyclical, with consumers engaging in short bursts over time, depending on current needs and goals. Research on the relationship between engagement and outcomes is mixed, indicating the study of engagement is incomplete without careful tracking of DMH's impact on improving mental well-being. Thus, the field currently lacks an understanding of DMH engagement patterns and which practices are effective at sustaining engagement or re-engaging users who are likely to benefit. In this partnership among Mental Health America (MHA), Talkspace (TS) and the University of Washington (UW), we aim to study 1) how consumer engagement in DMH varies, 2) the association between engagement and positive outcomes, and 3) the effectiveness of personalized strategies for optimal engagement with DMH treatment. We leverage established theories of health behavior change and the use of DMH to achieve health goals (the Health Action Process Approach and the Lived Informatics Model). This study will prospectively follow a very large, naturalistic sample of MHA and TS consumers, and will apply micro-randomized trials to address the following aims:

AIM 1: To characterize patterns of DMH engagement, the proportion of DMH consumers who fall into different engagement categories, and the outcomes associated with different engagement categories.

H1a: Engagement longevity, content, and selected DMH services will vary across baseline characteristics (symptom severity, stated goals, demographics).

H1b: DMH engagement will cluster into (1) non-engagers (visit MHA or TS, do not use any services), (2) pre-intenders (use screen, use materials about condition), (3) intenders (e.g.: review psychoeducation materials or conduct an initial intake), (4) actors (click on MHA services or communicating with TS therapist) and (5) cyclers (re-engage with screens, materials, providers over time). Data will include observational data from webpage and

app use behavior (demographics, logins, time between logins, re-enrollments, time between re-enrollments, click-throughs, time on pages, text frequency between TS consumers and therapists) and self-report measures currently collected by MHA and TS (self-reported goals/needs, self-efficacy, symptom severity, working alliance, service satisfaction, perceived match of service to needs).
AIM 2: Create predictive engagement subtypes based on descriptive findings in Aim 1 and identify consumer engagement characteristics and behavior that predict future DMH engagement.
H2a: Using supervised machine learning approaches with existing and prospectively collected data, we predict that new engagement subtypes will emerge based on consumer demographics (e.g.: age, gender, income level, ethnicity, symptoms severity), engagement patterns identified in Aim 1, reasons for disengagement (self-efficacy; perceived need; outcome expectations; goals were met, not met, or changed), and satisfaction with the DMH tools. We predict these subtypes will vary in their engagement patterns and will be predictive of outcomes from prospective micro-trials of engagement strategies based on HAPA and LIM principles conducted in Aim 3.
H2b: (TS only) Enable language content in machine learning methods for subtype discovery. We will analyze text-based consumer-therapist interactions using Natural Language Processing (NLP) approaches to identify language markers predictive of engagement and HAPA-informed constructs: task, maintenance and recovery self-efficacy, planning quality, perceived risks/needs of behavior change, and outcome anticipation.
AIM 3a: Develop and test the effectiveness of engagement strategies using a series of micro-randomized trials on thousands of consumers, to be developed based on what we learn about engagement subtypes that are at risk of poor outcomes.
AIM 3b. Using a SMART designed trial of 10,000 TS consumers, of which 250 will participate in a survey after they discontinue treatment for two weeks, we will compare effective engagement strategies tailored to subtypes developed under Aim 2 to study the mediated impact of engagement strategies on consumer mental health outcomes (e.g. PHQ9). This activity will occur in Y04 of the partnership. We will prospectively recruit participants into micro-randomized and SMART trials to collect additional survey information on participants about self-efficacy (task, coping and recovery), perceived risk/needs, planning skills and anticipated outcomes. We will determine if engagement strategies targeted to consumer engagement subtype will enhance engagement and in turn result in improved clinical outcomes. These will be compared to generic strategies that are not subtype targeted.
Update August 2023: Talkspace will no longer be involved for year 4 of the project and will not complete activities for aim 3B. All aim 3B activities will occur with MHA, broken down into two parts: (1) a Sequential Multiple Assigment Randomized Trial (SMART) of a projected 50,000+ participants and (2) a DIY tool longitudinal randomized control trial (RCT). This is possible with no change in our aim purpose or final budget.

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.

This is a prospective, longitudinal and iterative study, divided into three phases:
Phase 1: Data analysis of existing data from 100,000 MHA and TS of data collected between 2020 and the end of Y01 of the project.
Phase 2: Building off findings from Phase 2, rapid and iterative micro-trials (MRTs) of engagement strategies
Phase 3: a culminating sequential multiple assignment randomized trial (SMART) used to optimize match between client subtypes identified in Phase 2 and engagement strategies identified in Phase 1.

This initial IRB application is for Phase 1 activities only. Subsequent modifications will be submitted for Phase 2 and Phase 3 once appropriate.

February 2022: This modification is for Phase 2 activities. A modification for approval of Phase 3 activities will be submitted when appropriate.

August 2023: This modification is for Phase 3b, including modifications requiring approval for phase 3B related activities, and with the pivot of aim 3B to be conducted with MHA, we will be carrying out two studies to meet our aims. Study 1 will use a SMART to examine methods to optimize engagement with MHA's website (50,000 participants) and Study 2 will recruit 300 participants for a longitudinal monthlong study where they are randomly assigned to a control group, the use of a DIY tool without AI, or the use of a DIY tool with AI to examine the efficacy of using a digital too to improve mental health functioning.

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.
X	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:

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)
- 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.

Digital mental health (DMH) is the use of technology to improve population well-being through rapid disease detection, outcome measurement, and care. DMH is a rapidly evolving sector, and it is estimated that the market share will reach $509.2 billion by 2025. Several randomized clinical trials have demonstrated that DMH tools are highly effective and capable of incredible reach with impressive return on investment. However, most consumers do not fully engage; the average length of engagement is only 2-4 weeks, with most consumers discontinuing use within hours of downloading. Studies on the impact that limited DMH engagement has on consumer outcomes are mixed. For instance, our work found that DMH engagement may be cyclical, with consumers engaging in short bursts over time, depending on current needs and goals. Research on the relationship between engagement and outcomes is mixed, indicating the study of engagement is incomplete without careful tracking of DMH's impact on improving mental well-being. Thus, the field currently lacks an understanding of DMH engagement patterns and which practices are effective at sustaining engagement or re-engaging users who are likely to benefit.

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.

The three institutional partners have deep expertise relevant to the current proposal. The scientific team consists of experts in mobile mental health technology, remote research methods, mental health clinical trials and engagement in mental health services, and machine learning/natural language processing.

1. Ability test hypotheses with a very large sample of DMH consumers. We propose to test our hypotheses with a very large sample of DMH consumers, proposing to analyze 100,000 consumers in Aim 1, 50,000 in Aim 2 and 10,000 in Aim 3, where we will also prospectively recruit and collect ground truth data on 250 consumers at TS. MHA Screening (mhascreening.org) is a confidential and anonymous screening and self-guided service platform. Nearly 3,000 people complete MHA's online mental health screens every day, resulting in nearly 5 million screens to date. An average of 2,000 individuals a month will click through to

educational materials, testimonials, videos, forums and self-guided strategies. Currently, an average of 700 users per month will continue onto one of several recommended service providers. TS is a digital mental health platform that provides access to licensed clinicians via text-messaging and video chats. Talkspace experiences similar numbers to MHA. Their website receives 50,000 visits daily and has 30,000 individuals receiving care on average at any given time. Given the volume of users that use MHA and TS services, we will easily meet our needed sample of 100,000 for Aim 1, 50,000 for Aim 2 and 10,000 for Aim 3.

2. Ability to create DMH engagement subgroups using data currently collected by MHA and TS. Both MHA and TS currently collect a considerable amount of objective and subjective information from their consumers regarding their demographics, symptom severity, goals for seeking care, and their use of services. Demographically, the two organizations serve similar populations. At MHA, consumers are primarily a help-seeking population with higher percentages of low-income individuals (over 50% report household income below $40,000 a year), who are at risk for mental health conditions (74% of screeners score "positive" or above criteria of concern), and have never been treated for their condition (65% of those who screen positive report having no current or past mental health diagnosis). TS consumers are also primarily first-time treatment seekers (60% report no prior mental health treatment) and most report symptoms at baselines that indicate risk for a mental health condition (70% score above clinical thresholds). Whether paying out of pocket or using insurance, TS users tend to be middle-higher income individuals and 75% report a Bachelors' degree or higher. Information on service use differs between MHA and TS because of the differences in their platforms and DMH offerings. MHA service use is defined by the use of self-help tools, use of services MHA recommends (including therapeutic video games, forums and linkages to Talkspace), and time using MHA created tools. Self-reported tools at MHA include screeners, reasons for searching, and satisfaction with tools offered and used. TS service use is defined by number of texts sent, time between texts, use of educational materials TS creates, completion of self-rating scales, and text content. Self-report measures collected by TS include measures of working alliance, treatment satisfaction and an exit interview at time of termination. See Table 1 for full details. The wealth of data available for analysis will allow us to create rich, informative engagement clusters that will inform future subgroups for Aim 2 and to be tested in Aim 3.

3. DMH services at MHA and TS. MHA has been testing use and engagement of DMH in four categories: mental health information (Like WebMD), referrals to care, peer to peer communities and forums, and "Do it Yourself" internet interventions and apps. Included in this are therapeutic games, and app-based CBT strategies. Talkspace offers three plan types: unlimited texting (92% of consumers choose this plan), unlimited texting plus monthly video chat (6%), and unlimited texting plus weekly video chat (2%). Therapists respond to text within 15 minutes to an hour during office hours, and within 3 hours outside of office hours (except at night when up to 10 hours can separate responses). Thus, texting is not fully synchronous. This enables therapists to deliver care to a larger number of patients than is possible under synchronous methods by disentangling the therapist's time to respond from the patient's time to generate a message. It also has the potential to improve quality as it gives the therapist time to think through the most effective response and intervention. Texting is based on CBT, PST or IPT intervention strategies. In addition to this standard of care, consumers also may access mental health apps focused on relaxation, mindfulness training and goal setting. Between the two platforms, MHA and TS offer the most common forms of DMH on the market: screening, symptom monitoring, educational materials, peer communities, therapeutic games, CBT based tools and apps, message-based care and video chat care.

