Study Protocol for

Real-time Intervention for Suicide Risk Reduction: Primary Open Pilot

Clinical Trials Number: NCT03950765

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RESEARCHER INFORMATION

Principal Investigator Name	**Evan Kleiman, Ph.D.**
Affiliation (check all that apply)	☐Faculty ☐Graduate Student ☐Post-Doc ☐Undergraduate ☐Extension School Student ☒Staff ☐Visiting Scholar ☐Other (specify):
Faculty Sponsor (if PI is not PI Eligible)	**N/A**
Other Advisor Name (if applicable)	**N/A**

STUDY INFORMATION

Study Title	**Real-time intervention for suicide risk reduction (pilot phase)**
ESTR Number	IRB18-1813
Version Number	**1.0**
Is this a re-submission of a previous Harvard IRB-approved study that has been closed?	☐Yes - Include previous IRB submission # here: ☒No

1. FUNDING INFORMATION

1.1 Is your study funded (either directly or through a sub-award) by a Federal Agency (i.e., NIH, NSF, DOD, DOE, DOJ, or EPA, etc.)?

☒Yes
☐No

1.2 Is your study funded (or will it be) by the National Institutes of Health (NIH)?

☒Yes
☐No ***(please go to next section)***

1.3 Does your study meet the NIH definition of a "Clinical Trial"?

☒Yes
☐No

2. RESEARCH COLLABORATIONS AND LOCATIONS

LOCATIONS

Locations refer to the geographic location where the research will take place, not to the people or institutions that you may be collaborating with. Knowing the location helps the IRB determine the local context of the research as well as if there are additional laws, regulations, and policies researchers need to adhere to. If conducting online studies, please indicate the location of the researcher who is hosting.

2.1 Where will this study take place?

☒Harvard University
☒At another location in Massachusetts
☐In another US state ***(see below)***
☐Internationally ***(see below)***

If you chose "in another US state" or "Internationally" describe the laws that will need to be considered:

Please ensure that what you have marked above matches what has been indicated in the ESTR SmartForm, section "Research Locations."

2.2 Do you plan to obtain data from individuals located in the European Economic Area (EEA)*?

☐Yes – *Please go to next question*
☒No – *Skip to #2.4*

If "YES" the data you obtain may be subject to the E.U. General Data Protection Regulation (GDPR). Click here for more information.

**** The EEA includes the 28 states of the European Union and four additional countries: Iceland, Liechtenstein, Norway, and Switzerland. Note that this regulation may also apply to data obtained over the internet.***

2.3 Will data collected from individuals located in the EEA include any of the following? (mark all that apply)

☐Racial or Ethnic Origin
☐Political Opinions
☐Religious or Philosophical Beliefs
☐Trade Union Membership
☐Sexual Orientation
☐Data concerning a person's sex life
☐Biometric Data
☐Genetic Data

2.4 Are there any U.S. state laws, international laws, or other laws that the IRB will need to consider when reviewing this study?

☐Yes ***(see below)***
☒No

If "Yes" describe the laws that will need to be considered:

2.5 Thinking about the locations where this study will take place, are there any permissions that must be obtained from cooperating institutions, community leaders, government officials? *This may include a review by a local ethics board, school district, Ministry of Health, or other institutional approval process, whether domestic or international. A statement that formal review is not required along with your source*

of information that the proposed research is in accordance with local laws, regulations, and customs is also acceptable.

☒Yes ***(see below)***

☐No

If "Yes" describe and if available, upload any permission documents to the ESTR SmartForm section "Local Site Documents."

Reliance agreements will be established with:

1. Partners Healthcare/MGH: Where data collection will take place.
2. Rutgers University: Where some data analysis will take place.

2.6 Are there any community or cultural differences for the local population of participants that require consideration? *For example, cultural or gender dynamics or social structure considerations.*

☐Yes ***(see below)***

☒No

If "Yes" describe:

COLLABORATIONS/SITES

Collaborations, known as "sites" in ESTR, refer to people or institutions that are also taking part in the research study. An important part of knowing about these collaborations is knowing what each person/institution is doing in the research in order to determine the scope of IRB review.

2.7 Will you be collaborating with any researchers not affiliated with Harvard University Area to carry out this study? *HMS, HSPH, and HSDM are not part of Harvard University Area.*

☒Yes

☐No ***(skip to next section)***

2.8 Will the actions of these collaborators include any of the following: Have contact with human subjects; Have access to data that is identifiable; OR Are responsible for the design, conduct, or reporting of the research?

☒Yes

☐No ***(skip to next section)***

2.9 Will these collaborators receive their own IRB review?

☐Yes, all will receive their own IRB review (skip to next section)

☒No, none will receive their own IRB review

☐Some will receive their own IRB review and some will not

2.10 Is another institution and/or researcher requesting that the Harvard University Area IRB act as the IRB of record ("Reviewing IRB") for that institution's or that researcher's activities on the study?