4. Preliminary work to create engagement subgroups. MHA has conducted research to identify and better serve user subtypes based on presenting need and other issues, and worked to improve access and relevance of the site to these users. As one example, in 2019 MHA focused on Bipolar Disorder. Nearly half of a million people either took a screen for Bipolar Disorder or read resources. MHA found that these people were more likely than average to be seeking information and treatment resources, especially urgently. This led to the development of additional articles and materials to support this subgroup of consumers, such as a podcast, and to better organize online materials relevant to this population. TS has also been involved in research to uncover engagement patterns and search for methods to increase engagement. We conducted preliminary

analyses on over 10,000 TS consumers to identify engagement patterns that determine initial predictors of DMH engagement. TS collected the PHQ-9 on consumers every 3 weeks. Completion of these measures is a good indicator of clinical engagement in treatment. Results indicated engagement was a function of plan type and symptom severity. Of the three plan types, weekly video chat had the largest early disengagement, with only 17% of those enrolled engaged longer that 6 weeks (fig 2a). 40% of consumers initiate treatment but do not engage for 3 weeks, 21% do not engage longer than 6 weeks and another 12% do not engage past 9 weeks. Only 2% engage for a full year (fig 2). Consumers who exhibit more symptoms at intake assessment are less likely to disengage from treatment, with the odds of disengagement decreasing by 3.3% for each additional point on intake PHQ-9. However, higher symptoms over the course of care results in greater disengagement, with the odds of disengagement increasing by 5.3% for each additional point on the final PHQ-9 assessment completed. Both MHA and TS are highly motivated to understand engagement and the impact engagement has on clinical outcomes.

5. Ability to conduct micro-randomized trials and SMART trials of engagement strategies. Both MHA and TS continuously conduct marketing-based research to improve their outreach and engagement of consumers with mental health needs. MHA conducts experimental user testing on engagement such as modifying tone, placement, and medium (written vs audio) of education materials, modifying language and linkages to services like telehealth partners, adding relevant links to other materials, and improving the formatting of articles for clarity. These efforts reduced the bounce rate (the rate at which users leave a page without taking any further actions on the site) for edited pages from 91% to 68% on average, and increased the average time spent on the site during a session by 15%. MHA has conducted microtrials evaluating user experiences comparing algorithm-driven resource selection to manually selected resources, and found users prefer manually selected resources. These tests have used simple pre-post manipulation of website materials; the current grant proposal would provide funding for more complex, causal design testing using MRTs and SMART methods. The goal of the projects is to understand what level of engagement users in the earliest stages of recovery are willing to engage in and what factors might increase utilization of high investment services. TS has similarly designed and tested onboarding and treatment engagement strategies that seek to 1) increase likelihood of beginning treatment, and 2) increase the likelihood of treatment completion. Onboarding strategies include modifying informational pages with different media (testimonials, therapist background information, patient education and self-assessment materials, an interactive chatbot experience, etc.), therapy benefits, financial incentives, and calls to action. Once individuals begin treatment, TS shifts effort to improving treatment completion rates by providing therapist match recommendations, collecting and reporting outcomes to users and therapists, integrating evidence-based exercises/worksheets in an interactive interface, and providing feedback to therapists regarding user engagement and pacing of therapy.

In summary, these preliminary data point to our ability to test critical questions about DMH engagement and its impact on outcomes with a very large and representative sample of DMH users in the time frame we specify for this project, owing to exiting data, a continuous stream of consumers, existing platforms to conduct clinical trials and expertise in engagement research and big data analysis.

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.	SUPPLEMENT Department of Defense

☐	**Department of Energy** The research involves Department of Energy funding, facilities, data, or personnel.	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	SUPPLEMENT Drugs
☐	**Emergency exception to informed consent** Research that requires this special consent waiver for research involving more than minimal risk	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	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	SUPPLEMENT Devices
☒	**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.	SUPPLEMENT: Multi-site or Collaborative Research
☐	**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
☐	None of the above	

1.10 Confirm by checking the box below that you will have (a) developed and implemented the Return to In-Person Research Plan and (b) completed all of the relevant activities listed on the CHECKLIST Human Subjects Research During the COVID-19 Pandemic before beginning your research. Failure to meet the applicable requirements in these Checklists will be considered non-compliance.

Review the HSD website for current guidelines about which in-person research activities are allowable.

☒ **Confirmed**

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.

The initial IRB application is for Phase 1 activities only. Modifications will be submitted when appropriate for Phase 2 and 3 procedures.

Phase 1

Phase 1 data analysis (100,000) participants will be consumers who are seeking services from Mental Health America (MHA) and Talkspace (TS). MHA and TS offer services in both English and Spanish, thus we will include both English and Spanish speakers. English and Spanish speaking MHA consumers will be identified as such based on the language in which they choose to interact with the website (e.g. taking an English language or Spanish language screen). For TS consumers, previous data analysis shows that 99.5% of services are provided in English. If services are provided in Spanish, this information is available via the site's meta-data and will be noted in the dataset. Participants will be largely female, representative of the US population and who have screened positive to any mental health problem. While we anticipate that most participants will be 14 and older, MHA consumers may be as young as 6. We anticipate that most will be suffering from depression or anxiety.

Phase 1 focus group participants will be randomly chosen from MHA and TS English speaking consumers aged 18 and over.

During Phase 1, Talkspace will invite consumers to complete a survey about communications from Talkspace. These survey respondents will be English speaking, TS consumers aged 18 and over who choose to respond to invitations received in-app, by email, or as a push notification.

Phase 2
Phase 2 micro-randomized trial (MRT) participants will be the same as Phase 1 participants: consumers seeking services from MHA and TS, including both English and Spanish speakers with no exclusion criteria around age, gender, clinical presentation or other attribute.

Phase 2 focus group participants will be English speaking MHA and TS consumers aged 18 and over.

Phase 3b: Participants for data collection of Study 1, (SMART trial) will be consumers seeking services from MHA who have chosen to start the PHQ-9 mental health test in English on the MHA platform. They will include those who can read English, with no exclusion criteria around age, gender, or clinical presentation or other attributes.

The inclusion/exclusion criteria for Study 2 (the survey data collection on 250 participants) will be more selective. These participants will be consumers seeking services from MHA, and more specifically those who based on either of these screeners have identified as experiencing at least moderate symptoms of depression and/or anxiety. Participants will be 18 and older with little to no experience with the concept of cognitive reframing.

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.

Phase 1
Phase 1 data analysis activities: Consumers seeking services from MHA and TS, English and/or Spanish speaking

Phase 1 Focus Group participants will be randomly chosen from MHA and TS English speaking consumers aged 18 and over

Phase 1 Talkspace Survey: English speaking TS consumers, aged 18 and over

Phase 2
Phase 2 micro-randomized trials (MRTs): Consumers seeking services from MHA and TS, English and/or Spanish speaking

Phase 2 focus groups: MHA and TS consumers aged 18 and over

- Talkspace only: Focus groups launching in November 2022 will focus on users' thoughts and reactions to receiving nudges (e.g., push notifications, emails) and their impact on engagement with the platform. For these focus groups only, inclusion criteria will be TS consumers aged 18 and over who have used Talkspace messaging-based therapy in the past 3 months, and have the Talkspace mobile app installed on their mobile device

Phase 3

Phase 3b Study 1 SMART trial participants will be consumers seeking to take a mental health test from MHA and able to read English

Phase 3b Study 2 longitudinal survey participants will be consumers who have completed an English PHQ or GAD test from MHA and scored greater than or equal to 10 either of the measures. They will be 18 years or older, residing in the United States and who indicate that they have little or no familiarity with the concept of cognitive reframing.

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.

Phase 1
Phase 1 data analysis activities: Non-English or Spanish speaking

Phase 1 Focus Group participants: non-English speaking, younger than 18

Phase 1 Talkspace Survey: Non-English speaking, younger than 18

Phase 2
Phase 2 MRTs: non-English or Spanish speaking consumers

Phase 2 Focus Groups: non-English speaking, younger than 18
Talkspace only: Focus groups launching in November 2022 will focus on users' thoughts and reactions to receiving nudges (e.g., push notifications, emails) and their impact on engagement with the platform. For these focus groups only, exclusion criteria will be TS users younger than 18, and/or have not used TS messaging-based therapy in the past 3 months (e.g., have only used non-messaging based TS services such as video based services, couples counseling, or psychiatry services), and/or do not have the TS mobile app downloaded on their mobile device

Phase 3b
Data collection of Study 1 SMART: Consumers outside of the US, non-English speaking consumers will be excluded

Data Collection of longitudinal surveys in Study 2: Consumers outside of the US, non-English speaking, younger than 18, scoring below 10 on neither the GAD nor PHQ, those who indicate they are familiar with and have practiced cognitive reframing will be excluded

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".

☒ **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.

☒ **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.

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.

☒ **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.

☒ **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***
Phase 1: Data Analysis Activities	100,000
Phase 1: Focus Groups	48
Phase 1: Talkspace Survey	Approx.. 500
Phase 2: Micro-randomized Trials (MRTs)	50,000
Phase 2: Focus Groups	48

Phase 3: SMART Study 1	50,000
Phase 3: Longitudinal Surveys Study 2	300

2.8 COVID-19 Screening. If there will be any in-person interactions with the subjects, describe how you will screen them for COVID-19 symptoms within the 24 hours before the interaction. Also, describe the COVID-19 screening procedures for the study staff who will interact with the subjects.

Acceptable procedures include some type of symptom check or attestation, or a SARS-CoV-2 test with quick access to results. Symptom attestation involves an individual reviewing a list of symptoms and declaring the presence or absence of those symptoms. HSD strongly encourages adapting this Washington State Department of Health Screening Tool https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/Employervisitorscreeningguidance.pdf or the UW EH&S Example Symptom Self-Attestation in this document: https://www.ehs.washington.edu/system/files/resources/guidance-symptom-monitoring-COVID-19.pdf. If you will test for the virus, you must also describe here whether the testing lab is CLIA-certified and how the results will be reported to the subjects.

N/A – all procedures are remote

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.

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

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.

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.

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

☐ **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.

Phase 1

Phase 1 Data Analysis: Participants will not be actively recruited into this phase of the study. Participants will be all consumers who naturalistically engaged with MHA and/or TS over the past 2 years (2018-2020) and who naturalistically engage during the study. Both MHA and TS, as part of routine practice and as part of their terms and conditions, explain to consumers that their information may be used for research purposes and shared with researchers in academic settings to better understand mental illness and for quality improvement purposes.

Phase 1 Focus Groups: Potential participants will be randomly selected from MHA and TS consumers who will receive an invitation to participate in the focus groups.

Phase 1 Talkspace Survey: Potential participants will be TS consumers who choose to respond to invitations received in-app, by email, or as a push notification. This method of recruitment follows procedures used by TS marketing for non-study related surveys.

Phase 2

Phase 2 MRTs: Participants will not be actively recruited into this phase of the study. Participants will be consumers who naturalistically engage with MHA and/or TS during this phase. Both MHA and TS, as part of routine practice and as part of their terms and conditions, explain to consumers that their information may be used for research purposes and shared with researchers in academic settings to better understand mental illness and for quality improvement purposes.

Phase 2 Focus Groups: Potential participants will be randomly selected from MHA and TS consumers who will receive an invitation to participate in the focus groups.

- Talkspace will host focus groups in Phase 2 where participants are invited based on their previous experience with therapy. TS consumers that have recently signed up for services will receive an invitation to complete a brief screening survey about previous engagement with therapy and demographic questions. Invitations to participate in the focus groups will be extended to individuals based on their responses to the screening survey. For example, individuals with no previous experience in therapy will be invited to a focus group with other individuals with no previous experience in therapy. All individuals that respond to the survey will receive an invitation to a focus group (the specific focus group they are invited to will depend on their response to the survey).

Phase 3b Study 1 MHA SMART of 50,000 consumers: Participants will not be actively recruited into this phase of the study. Participants will be consumers who naturalistically engage with MHA and the optional mental health questions and tests, and content connected to this study on the MHA website. As part of routine practice and as part of their terms and conditions, MHA explains to consumers that their information may be used for research purposes and shared with researchers in academic settings to better understand mental illness and for quality improvement purposes.

Phase 3b Study 2 MHA longitudinal surveys of 250 consumers: Recruitment will be conducted through the Mental Health America website (MHA). MHA hosts a wide range of tools for mental health screening. Users who take the depression (PHQ-9) or anxiety (GAD-7) screening and score greater than or equal to 10 on either of those will be shown the recruitment invitation. This invitation will be displayed on the MHA website using methods standard for marketing and R&D research at MHA (e.g., pop up bubble on web page). If consumers are interested in learning more, they can respond to the invitation by clicking on a link, which will direct them to a landing page (displayed via REDCap survey) with more information about the study and where they can then proceed with the screening survey if interested

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.

Phase 1 & Phase 2 Focus Groups: Potential participants will receive an invitation to participate in focus groups. These invitations will be distributed on the platforms (either MHA or TS) using methods that are standard for marketing and R&D research at both MHA and TS (including but not limited to emails, pop-ups, messages from chat bot features, or messages in the participant's inbox on the system). If consumers are interested in learning

more, they can respond to the invitation by clicking on a link, which alerts study team members at MHA or TS. Please refer to section 5.1 for additional focus group procedures.

Here is sample text for those invitations: "University of Washington and [Mental Health America OR Talkspace] are collaborating to learn more about how individuals engage with digital mental health resources. Would you be willing to talk with our team?" We request flexibility in the language used in these invitations.

- For the phase 2 focus groups at Talkspace, potential participants will receive an initial email with an invitation to complete a screening survey. Here is sample text for that invitation: "University of Washington and Talkspace are collaborating to learn more about how individuals engage with digital mental health resources. If you would be interested in talking with our team, please complete this brief questionnaire."

Phase 1 Talkspace Survey: TS consumers will be invited to participate in the survey via push notification, in app messaging, and/or email. A document with sample invitation text for each of these methods has been uploaded to Zipline in the modification to the Talkspace site (DOC: Talkspace_Nudge Survey Invitation Options_MHATS).

Phase 3b Study 2 :
Potential participants will be shown an invitation to participate in this portion of the study. This invitation will be displayed on the MHA website using methods standard for marketing and R&D research at MHA (e.g., pop up bubble on web page). If consumers are interested in learning more, they can respond to the invitation by clicking on a link, which will direct them to a landing page (displayed via REDCap survey) with more information about the study and where they can then proceed to the screening survey if interested. A document with the sample invitation text, landing page text and screening survey questions has been to Zipline in the modification (DOC: 'MHA DIY Study – Recruitment and Screening Materials') in the recruitment material templates section. We request flexibility in the recruitment language used.

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.

Phase 1 & Phase 2 Focus Group participants will be paid $40 for 90-120 minutes of their time. MHA and Talkspace will be responsible for distribution of these incentives via gift codes or secure transfer (e.g. PayPal, Cash App, Zelle). Each of these distribution methods requires only the participants' email address.

Phase 1 Talkspace Survey Participants: Participants who complete the survey will be entered into a drawing to win a $100 Amazon gift card.

Phase 3b Study 2 MHA longitudinal survey participants: Participants will be compensated up to $40-60 in the form of Amazon gift cards for their participation in the study, with the total potential amount depending on their randomly assigned mental health resource condition. For participants in the control condition, they will earn up to $40 total across the 6 surveys they complete after consenting – they will earn $5 for each of the surveys in weeks 1-4, and $10 for the exit survey in Week 5 and $10 for the follow up survey at week 8. For both DIY tool conditions, they will be eligible to earn up to $60 for their participation, and they will be compensated for the surveys the same as those in the control. DIY condition participants will also be eligible for an additional $5 each week for the first four weeks of the study, which will be awarded when they use the DIY tool at least 3 times in the week. Payments for all participants will be split up into 6 sections and sent out on a weekly basis. Payment will not be dependent on completion of the entire study, and $5 payments will solely be based on completion of surveys (and engagement with DIY tool for relevant conditions) at each timepoint. This distribution method requires only the participants' email address. UW will be responsible for the distribution of these incentives.

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.

N/A

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.

Phase 1 & 2 Focus Groups: MHA and TS will send focus group invitations to randomly selected English-speaking adult (age 18 and over) consumers. Metadata collected from user engagement with the MHA and TS websites as well as information provided directly by the participant (e.g. forms, surveys) provide information on age and language spoken, which will be used to ensure that participants are sent only to the target population for focus groups.

Talkspace will host focus groups in Phase 2 where participants are invited based on their previous experience with therapy. TS consumers that have recently signed up for services will receive an invitation to complete a brief screening survey about previous engagement with therapy and demographic questions (race, ethnicity, gender, age/date of birth). Invitations to participate in the focus groups will be extended to individuals based on their responses to the screening survey. Here are examples of questions from the screening survey:

- Before joining Talkspace, had you tried any of the following types of therapy? Select all that apply.
  - Traditional/face-to-face individual therapy (in person or via phone/video)
  - Traditional/face-to-face couples or family therapy (in person or via phone/video)
  - Traditional/face-to-face group therapy (in person or via phone/video)
  - Another digital/online therapy platform (e.g., BetterHelp, Ginger, Lyra, Noom Mood)
    - Please specify
  - Talkspace was the first therapy provider I tried.
- Since joining Talkspace, have you tried any of the following therapy types? Select all that apply.
  - Traditional/face-to-face individual therapy (in person or via phone/video)
  - Traditional/face-to-face couples or family therapy (in person or via phone/video)
  - Traditional/face-to-face group therapy (in person or via phone/video)
  - Another digital/online therapy platform (e.g., BetterHelp, Ginger, Lyra, Noom Mood)
    - Please specify
  - I have not tried any other forms of therapy since joining Talkspace.

We request flexibility in these questions. This survey will be completed via Google Forms hosted by Talkspace; Talkspace has a BAA (business associate agreement) with Google Workspace and is HIPAA compliant.

Phase 3b Study 2 MHA longitudinal survey participants: Metadata collected from user engagement with the MHA website as well as information provided directly by the participant (e.g. forms, surveys) provide information on age, US residence, and language spoken, which will be used to ensure that participants are sent only to the target population for the longitudinal study. Responses to screening questions will also be collected on the Institution of Translational Health Sciences (ITHS) instance of REDCap and stored on their server. A document with the sample invitation text, landing page text and screening survey questions has been to Zipline in the modification (DOC: 'MHA DIY Study – Recruitment and Screening Materials') in the recruitment material templates section. We request flexibility with the questions used. This information will be retained as a part of study data.

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.*

[X] **No** → If no, skip the rest of this section; go to question **5.1**.
[ ] **Yes** → If yes, describe the consent process.

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**?

[ ] **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), blood volumes and frequency of draws (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.*
Information about pediatric blood volume and frequency of draws that would qualify for expedited review can be found in this **reference table** *on the Seattle Children's IRB website.*

Phase 1

Phase 1 will consist of analysis of existing data curated from the beginning of 2020 (prior to award) and to the end of Y01, for a total of 100,000 consumers. Data include meta-data collected from MHA and TS websites as well as surveys and screens routinely collected at MHA and TS for marketing and QI purposes.

Screens & Surveys

Both MHA and TS collect information from consumers about their demographics such as age, gender, marital status, race/ethnicity, income status and education. MHA and TS also collects these symptom measures at initial engagement with services:

- PHQ9 (depression),

- GAD7 (anxiety),
- Prodromal Questionnaire-Brief Version (PQ-B; psychosis);
- Brief Bipolar Test;
- SWED (eating disorders),
- PC-PTSD (PTSD),
- CAGE-AID (Substance Use Disorder);
- Work Health Survey,
- caregiver status, and the
- Duke Social Support Scale, a measure of perceived social support.

These variables will be used to characterize consumers, and may serve as moderators of engagement (Aims 1, 2 and 3a) and clinical outcomes (Aim 3b). These measures have been uploaded to Zipline.

Meta-Data

To document engagement patterns, we will use meta-data (MD), which consists of passive data that is curated from each website and describes how consumers initiate, use and disengage from DMH services. Meta-data includes behaviors such as click throughs to pages and links, time spent on a page, mouse/cursor movement between screening and material selections on a webpage, number of text interactions, time texting, and time between texts. These data are collected on the order of milliseconds (cursor hovers), seconds (clicks), minutes (page views, time between sessions), and hours, days, weeks (number of texts, visits over time).

Identifiability of Data

All data from MHA and TSwill be transferred to UW via a secure BOX account for analyses. Both MHA and TS have internal processes for deidentifying data:

- Talkspace (TS): A program called MixPanel tracks a website user using a random identifier. If and/or once a user signs up for the service, only then can TS attach any identifier (e.g. email) to their website behavior, which is done retroactively by replacing MixPanel's random identifier with a new random, numeric identifier given by the system to all user accounts. TS does have access to identifiable information from participants, including PHI, but all identifiable information and PHI are removed prior to transfer to UW for analyses. Data transferred for analyses will only include the random, numeric identifier, which is the only information needed to analyze, store, and connect data tables. Data transferred will include dates of service, which will be transformed upon receipt by the UW team by altering all dates of service based on their relationship to a randomly selected date.
- Mental Health America (MHA): A user's IP address is automatically recoded using a hashtag (a randomized, unique set of characteristics). This hashtag can be used to track user activity on MHA's site and can be coded to follow users when they enter into TS. Participants may enter identifiable information into the website (e.g. email addresses, names). Any identifiable information is deleted from the data set prior to transfer to UW for analyses. While MHA does not provide direct service, if any dates are included in the data set, data transferred may include these dates and will be transformed by the UW team by altering all dates of service based on their relationship to a randomly selected date.