☒ Yes

☐No ***(see below)***

If you chose "No" describe the compliance/ethical oversight that this researcher will have in place:

2.11 If the Harvard University Area IRB will be providing review for the non-Harvard affiliated collaborating researchers, indicate which institutions they are affiliated with and their role and activities on this study (are they involved in recruitment, data collection, analyzing data, etc.) Add additional lines as necessary.

Name	Institution	Role on Study	Description of Activities that They will be Conducting
J. Huffman	Partners/Mass General Hospital; Harvard Medical School	Input on study design; Patient recruitment; Overseeing inpatient portion of the study	Advising RAs on appropriateness of potential participants for inclusion; Overseeing and refining Unified Protocol (UP) intervention implementation in inpatient unit
K. Bentley	Partners/Mass General Hospital; Harvard Medical School	Input on study design; Patient recruitment; Overseeing UP implementation	Advising RAs on appropriateness of potential participants for inclusion; Overseeing and refining UP intervention implementation
M. Stein	Partners/Mass General Hospital; Harvard Medical School	Clinical supervision	Advising RAs on appropriateness of potential participants for inclusion
C. Bucci	Mass General Hospital	Study therapist	Providing therapy sessions during the inpatient portion of the study.
S. Calderon	Mass General Hospital	Study therapist	Providing therapy sessions during the inpatient portion of the study.
E. Kleiman	Rutgers University (Dual affiliation with Harvard)	PI	Activities at Rutgers will be limited to data analysis (with data accessed on SharePoint hosted by Harvard)

Note: C. Bucci and S. Calderon are Clinical Psychology Interns at MGH. All clinical psychology interns are still students at their home institutions, which is why their attached CITI certificates list these institutions.

3. STUDY TEAM QUALIFICATIONS AND TRAINING

3.1 Describe the Principal Investigator's experience with the proposed research procedures, population, and local context.

Dr. Evan Kleiman is a Research Associate in Psychology at Harvard University and an Assistant Professor of Psychology at Rutgers, The State University of New Jersey. Dr. Kleiman has extensive experience in clinical research and has conducted and supervised numerous research projects with undergraduate and graduate students. Kleiman's research is aimed at advancing the prediction of and prevention of suicidal thoughts and behaviors. His research uses technologically-

advanced methodology (e.g., ecological momentary assessment, ambulatory physiological monitoring) that allows assessment of risky and harmful behaviors as they occur in real time with particular expertise in conducting research using smartphone-based ecological momentary assessment and intervention in individuals at high risk for suicide.

Data collection will be completed at Massachusetts General Hospital (MGH) – a Harvard Medical School teaching hospital. Our research team has a history of successful and ongoing collaborations with MGH. More specifically, we have completed recent projects using various longitudinal data streams to improve the understanding and prediction of suicidal behavior among hospital patients, including projects using: (a) electronic health record (EHR) data to predict suicide attempts and deaths, (b) iPad-based behavioral assessments (and blood samples) of patients recruited in the APS to improve the short-term prediction of suicidal behavior, and (c) smartphones and biosensors among psychiatric inpatients to create digital phenotypes of STBs and to improve the prediction of STB incidents among those at risk. Because of this earlier work, MGH already has a research infrastructure and a history of productive collaborations doing precisely this type of project, making our team extremely well-prepared to successfully complete the work.

3.2 Describe how the study staff are trained to ensure that they are adequately informed about this study and study-related duties.

All study staff will have completed human subjects training (NIH or CITI) prior to working with human subjects. The PI, Project Manager, and the research team will develop a Study Manual to be used as both a training and a reference tool. Study staff will be trained extensively by the key study staff (Kleiman, Nock) and will have access to Dr. Huffman and Dr. Bentley should any concerns arise while they are working on the research study. Research staff will practice consenting patients and administering the intervention/surveys with other members of the lab. Additionally, research staff will be approved by the PI and the IRB prior to any work with study participants. All study therapists will be doctoral-level trainees who will be trained and supervised by study staff at MGH (Bentley, Stein).

3.3 Are there any other additional study staff whose role in this study requires special qualifications in addition to ethics training (e.g., licensed clinical psychologist, phlebotomist, etc.)?

☒Yes ***(see below)***
☐No

If "Yes" describe:

Clinical psychology interns will be administering the UP in-person inpatient sessions and will have completed human subjects training (NIH or CITI) prior to working human subjects. Specific interns have not been identified yet; however amendments will be submitted as needed when interns have been identified. Several members of the study staff are licensed: Nock and Stein are licensed clinical psychologists, Huffman is a licensed medical doctor. Kleiman and Bentley are in the process of obtaining licensure.