Characterization of DMH Engagement

This data will be used to characterize patterns of DMH engagement, consumer engagement characteristics and behavior that predict time to disengagement. During this phase, we will periodically review our findings (in samples of approximately 25,000 consumers), to determine if new information is needed to help build predictive models. For instance, we may find that consumers engage in DMH in ways we did not anticipate. To better understand these unanticipated patterns of behavior, we will work with MHA and TS focus groups to rapidly identify what information is needed, and the most efficient way to obtain that information. This is a process that is very common for marketing and R&D research at MHA and TS. (See below for more information on Phase 1 focus groups.)

- Non-engagers are consumers who visit MHA and TS websites once and do not return.

- Pre-intenders are those who complete screens on both websites: at MHA pre-intenders will also be those who read and spend time on informational pages (e.g., "Will This Feeling Last Forever?") and at TS be those who begin exploring the TS app but have not moved onto using the app.
- Intenders are those who spend time in self-directed readings, videos and other self-directed materials aimed at reviewing different types of treatment, or motivational readings (MHA) and who complete an initial intake with a TS therapist.
- Actors are those who start treatment with a TS therapist and engagement/disengagement will be measured over the course of days and weeks.
- Cyclers are those who return to MHA screenings and materials and those who stop and restart treatment at TS.

Transition between phases will be measured by consumer behavior change in meta-data. For instance, transition from pre-intender to intender may be modeled by a consumer who completed an MHA screen and then clicked through to pages or tools covering information about mental health. Transition from intender to actor maybe modeled by downloading the TS app and beginning a chat with a therapist. Transition from actor to cycler will be measured by number of returns to TS after initiating treatment. Although we will use these constructs to initially define theory-driven engagement patterns, we will also use these meta-data to explore whether unanticipated engagement patterns exist.

Focus Groups

Phase 1

Focus group participants will be randomly chosen from MHA and TS adult consumers. Focus groups will be recruited at 3 different time points (6 groups, 3 for TS and 3 for MHA). Potential participants will receive an invitation to participate in focus groups. These invitations will be distributed on the platforms (either MHA or TS) using methods that are standard for marketing and R&D research at both MHA and TS (including but not limited to emails, pop-ups, messages from chat bot features, or messages in the participant's inbox on the system). If consumers are interested in learning more, they can respond to the invitation by clicking on a link, which alerts study team members at MHA or TS.

- Talkspace Focus Groups: A member of the study team will reach out to the consumer to provide more information, schedule activities, and provide information on engaging in the focus group (e.g. Zoom info).
- MHA Focus Groups: After viewing/receiving the invitation, consumers complete an interest form to indicate their interest in the focus group. A member of the study team emails interested participants to provide information about the focus group, which is all done online including instruction, options for anonymity, and any recording that may happen.

Participants will first be presented with the study we are conducting, its purpose and then results from initial data analysis on engagement patterns. Participants will be asked their impressions of the data and potential engagement subtypes and patterns that have been identified (e.g. preintender, intender, actor). If from the discussion we determine that more information is needed in the form of a survey to the next cohort of consumers, we will the ask them to help us write and design the survey (which will be submitted to IRB via a modification if needed). If they determine that we do not require more information, we will thank the participants for their time and ask their interest in participating in a future focus group. Focus groups may be audio and video recorded; consent for this audio and videorecording will be provided by participants in order for any recordings to take place, and participants may choose to turn their video off prior to the start of video recording.. Focus group participants will receive $40 for 90-120 minutes of their time.

Talkspace Nudge Survey

Talkspace nudge survey respondents will be English speaking TS consumers aged 18 and over who has a messaging therapy or messaging + live therapy plan and who choose to respond to invitations received in-app, by email, or as a push notification. The invitations will contain a link to the survey, which has been programmed in Qualtrics hosted by UW. The TS consumers will review the statement that contains all necessary elements of consent and confirm their age. If the consumer indicates that they are younger than 18, the survey will not allow

them to continue. Respondents are made aware that their responses to this survey are tied their other information on Talkspace (e.g., the meta-data described above).

The survey asks questions about how receiving communication from Talkspace may change a consumer's use of the services including requesting feedback on language used in different types of communications, frequency of communications, and preferences around communications. Respondents are asked demographic questions (e.g., age, race, ethnicity, education, income, household size, health status, and language) and questions about which device(s) they use Talkspace on. Participants are then given a vignette about a Talkspace user and shown example text for potential push notifications. The exact copy (language, etc.) seen by each participant will be randomized but all respondents will answer the same questions. Examples of the copy that participants will be randomly exposed to have been uploaded to Zipline in the Talkspace site ("Talksapce_Nudge Survey Copy Options_MHATS"). They are then asked to respond to questions about how that language may impact their utilization of Talkspace (e.g., would they be more or less likely to message their therapist after seeing that language). Respondents are then asked questions about their preferences related to receiving push notifications (e.g., how often, how many, do they currently receive push notifications from TS) and whether or not seeing a push notification impacts their utilization of TS. We request flexibility in the specific language of both the copy and survey questions; we will submit a modification if any edits go beyond the scope described here. We expect that the survey will take approximately 10 minutes to complete.

Phase 2

Micro-Randomized Trials (MRTs)

Phase 2 will consist of rapid deployment of micro-randomized trials (MRTs) on both MHA and TS platforms to understand what factors and engagement strategies may lead to increased engagement with digital mental health services. As with Phase 1, we are requesting a waiver of consent for these activities Data collected in Phase 2 MRTs will include meta-data and content data. Meta-data includes behaviors such as click throughs to pages and links, time spent on a page, mouse/cursor movement between screening and material selections on a webpage, number of text interactions, time texting, and time between texts. These data are collected on the order of milliseconds (cursor hovers), seconds (clicks), minutes (page views, time between sessions), and hours, days, weeks (number of texts, visits over time). Content data includes survey measures, transcripts (TS only), demographics, type of articles/resources accessed. All data types are routinely collected by MHA and TS. Both MHA and TS, as part of routine practice and as part of their terms and conditions, explain to consumers that their information may be used for research purposes and shared with researchers in academic settings to better understand mental illness and for quality improvement purposes.

We will perform micro-randomized trials (MRTs) using methodology of simultaneous A/B trials. In these trials, full access to all tools, resources, and other information provided by the platforms for users will be maintained for participants in the trials. Participants will not lose access to any information or features of the sites of which they previously had access to. Already existing features, tools and/or information may only be modified in their visual presentation on the platforms. The MRTs will be deployed on both MHA and TS, with some requiring coordination across both platforms, throughout Phase 2. The following describes the type and scope of activities that will be conducted for each organization:

Mental Health America

MHA trials will focus on modifying current features on the website. In the past, MHA has conducted experimental user testing on engagement such as modifying tone, placement, and medium (written vs audio) of education materials, modifying language and linkages to services like telehealth partners, adding relevant links to other materials, and improving the formatting of articles for clarity. The future trials use this testing as a foundation for experimentation. For example, one focus of a future trial will be to present different online resources to MHA site users after they complete a survey that evaluates where they are in their help-seeking journey.

Talkspace

Trials conducted with Talkspace may focus on similar elements of user design in search of understanding better what design and presentation of information best helps potential and actual clients get the appropriate care that is the best fit for them and where they are at in their mental health journey. Strategies may include modifying informational pages in their visual presentation, adjusting the onboarding process to address areas of likely attrition, integrating new tools and information into treatment interface.

We have uploaded a table of example potential MRTs to Zipline to provide further clarification (File Name: MHATS_Proposed MRTs). While we are providing these examples, we request flexibility to implement MRTs within the scope of the project (understanding what factors and engagement strategies lead to increase utilization of digital mental health services).

Data Transfer, Identifiability, and Analysis
All procedures regarding data transfer, identifiability, and analysis in Phase 2 are the same as those in Phase 1.

Focus Groups
Phase 2 focus group procedures are the same as those in Phase 1.

Talkspace will host focus groups in Phase 2 where participants are invited based on their previous experience with therapy. TS consumers that have recently signed up for services will receive an invitation to complete a brief screening survey about previous engagement with therapy and demographic questions. Invitations to participate in the focus groups will be extended to individuals based on their responses to the screening survey. For example, individuals with no previous experience in therapy will be invited to a focus group with other individuals with no previous experience in therapy. All individuals that respond to the survey will receive an invitation to a focus group (the specific focus group they are invited to will depend on their response to the survey). While the focus group the individual is invited to will be based on their response to the screening survey, the structure, content, and procedures for the focus groups are all the same as previously described in Phase 1. As part of the informed consent process, focus group participants will have the option to give consent for their responses during the focus group to be linked to data on their usage of the Talkspace platform (e.g., engagement with TS platform, number of texts sent, response to push notifications). All data will be anonymized prior to transfer from TS to UW using the procedures outlined previously.

Phase 3

Phase 3:
Study 1 (SMART): We will use a Sequential Multiple Random Assignment Trial (SMART) with an expected 50,000 users, with the goal of optimizing engagement strategies so that web users engage with MHA resources most relevant to their needs, including psychoeducation, links to treatment providers, or self-help tools. Participants will be randomized to type of screening results language, with conditions including results-as-usual, or tailoring by: 1) demographics (race, LGBTQ status, age) or 2) mental health severity (screening results) & perceived need. Subsequent randomization will determine whether single-item self-help tools embedded in content pages serve to engage users in active mental health strategies. Participants will be MHA consumers who land on the PHQ-9 mental health test page on the MHA website.

Recruitment Procedures
No recruitment measures will be put in place, as we will be collecting data on participants who enter the PHQ screening page naturalistically.

Consent Procedure
As MHA consumers will be engaging with the website naturalistically, and the terms and conditions in the site include provisions around the use of user data for research, we will not be collecting formal consent from participants.

Screens/Surveys
PHQ-9
Mini quiz/Next Steps Quiz (DOC: Study 2 Next steps brief survey) – we request flexibility with the language used for these questions

Metadata collection
We will use metadata, which consists of passive data that is curated from each website and describes how consumers initiate, use and disengage from DMH services. Metadata includes behaviors such as click throughs to pages and links, time spent on a page, mouse/cursor movement between screening and material selections on a webpage, number of text interactions, time texting, and time between texts. These data are collected on the order of milliseconds (cursor hovers), seconds (clicks), minutes (page views, time between sessions), and hours, days, weeks (visits over time).

Randomization sequence
The drafted randomization sequence is outlined on the MHA SMART Flow.pdf uploaded to zipline. Participants will be randomized first between a standard demographics survey to start or demographics along with a mini quiz focusing on asking a participant's primary website action intention (e.g., reading more about depression, connecting with therapists, using a DIY tool) and perceived need to do something to improve their mental health. Participants will then be randomized to types of screening results pages, with combinations of tailored responses and resources based on their responses to the demographics quiz and/or the mini quiz. For instance, if the participant chooses to continue to visit further content, they will be randomized to conditions of different presentations of a DIY question or tool on the page. Length of engagement, bounce rates, and other variables listed under metadata collection will be used to examine the impact of tailoring on engagement, which conditions and combinations of conditions result in increased engagement, and how the use of DIY tools impact engagement.

Study 2

As previously proposed in Aim 3, we have developed an AI tool that uses machine learning / NLP / AI methods to personalize and tailor an intervention to improve engagement and completion outcomes. We focus on a specific, popular DIY tool (~10,000 users /month) that teaches cognitive restructuring. Our pilot work found that (1) engagement and completion rates on DIY tools can be low, and (2) a pilot AI tool had significantly higher engagement and completion rates. These differences may arise due to AI support, UI/UX/design differences, other factors, or a combination thereof. Additionally, the efficacy of the digital tool to improve mental health functioning is unknown. Study 2 will recruit 300 participants who will be randomly assigned to one of three groups for a longitudinal month-long study: twice-weekly DIY tool use with AI, without AI, or a control group.

Recruitment Procedures
Potential participants will be shown an invitation to participate in this portion of the study and displayed on the screening results page for users after the PHQ-9 and GAD-7 mental health tests. If consumers are interested in learning more, they can respond to the invitation by clicking on a link, which will direct them to a landing page (displayed via REDCap survey) with more information about the study and the screening survey.

Screens/Surveys: All measures in this section will be completed using REDCap – refer to DOC: DIY Study – Measures for all measures listed in this section, and refer to DOC: Demographic questions for the demographics measure. Participants will receive links to complete these surveys via email and/or text message using Twilio, a REDCap extension that allows for SMS communication with participants. Participants will complete an initial screening assessment to determine eligibility, and then complete the same list of measures for 4 weeks while using intervention (consistent to each condition), an exit survey at week 5 and follow up measures consistent with the weekly measures at week 8 follow up. All participants will be asked to complete the demographics measure in addition to the measures included in the first week's battery of assessments.
Participants will be asked to complete the following measures in the screener:
- PHQ-9

- GAD-7
- Hopefulness Item
- Emotion Mechanisms

At the end of weeks 1-4 and week 8 follow up, participants will be asked to complete the following measures, some measures adjusted depending on condition:
- Questions Post DIY AI [DIY Tool, AI condition ONLY]
- PHQ-9
- GAD-7
- Hopefulness Item
- Emotion Mechanisms
- Competencies of Cognitive Therapy Scale – Self Report
- Tool Use (sustain) [DIY Tool, No AI condition ONLY WEEKS 1-4, BOTH DIY TOOL CONDITIONS at WEEK 8]
- Tool Use (AI) [DIY Tool, AI condition ONLY, JUST WEEKS 1-4]

Demographics Measure (just week 1)

At week 8 only, participants will be asked the following questions (in addition to those previously approved):
- What is your total annual household income? (Less than $20,000; $20,000 - $39,999; $40,000 - $59,999; $60,000 - $79,999; $80,000 - $99,999; $100,000 - $149,999; $150,000 or more; Prefer not to answer)
- To what extent did you participate in the study for each of the following reasons (answer scale is 1 (strongly disagree) to 5 (strongly agree): For fun; Was curious to learn about mental health; Really needed the money; Wanted the money, but didn't need it; Other [open text field]; Prefer not to answer

For the exit survey, participants will be asked to complete:
- Exit Survey (Control) [Control condition ONLY]
- Exit Survey (DIY) [DIY Tool, AI and DIY Tool, no AI conditions ONLY]

Consent Procedure
We have uploaded the consent form

Randomization Procedures
Once consenting to the study, upon beginning the REDCap screening survey, potential participants will automatically be randomly assigned to one of three conditions. .This random assignment will not impact their screening process, eligibility, or the consent process. Their randomly assigned condition will not be revealed to them until after they consent to the study. Upon their consent, the information will be delivered to them via email, informing them of their assigned condition, outlining the study tasks and payment structure.

The three conditions are as follows: Control condition with psychoeducational reading material, a DIY worksheet, or a DIY tool with artificial intelligence, and are all concerned with the idea of thinking traps and learning how to apply the concept of cognitive reframing to situations in one's own life. Folks in both DIY tool conditions will be prompted to use their tools 3x a week, and all participants will be asked to respond to weekly surveys for the duration of 4 weeks.

Conditions:
DIY Tool with AI
This tool uses AI to help users learn about thinking traps and cognitive reframing, and practice applying these concepts to situations in their own life. Participants will be asked to describe a thought and a situation they are struggling with. They will then identify potential "thinking traps" (or cognitive distortions) in the thought and reframe it in a way that is more positive, realistic, or helpful. The tool uses artificial intelligence to help generate

reframed thoughts. Please refer to the document With-AI-DIY-Tool-Static-Pages.pdf that has been uploaded to zipline.

- **Metadata collection:** We will use metadata, which consists of passive data that is curated from the host site for the DIY tool and describes engagement patterns from the DIY tool. This metadata includes the length of time spent on the measure, percentage of measure completion, counts of tool visits and frequency of visits

DIY Tool (no AI)
3x weekly, participants will be prompted to use the DIY tool which covers the concept and practice of cognitive restructuring using the same framework as from the DIY tool with AI, however without the AI component, as shown in the document Without-AI-DIY-Tool-Static-Pages.pdf that has been uploaded to zipline.

- **Metadata collection:** We will use metadata, which consists of passive data that is curated from the host site for the DIY tool and describes engagement patterns from the DIY tool. This metadata includes the length of time spent on the measure, percentage of measure completion, counts of tool visits and frequency of visits

Control Psychoeducation
At the start of participation after consenting, participants in the control condition will be asked to read the psychoeducation materials that describe types of cognitive restructuring and tips for practicing them in the document DIY Study – Psychoeducation.docx that has been uploaded to zipline.

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

☐ **No** → If no, go to question **5.3**.
☒ **Yes** → If yes, verify that you have described what will be recorded 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.

☒ **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).

☒ **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***.

Phase 1
Both MHA and TS collect information from consumers about their demographics such as age, gender, marital status, race/ethnicity, income status and education. MHA and TS also collect these symptom measures at initial engagement with services:

- PHQ9 (depression),
- GAD7 (anxiety),
- Prodromal Questionnaire-Brief Version (PQ-B; psychosis);
- Brief Bipolar Test;
- SWED (eating disorders),
- PC-PTSD (PTSD),
- CAGE-AID (Substance Use Disorder);
- Work Health Survey,
- caregiver status, and the
- Duke Social Support Scale, a measure of perceived social support.

These measures have been uploaded to Zipline.

Phase 1 Talkspace Survey: Demographics (e.g., age, race, ethnicity, education, income, household size, health status, and language); Device usage; Opinions on sample language for push notifications; Opinions on how push notifications and specific language in those notifications impact or may impact their utilization of TS services

Meta-Data
To document engagement patterns, we will use meta-data (MD), which consists of passive data that is curated from each website and describes how consumers initiate, use and disengage from DMH services. Meta-data includes behaviors such as click throughs to pages and links, time spent on a page, mouse/cursor movement between screening and material selections on a webpage, number of text interactions, time texting, and time between texts. These data are collected on the order of milliseconds (cursor hovers), seconds (clicks), minutes (page views, time between sessions), and hours, days, weeks (number of texts, visits over time).

Phase 2
Data collected in Phase 2 MRTs will include meta-data and content data. Meta-data includes behaviors such as click throughs to pages and links, time spent on a page, mouse/cursor movement between screening and material selections on a webpage, number of text interactions, time texting, and time between texts. These data are collected on the order of milliseconds (cursor hovers), seconds (clicks),

minutes (page views, time between sessions), and hours, days, weeks (number of texts, visits over time). Content data includes survey measures, transcripts (TS only), demographics, type of articles/resources accessed. Talkspace transcripts are of message-based therapy interactions. All identifiable information (e.g., names, usernames, links) are scrubbed from the transcripts by an automated process internal to TS prior to transfer to UW. Additional anonymization occurs on secure servers at UW including generalizing specific mentions of places (e.g., changing Seattle to Pheonix or Duluth) and proper nouns (e.g., changing UW to USC), and adding or removing filler words with less unique word choices or phrases (e.g., changing 'My girlfriend's XBOX playing irritates me' to 'My sister's game playing makes me angry'). These methods are outlined in our Data Security Protocol (previously uploaded to Zipline).

Phase 3

Data collected in Study 1 and Study 2 of Phase 3B will both include metadata from MHA and content/survey data. Meta-data includes behaviors such as click throughs to pages and links, time spent on a page, mouse/cursor movement between screening and material selections on a webpage, number of text interactions, time texting, and time between texts. These data are collected on the order of milliseconds (cursor hovers), seconds (clicks), minutes (page views, time between sessions), and hours, days, weeks (number of texts, visits over time). At initial engagement for Study 1, the PHQ-9 and for study 2, either the PHQ or GAD measures will be collected on the MHA website. The following describes more specific data variables for each study:

Study 1 –

- PHQ-9
- Mini quiz/next steps quiz--two items, collecting the participant's primary website action intention. The first question asks, "What is the main thing you want to do after taking this mental health test" and answer choices such as "Take another mental health test", "Understand what depression is like", "Find a treatment provider near you". The second question asks "Do you feel like you need to do something to improve your mental health?" (Yes, No, Don't know)

Study 2 –

DIY Tool Metadata (both with AI and without AI)

In addition to metadata collected from the MHA website, metadata will also be collected from the DIY tool which is hosted on the Microsoft Azure platform. These specific variables will be measured:

- Engagement in length of time spent on the measure
- Completion rate of measure (% of measure completed)
- Dosage, in number of times/sessions using/visiting measure or psychoeducation
- Amount of use on the MHA website

Participants will be asked to complete the following measures in the screener:

- PHQ-9
- GAD-7
- Hopefulness Item
- Emotion Mechanisms

At the end of weeks 1-4 and week 8 follow up, participants will be asked to complete the following measures:

- Questions Post DIY AI [DIY Tool, AI condition ONLY]
- PHQ-9

- GAD-7
- Hopefulness Item
- Emotion Mechanisms
- Competencies of Cognitive Therapy Scale – Self Report
- Tool Use (sustain) [DIY Tool, No AI condition ONLY WEEKS 1-4, BOTH DIY TOOL CONDITIONS WEEK 8]
- Tool Use (AI) [DIY Tool, AI condition ONLY, JUST WEEKS 1-4]
- Demographic questions (JUST WEEK 1)

For the exit survey, participants will be asked to complete:
- Exit Survey (Control) [Control condition ONLY]
- Exit Survey (DIY) [DIY Tool, AI and DIY Tool, no AI conditions ONLY]

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.

Surveys and screeners are completed by participants (MHA and TS consumers). Meta-Data is curated from each website (MHA and TS)

Focus group data is provided by participants.

Phase 3B Study 2: Screener and surveys are completed by participants. Meta-data is also curated from DIY tool website.

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.

Phase 1 Data Analysis Activities & Phase 2 MRTs: Both MHA and TS have access to identifiers (including names, email addresses, etc) provided by users. We have described the processes for deidentification of this data in Section 5.1. UW will have no access to

any direct identifiers; all direct identifiers will be removed from data sets prior to transfer via a secure BOX folder. All team members will have access to indirect indentifiers (e.g. random, numeric identifier generated by TS, hashtag generated by MHA).

Phase 1 & Phase 2 Focus Groups: MHA and TS will have access to names, email addresses, and contact information. MHA, TS, and UW will have access to direct identifiers as a result of video recordings. For TS focus group participants that have given permission for their focus group data to be linked to their platform usage data, the platform usage data will be anonymized prior to transfer to UW (using previously described methods) and the focus group data used in these analyses will be an anonymized transcript. The anonymized transcript will be stored separately from the video and analysis will take place only with the deidentified transcripts and usage data so that the personnel completing the analysis do not have the ability to link the datasets.

Phase 1 Talkspace Survey: TS and UW will have access to email addresses and names (the survey requests first names only in order to personalize the copy reviewed by each respondent). The survey information is tied to respondents' TS metadata via the email address provided. Email addresses will be removed and the unique, indirect identifiers will be applied prior to analysis.

Phase 3 Study 1 SMART: MHA has access to user IP addresses. We have described the processes for deidentification of this data in section 5.1 UW will have no access to any direct identifiers; all direct identifiers will be removed from data sets prior to transfer via a secure BOX folder. All team members will have access to indirect identifiers (e.g., generated hashed IP address)

Phase 3 Study 2 Screening Survey: MHA and UW will have access to email addresses and phone numbers, which will be stored separately from study data within REDCap.

☐ **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.

Phase 1 Data Analysis Activities & Phase 2 MRTs: Both MHA and TS will obtain identifiers (including names, email addresses, etc) provided by users. We have described the processes for deidentification of this data in Section 5.1. UW will neither obtain nor have access to any direct identifiers; all direct identifiers will be removed from data sets prior to transfer via a secure BOX folder. All team members will have access to indirect indentifiers (e.g. random, numeric identifier generated by TS, hashtag generated by MHA).

Phase 1 & Phase 2 Focus Groups: Focus group participants ONLY: MHA and TS will obtain names, email addresses, and Names, contact information. UW will receive identifiable video recordings which will transferred via a secure BOX folder. For TS focus group participants that have given permission for their focus group data to be linked to their platform usage data, the platform usage data will be anonymized prior to transfer to UW (using previously described methods) and the focus group data used in these analyses will be an anonymized transcript. The anonymized transcript will be stored separately from the video and analysis will take place only with the deidentified transcripts and usage data so that the personnel completing the analysis do not have the ability to link the datasets.

Phase 1 Talksapce Survey: TS and UW will obtain names and email addresses in the Qualtrics survey hosted by UW.

Phase 3 Study 1 SMART: : MHA has access to user IP addresses. We have described the processes for deidentification of this data in section 5.1 UW will have no access to any direct identifiers; all direct identifiers will be removed from data sets prior to transfer via a secure BOX folder. All team members will have access to indirect identifiers (e.g. generated hashed IP address)

Phase 3 Study 2 Screening Survey: MHA and UW will obtain email addresses and phone numbers, which will be stored separately from study data within REDCap.
Phase 3 Study 2 DIY tool: The Microsoft Azure service is used to host the tool data entered by participants while using the tool. The tool does not request any identifying information, however there is the possibility that participants share indirect identifiers in qualitative responses to tool prompts.

[ ] **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:

Focus groups ONLY: Identifiers will be stored with the data due to the nature of video recordings.

☒ 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:

Both MHA and TS have internal processes for handling identifiers. At TS, a program called MixPanel tracks a website user using a random identifier; if and/or once a user signs up for the service, only then can TS attach any identifier (e.g. email) to their website behavior which is done retroactively by replacing MixPanel's random identifier with a new random identifier given by the system to all user accounts. At MHA, a user's IP address is automatically recoded using a hashtag (a randomized, unique set of characters). Any identifying information that users may enter into the website (e.g. email addresses, names) is deleted from the data set prior to sending to UW.

Phase 1 Talkspace Survey: All identifiers will be obtained by Qualtrics hosted by UW. The data collected will be accessible to both UW and TS study team members. The survey information is tied to respondents' TS metadata via the email address provided. Email addresses will be removed and the unique, indirect identifiers will be applied prior to analysis.

For TS focus group participants that have given permission for their focus group data to be linked to their platform usage data, the platform usage data will be anonymized prior to transfer to UW (using previously described methods) and the focus group data used in these analyses will be an anonymized transcript. The anonymized transcript will be stored separately from the video and analysis will take place only with the deidentified transcripts and usage data so that the personnel completing the analysis do not have the ability to link the datasets.

Phase 3 DIY Study 2 Longitudinal Surveys: All identifiers will be obtained by REDCap hosted by ITHS. The data collected will be accessible to both UW and MHA study team members. The survey information is tied to respondents' MHA metadata via the email address provided. Email addresses will be removed and the unique, indirect identifiers will be applied prior to analysis.

DIY tool data storage details
The Microsoft Azure service is used to host the tool data entered by participants while using the tool. The tool does not request any identifying information, however there is the possibility that participants share indirect identifiers in qualitative responses to tool prompts. For data that is entered by participants while using the tool, in-transit data is encrypted. A validated cryptographic module is used for the storage encryption for data at rest. 24-hour threat management protects the infrastructure and platform against malware, distributed denial-of-service (DDoS), man-in-the-middle (MITM), and other threats.

☐ 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.

N/A

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?*

MHA is not a covered entity, therefore no information included in the MHA dataset is not considered PHI. Talkspace is a covered entity, thus information included in the TS dataset is considered PHI. This information includes demographics such as age, gender, marital status, race/ethnicity, income status and education; PHQ9 (depression); GAD7 (anxiety); Prodromal Questionnaire-Brief Version (PQ-B; psychosis); Brief Bipolar Test; SWED (eating disorders); PC-PTSD (PTSD); CAGE-AID (Substance Use Disorder); Work Health Survey; caregiver status; the Duke Social Support Scale, a measure of perceived social support; and meta-data collected from consumers' interaction with the TS website. Only members of TS' study team will have access to any identifiable information, with the exception of information provided during the Phase 1 Talkspace Survey.

Phase 3B Study 2 ONLY: PHQ-9 scores, GAD-7 scores are used in the screening process for the study in REDCap and to determine eligibility for the study.

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

[X] **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.*

Consumers provide information on demographics and complete surveys within the Talkspace platform. All TS metadata is collected within the Talkspace platform.

Phase 3B Study 2 ONLY: The PHQ-9 and GAD-7 information gathered at eligibility screening will be provided by participants within the REDCAP instance hosted by ITHS at the University of Washington.

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

N/A

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?

All PHI listed above.

Provide the following assurances by checking the boxes.

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

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

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

[X] 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?

[X] **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 **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**

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

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

All data will be stored for future use.

Phase 1 Assessment & Phase 2 MRTs data & Phase 3 Study 1 SMART data: Both MHA and TS assign random identifiers to consumers, which will be stored with the data, to allow for longitudinal analysis. The random identifiers are indirect; the data sets used and stored for analyses will not contain direct identifiers.

Focus group data: All data, other than video recordings, will be stored separately from identifiable information. Focus group data is coded with a unique study ID number, which cannot be used to identify the participant. The ID number will be stored along with the focus group data for data transfer and data analysis. This ID number is not tied to any identifiers. Video recordings will be stored in a secure BOX folder separate from all other data.

Phase 1 Talkspace Survey: The survey information is tied to respondents' TS metadata via the email address provided. Email addresses will be removed and the unique, indirect identifiers will be applied prior to analysis and storage.

Phase 3 Study 2 Longitudinal surveys: All assessment data will be stored separately from identifiable information. Assessment data is coded with a unique study ID number, which cannot be used to identify the participant; the ID number will be stored along with the assessment data for future use.

Phase 3 Study 2 DIY Tool MetaData: All metadata collected from the DIY tool that will be stored for future use does not contain direct or indirect identifiers. A unique ID will be connected to participant REDCap data.

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.

All assessment data may be shared with other researchers. No direct identifiers, including video recordings, will be shared.
Phase 3B Study 2 ONLY: Participants consent to this sharing of data during informed consent.

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

The oversight/management of the sharing will be the responsibility of the PIs (Dr Althoff).

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.

Possible future uses of this data include ongoing data analysis for publication and informing future grant proposals for clinical trials.

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

☐ **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?

☒ **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.

Phase 1 Data Analysis & Phase 2 MRTs Activities: The study team will have no communication with participants.
Phase 1 & Phase 2 Focus Groups: The study team may email or call participants to schedule the focus groups and/or send reminders. Study team members from MHA and TS will communicate with participants to distribute the incentive.
Phase 1 Talkspace Survey: The study team will email those participants that are selected to receive a $100 Amazon gift card.
Phase 3B Study 2: Participants will receive reminders via email and/or SMS from REDCAP to complete surveys throughout the study protocol. Participants will be directed to raise any study related questions responding to emails from the study team or contacting the study team via email. The study team will email participants to distribute each of their weekly incentives.

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.

Phase 1 & Phase 2 Focus Group Participants ONLY: Focus group participants will be offered the opportunity to participate in future groups, if those future groups take place. If future groups are needed, those participants may be contacted for potential participation.

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

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

[X] **No**
[ ] **Yes** → If yes, describe the alternatives.

5.14 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.)

5.15 SARS-CoV-2 testing. Will the subjects be tested for the SARS-CoV-2 coronavirus?

If the only testing is to screen the subjects (question 2.8), you do not need to answer this question

[X] **No**

[ ] **Yes** → If yes:

- Name the testing lab
- Confirm that the lab and its use of this test is CLIA-certified or certified by the Washington State Department of Health
- Describe whether you will return the results to the participants and, if yes, who will do it and how (including any information you would provide to subjects with positive test results).

5.16 Research equipment and COVID-19. Does you research involve any equipment that will be used on more than one subject that is not part of a clinical facility?

Examples: a computer tablet, a portable research ultra-sound device).

[X] **No**

☐ **Yes** → If yes: confirm by checking the box below that the disinfection and cleaning of the equipment will meet the enhanced UW Environmental Health & Safety requirements described here: https://www.ehs.washington.edu/system/files/resources/cleaning-disinfection-protocols-covid-19.pdf

☐ **Confirmed**

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.

Phase 1: We will be using the entire data set of consumers for MHA and TS from 2018 until the final year of the project. While we expect most consumers will be aged 14 and older, we will include data from consumers aged 6 and over. All focus group participants will be aged 18 and over.

Phase 2 MRTs: We will be using data from all naturalistic consumers of MHA and TS. While we expect most consumers will be aged 14 and over, we will include data from consumers of all ages.

Phase 3 Study 1 SMART: We will be using data from all naturalistic consumers of MHA who engage with the site materials that are part of the study. While we expect most consumers will be aged 14 and over, we will include data from consumers of all ages.

☐ **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
MHA and TS Consumers	All study procedures (children will not be included in focus groups)	Participants will be all consumers who naturalistically engaged with MHA and/or TS over the past 2 years (2018-2020) and who naturalistically engage during the study. Both MHA and TS, as part of routine practice and as part of their terms and conditions, explain to consumers that their information may be used for research purposes and shared with researchers in academic settings to better understand mental illness and for quality improvement purposes. Because the purpose of this research is to better understand engagement in DMH tools, any interference from the study team would undermine our findings. Additionally, this study could not be done without a very large sample. Collecting formal consent from participants will prevent us from identifying a large sample and as has been found in previous studies of DMH, participants recruited explicitly for research engage differently than consumers who access DMH and are not participating in research.	☐	☒
			☐	☐
			☐	☐

	☐	☐
	☐	☐
	☐	☐

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.**

[X] 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
MHA and TS Consumers	All study procedures (children will not be included in focus groups)	Participants will be all consumers who naturalistically engaged with MHA and/or TS over the past 2 years (2018-2020) and who naturalistically engage during the study. Both MHA and TS, as part of routine practice and as part of their terms and conditions, explain to consumers that their information may be used for research purposes and shared with researchers in academic settings to better understand mental illness and for quality improvement purposes. Because the purpose of this research is to better understand engagement in DMH tools, any interference from the study team would undermine our findings. Additionally, this study could not be done without a very large sample. Collecting formal assent from participants will prevent us from identifying a large sample and as has been found in previous studies of DMH, participants recruited explicitly for research engage differently than consumers who access DMH and are not participating in research.

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.

N/A

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.

N/A

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?

[ ] **No**

[X] **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
Phase 1: MHA and TS Consumers	All study procedures (other than focus groups)	Participants will be all consumers who naturalistically engaged with MHA and/or TS over the past 2 years (2018-2020) and who naturalistically engage during the study. Both MHA and TS, as part of routine practice and as part of their terms and conditions, explain to consumers that their information may be used for research purposes and shared with researchers in academic settings to better understand mental illness and for quality improvement purposes. Because the purpose of this research is to better understand engagement in DMH tools, any interference from the study team would undermine our findings. Additionally, this study could not be done without a very large sample. Collecting formal consent from participants will prevent us from identifying a large sample and as has been found in previous studies of DMH, participants recruited explicitly for research engage differently than consumers who access DMH and are not participating in research.	☐	☒
Phase 2: MHA and TS Consumers	All study procedures (other than focus groups)	Participants will be all consumers who naturalistically engaged with MHA and/or TS over the past 2 years (2018-2020) and who naturalistically engage during the study. Both MHA and TS, as part of routine practice and as part of their terms and conditions, explain to consumers that their information may be used for research purposes and shared with researchers in academic settings to better understand mental illness and for quality improvement purposes. Because the purpose of this research is to better understand engagement in DMH tools, any interference from the study team would	☐	☒

		undermine our findings. Additionally, this study could not be done without a very large sample. Collecting formal consent from participants will prevent us from identifying a large sample and as has been found in previous studies of DMH, participants recruited explicitly for research engage differently than consumers who access DMH and are not participating in research.		
Phase 3B: Study 1 SMART	All study procedures (this does not include Study 2 procedures for Phase 3B	Participants will be those who naturalistically engage during the study. Both MHA and TS, as part of routine practice and as part of their terms and conditions, explain to consumers that their information may be used for research purposes and shared with researchers in academic settings to better understand mental illness and for quality improvement purposes. Because the purpose of this research, among other aims, is to better understand engagement in DMH tools, any interference from the study team would undermine our findings. Additionally, this study could not be done without a very large sample. Collecting formal consent from participants will prevent us from identifying a large sample and as has been found in previous studies of DMH, participants recruited explicitly for research engage differently than consumers who access DMH and are not participating in research	☐	☐
			☐	☐
			☐	☐

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*

Phase 1 & Phase 2 FOCUS GROUPS ONLY: MHA and TS adult consumers will be invited to participate in focus groups by receiving messages via their preferred communication method on the platform on which they are active (including but not limited to emails, pop-ups, messages from chat bot features, or messages in the participant's inbox on the system). If consumers are interested in learning more, they can respond to the invitation by clicking on a link, which alerts study team members at MHA or TS.

- Talkspace Focus Groups: A member of the study team will reach out to the consumer via email to provide more information, consent form, schedule activities, and provide information on engaging in the focus group (e.g. Zoom info). Verbal consent is collected at the beginning of each remote focus group. Participants will be given the option to consent to having their focus group data linked to the platform usage data (e.g., engagement with the TS platform, number of texts sent). A study team member on the focus group Zoom call will send a private, direct message to each participant with the following (this is also included in the consent form sent to participants via email):
    - "This is completely voluntary. You may continue to participate in this focus group whether you agree with this statement or not. Please respond YES or NO to the following statement: I give permission to the research team to link my responses in this focus group to data on my activity on the Talkspace platform."
- MHA Focus Groups: After viewing/receiving the invitation, consumers indicate their interest by clicking on the invitation and completing a brief survey. A member of the study team emails interested participants the consent form and to provide information about the focus group, which is all done online including instruction, options for anonymity, and any recording that may happen. Verbal consent is collected at the beginning of each remote focus group.

Phase 1 Talkspace Survey: After clicking on link in the invitation, potential respondents will review a brief statement that describes the survey, procedures, voluntariness, opportunity to ask questions, and compensation potential. This text has been uploaded to Zipline ("Talkspace_Nudge Survey_MHATS"). Respondents then indicate consent by clicking a box that specifically states they consent to the survey.

Phase 3B Study 2: After clicking on the study invitation, completing the initial screening questionnaire on REDCap and learning eligible status, informed consent will be obtained electronically via REDCap. Participants will review the consent and provide consent online. Participants are encouraged to contact the study team via email if parts of the informed consent form are unclear, or if additional information is desired. Consent will be documented in REDCap. Participants must select that they agree to participate in the study at the end of the consent form in order to move forward with study procedures.

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

Phase 1 & Phase 2 FOCUS GROUPS ONLY: Potential participants will be given ample opportunity to ask questions of MHA and TS study staff.

Phase 1 Talkspace Survey: Contact information for the study team at both TS and UW is provided.

Phase 3B Study 2: Contact information for the study team at UW is provided, and participants are encouraged to contact the team with any questions.

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.

Phase 1 & Phase 2 FOCUS GROUPS ONLY: Focus groups are routinely used by MHA and TS for marketing and QI purposes. Members of the study team are experts in remote research with populations accessing digital mental health tools. Our study team has done previous work to determine the information that a user of digital mental health tools would want to know and what elements of remote study procedures are acceptable to remote study participants (Phase 1 of STUDY00004997; STUDY00004625; STUDY00001973; and STUDY00005434).

Phase 1 Talkspace Survey: TS routinely completes surveys as part of market research and the UW study team frequently completes study research.

Phase 3B Study 2: Both the UW and MHA study teams are frequently involved in study research.

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.

N/A

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.

☐	**No**	→ If no, skip to question 8.4
X	**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.

Phase 1 & Phase 2 FOCUS GROUPS ONLY: MHA and TS consumers will receive information via the preferred method of communication for the platform (e.g., email, text, on-site message).

- Talkspace Focus Groups: A member of the study team will email the consumer to provide more information, provide the consent form, schedule activities, and provide information on engaging in the focus group (e.g., Zoom info).
- MHA Focus Groups: After viewing/receiving the invitation, consumers indicate their interest by clicking on the invitation and completing a brief survey. A member of the study team emails interested participants to send the consent form and provide information about the focus group, which is all done online including instruction, options for anonymity, and any recording that may happen.

Phase 1 Talkspace Survey: Potential respondents review consent information online. Email addresses for the TS and UW study team are provided. We expect the review of consent information should take 2-4 minutes.

Phase 3B Study 2: Informed consent will be obtained electronically via REDCap. The participant will review the consent and provide consent online. Participants are encouraged to contact the study team via email if parts of the informed consent form are unclear, or if additional information is desired. Consent will be documented in REDCAP. Participants must select "I consent" at the end of the consent form in order to move forward with study procedures.

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?*

Phase 1 & Phase 2 FOCUS GROUPS ONLY: Participants will retain the information they receive. Both TS and MHA consumers will receive consent information via email, and will be able to reference materials as desired.

Phase 1 Talkspace Survey: Information is reviewed on a single screen. If a participant is unable to complete consent and wishes to return to it in the future, they would need to return to the invitation link and restart the process.

Phase 3B Study 2: Participants will be able to access the full consent document on the web page from REDCAP. Participants will also receive a copy of the consent form via email.

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.

Phase 1 & Phase 2 FOCUS GROUPS ONLY: Participants will be able to respond to study staff via email. Prior to the focus groups starting, study staff will review focus group procedures and allow time for questions.

Phase 1 Talkspace Survey: Email addresses for the TS and UW study team are provided.

Phase 3B Study 2: Participants will have the ability to ask questions of the study staff during initial consent activities and will have the ability to send questions to the study team via phone and/or email.

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.

Phase 1 & Phase 2 FOCUS GROUPS ONLY: All potential participants will be MHA or TS consumers. All services provided by both MHA and TS are provided electronically/virtually. While in-person focus groups in the New York and Seattle areas may be a possibility, we anticipate these focus groups will be completed virtually due to COVID-19 and our participant population.

Phase 1 Talkspace Survey: The survey is asking about engagement with TS, an online therapy service. If a participant does not have access to the internet, they would not engaged with TS and therefore would not be exposed to this survey.

Phase 3B Study 2: All potential participants will be MHA consumers, so they have some access to the internet and must be willing to access the internet to engage in the study.

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.

Phase 1 & Phase 2 FOCUS GROUPS ONLY: N/A – we anticipate these will be a one-time engagement.

Phase 1 Talkspace Survey: N/A

Phase 3B Study 2: Email and/or SMS

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
Phase 1 & 2: Focus Group Participants	Phase 1 & Phase 2 Focus Groups	☒	☐
Phase 1 Talkspace Survey Respondents	Phase 1 Talkspace Survey	☐	☒
Phase 3B MHA PHQ-9 responders/engagers	Phase 3B Study 1 SMART	☐	☒
		☐	☐
		☐	☐

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**

X **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.

Phase 1 Data Analysis & Phase 2 MRTs Activities: No consent procedures planned. Participants will be all consumers who naturalistically engaged with MHA and/or TS over the past 2 years (2018-2020) and who naturalistically engage during the study. Participants will be English and/or Spanish speaking. Both MHA and TS, as part of routine practice and as part of their terms and conditions, explain to consumers that their information may be used for research purposes and shared with researchers in academic settings to better understand mental illness and for quality improvement purposes. These procedures are offered to consumers in their chosen language. Because the purpose of this research is to better understand engagement in DMH tools, any interference from the study team would undermine our findings. Additionally, this study could not be done without a very large sample. Collecting formal consent from participants will prevent us from identifying a large sample and as has been found in previous studies of DMH, participants recruited explicitly for research engage differently than consumers who access DMH and are not participating in research.

Phase 1 & Phase 2 FOCUS GROUPS ONLY: Participants will be either English speaking only

Phase 1 Talkspace Survey: Respondents will be English speaking only.

Phase 3 Study 1: No consent procedures

Phase 3 Study 2: Participants will be English speaking only.

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.

N/A

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.

N/A

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.

N/A

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.

☐ **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).

To properly execute the control condition for the study specifically while maintaining a uniform consent process across all conditions so that the control condition and DIY tool without AI condition are not aware they are not receiving the DIY tool with AI which could influence their perception of their own intervention and their outcomes in turn, in the informed consent participants are not given a detailed description of the intervention with which they will be engaging.

In the consent form, prior to randomization, participants will not be given a full explanation about incentives for their participation, and this information is not given in detail because the incentive amounts vary depending on what condition they are randomized to and knowing these details prior to randomization may influence their perception of a condition and engagement in the study depending on the condition to which they are randomly assigned.

Participants in the DIY tool study will also be randomly assigned to their condition prior to consenting, and not informed of this assignment until they have consented to participate in the study. Randomization takes place prior to consent to provide a smoother and more consistent participant experience with less time delays across all participants and does not impact the participant's eligibility nor their experience with the screening surveys prior to consent. This information must be withheld to prevent the potential differential enrollment of folks depending on what condition to which they are randomly assigned. Knowing their assigned condition may influence their overall perception of the study and their likelihood of choosing to participate in the study.

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***.

At the conclusion of the study after their 8 week follow up assessment, participants will be referred to the DIY tool with AI that is available through the MHA website as a resource that they can use to help with cognitive restructuring.

Participants will be informed about the incentive payment structure for their specific condition in an email sent to them immediately (see 'incentive language by condition post randomization' document on 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.

[X] **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.

[ ] 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 dxuploaded: 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.*

Phase 1 & Phase 2 FOCUS GROUPS ONLY: Potential participants will receive an invitation from MHA or TS to participate in a focus group. Both MHA and TS consumers agree to these types of invitations as part of their terms and conditions. The consent form will include information about privacy protection for focus groups including that participants can participate without video turned on, using a blurred or image background, and with a name other than their own. Facilitators of the focus group will share specific directions on how to engage in these privacy measures as participants join the focus groups.

Phase 1 Talkspace Survey: Potential participants receive an invitation from TS to participate in this survey. TS consumers have agree to these types of invitations as part of their terms and conditions. The consent information includes information about how the survey information is not shared outside of the study team.

Phase 3B Study 2: Potential participants are shown an invitation from MHA to participate in the study. MHA consumers agree to these types of invitations as part of their terms and conditions. The consent form will

include information about privacy protection measures in place for the study, including the deidentification of their information and how survey info will be secure and not shared outside of the study team.

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 **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.

We will apply Level 5 protections to data sets that include any identifiable information (e.g., dates of service).

We will apply Level 1 protections to deidentified data sets.

We will comply with all applicable requirements as outlined in our Data Security Protocol (uploaded to Zipline).

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.

Computer and storage servers are physically located in highly secure, locked, dedicated Allen School datacenter facilities with controlled access. They are accessible only to authorized Allen School technical staff. All our machines that are used to process the data are behind a NAT router and hence are not publicly available on the internet. Our networks are also monitored for suspicious traffic. The data will be stored on a Linux filesystem and restricted with standard Unix file permissions, which will allow us to restrict the data access on a per user basis. All user computer accounts are managed and authorized via a centralized Allen School identity management system, managed by Allen School technical staff. Only PIs and researchers on the project will be given access to the files. This ensures that people have to get 1) access to the UW network, 2) access to a lab-computer behind a firewall and NAT router, 3) access to the dataset only accessible to project staff (several layers of protection). Data will never be stored on private computers and laptops.

Phase 2 Talkspace Focus Groups Screening Survey: The screening survey will be hosted on Talkspace's Google Forms. Talkspace has a BAA with Google Workspace and this platform is HIPAA compliant. Deidentified information will be shared with UW for reporting purposes through previously outlined methods used for other study procedures.

Phase 3 MHA Study 2 DIY Tool Data: The Microsoft Azure platform hosts the DIY tool. This application is HIPAA compliant. For data that is entered by participants while using the tool, in-transit data is encrypted. A validated cryptographic module is used for the storage encryption for data at rest. 24-hour threat management protects the infrastructure and platform against malware, distributed denial-of-service (DDoS), man-in-the-middle (MITM), and other threats. Deidentified information will be shared with UW for analysis through previously outlined methods used for other study procedures.

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.*

Phase 1 Data Analysis Activities & Phase 2 MRTs: Participants will be all consumers who naturalistically engaged with MHA and/or TS over the past 2 years (2018-2020)(Phase 1) and who naturalistically engage during the study (Phase 1 and 2). We do not anticipate any risks as participants will be consuming services from MHA and TS as they typically would.

Phase 1 & Phase 2 Focus Groups: Participants may experience fatigue during the focus groups. They will be able to take breaks and/or stop participating at any time. Video recording of participants may cause some stress for participants and presents a risk of loss of confidentiality. They will be informed prior to joining that they can to turn off their video camera at any time. Video recordings will be stored securely and only accessible to researchers. Data from focus groups will be coded and analyzed by study team members resulting in deidentified outputs.
Phase 1 Talkspace Survey: Participants may experience fatigue while responding to the survey. They will be able to take breaks and/or stop participating at any time.

Phase 3B Study 1 SMART: Participants may experience emotional distress and/or discomfort while engaging with survey questions or reading content on the MHA website. When scoring positively on questions regarding suicidality on the PHQ-9, MHA provides the following message to users: If you need immediate help, you can reach the Suicide & Crisis Lifeline by calling or texting **988** or using the chat box at **988lifeline.org**. You can also **text "MHA" to 741-741** to reach the Crisis Text Line. **Warmlines** are an excellent place for non-crisis support. There is also a 'contact us' feature on the MHA website that allows users to contact organization staff with questions.

Phase 3B Study 2: Some of the questions/prompts asked during assessments or when engaging with the DIY tool might make participants feel uncomfortable or upset; however, participants may choose not to answer any question at any time and still continue with the study. They are also informed during consent that if experiencing emotional distress and/or thoughts of self-harm or suicide, to text MHA to 741741 or call or text 988 to be connected to immediate help.

Participants may experience fatigue while responding to the survey. They will be able to take breaks and/or stop participating at any time.

If the participant endorses any suicidal ideation during the PHQ-9 administration in REDCap, they will see the following information on the screen in REDCap: "If you are ever experiencing thoughts that life is not worth living, self-harm, or suicide and need to speak with someone immediately, you can reach the Suicide & Crisis Lifeline by calling or texting 988 or using the chat box at 988lifeline.org/chat. You can also text "MHA" to 741-741 to reach the Crisis Text Line."

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)

<u>If any of the boxes are checked</u>:
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.

The DSMP has been uploaded to Zipline as "MHATS DSMP"

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

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.

n/a

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.

n/a

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.

[X] **No**

☐ **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.

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

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*

b. Is there a plan 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.

☒ **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.*

☐ **Confirmed**

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

☒ **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).

Phase 1 & Phase 2: MHA services are free. TS consumers pay for their services. Because this phase examines data from consumers who are naturalistically engaged in MHA and TS services, TS consumers will continue to pay for their services.

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/

☒ **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.

Examples:

Research Study Coordinator: Obtain consent, administer surveys, blood draw. Will have previous experience coordinating clinical research and be a certified phlebotomist in WA.

Undergraduate Research Assistant: Obtain consent, perform all study procedures. Will have had coursework in research methods, complete an orientation to human subjects protections given by the department, and will receive training from the PI or the graduate student project lead on obtaining consent and debriefing subjects.

Acupuncturist: Perform acupuncture procedures and administer surveys. Must be licensed with WA State DoH and complete training in administering research surveys given by the project director, an experienced survey researcher.

Co-Investigator: Supervise MRI and CT scan procedures and data interpretation, obtain consent. MD, specialty in interventional radiology and body imaging. 5-years clinical research experience.

Project Manager: 4+ years experience in clinical research, remote clinical trials, and data acquisition; Responsible for coordinating all data collection activities, documenting study procedures, preparing study reports and ensuring regulatory requirements are met.

Graduate Student: Conduct data analyses and machine learning experiments on existing observational data of MHA and TS platforms

Data Analyst: Assist PIs in setting up the data management platform, code book, monitoring data quality, communicating with MHA and TS regarding technical issues, and generating reports on data quality

Research Study Assistant: Provide operational support to all facets of the study

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 have completed CITI trainings. The study team will meet regularly (biweekly at project start up and monthly thereafter).

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.

N/A

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?

- [X] **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.