4. RESEARCH PURPOSE

4.1 Provide a brief, non-technical description of the purpose of the research, including the research questions that you hope to answer.

Suicide is among the leading causes of death worldwide, and the risk of suicide is highest in the period immediately following discharge from inpatient psychiatric care.[1–3] Importantly, despite the enormously elevated risk during this period, nearly 50% of patients do not attend scheduled

therapy after discharge.[4] Even among those who do attend therapy, however, the skills learned in treatment may be difficult to use during the highly distressing time leading up to and during a suicide crisis.[5,6] **Most traditional treatments are not designed to be effective during a suicide crisis.** In order to reduce the risk of suicidal thoughts and behaviors in general and specifically during the post-discharge period, interventions are needed that: (1) are easily adhered to and (2) are accessible and effective during a suicide crisis.

The purpose of this research study is to test an innovative, new intervention in order to develop an effective and accessible intervention for those at high risk for suicide. The study will use two new technologies, ecological momentary intervention (EMI) and wearable physiological monitoring, to deliver the Unified Protocol (UP)[7] – an evidence-based transdiagnostic cognitive behavioral therapy. Delivery of this brief intervention will happen through three daily prompts on the participant's smartphone over a 28-day post-discharge period with the option for the participant to complete additional interventions if they choose. EMI and wearable monitors are uniquely suited for adherence and accessibility during a suicide crisis because more than 80% of Americans aged 18-49 carry a smartphone with them throughout the day,[10] and because the commercially-available wearable physiological monitoring device that will be used (Empatica Embrace) is unobtrusively worn on the wrist like a watch. The UP is uniquely suited for efficacy because it is a short-term, skills-based treatment that targets affective states that increase suicide risk by teaching adaptive responses to intense emotion (such as the intense emotion that characterizes a suicide crisis).[11] Moreover, initial findings by our team support the use of an adapted brief UP intervention with suicidal inpatients.

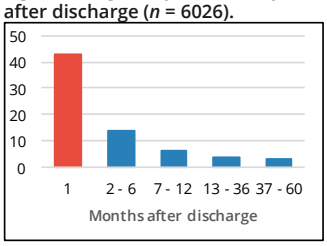
The present study will be a small, uncontrolled pilot of our intervention that then will inform a larger randomized controlled trial (RCT, which will be a separate IRB protocol submitted at a later date). Participants in this pilot study will be 25 inpatients from MGH Inpatient Psychiatry Service with elevated risk for suicidal thoughts and behaviors. The intervention will consist of three flexible in-person inpatient therapy sessions aimed at delivering core UP content and training participants on use of the EMI, followed by smartphone-based EMI with wearable physiological monitoring for the duration of the inpatient stay and the high-risk 28-day post-discharge period. The primary aim of the study will be to (a) examine feasibility and usability of the intervention in preparation for a larger RCT (including further refinements of our technique to use the Empatica Embrace to detect high risk periods) and (b) to test the initial efficacy of the intervention. We will solicit participants' feedback about the intervention, allowing us to assess feasibility and make modifications. We will assess real-time pre- to post- intervention changes in suicidal ideation, allowing us to assess efficacy. The data collected from this study will contribute information towards increasing the effectiveness of a technologically-advanced and easily administered intervention hypothesized to reduce risk for suicidal thoughts and behaviors. The intervention will be notable because of: (1) its focus on being available just in time during a suicide crisis, (2) its integration with inpatient treatment and potential compatibility with outpatient treatment, and (3) its wide scale applicability.

4.2 Describe the scientific background, rationale for the study, and importance of this research in adding to existing knowledge.

The rate of suicidal thoughts and behaviors (STBs) is alarmingly high. Suicide is a leading cause of death among all age groups, but is especially alarming among 18-34 year olds and 35-54 year olds (where it is the 2nd and 4th leading cause of death, respectively).[1] Despite a significant amount of research, the US suicide rate has not declined over the past 30 years. In the past 15 years, the suicide rate has increased year over year more often than not.

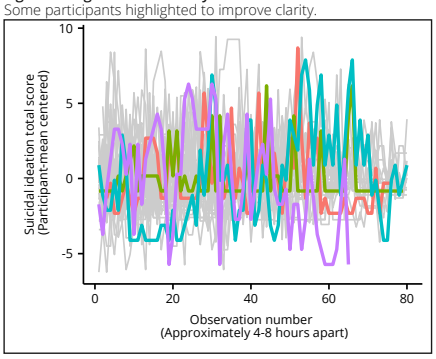
Moreover, for every person who dies by suicide each year, 25 people will attempt suicide, 50 will make a suicide plan, and 185 will have serious thoughts of suicide,[2,3] many of whom may ultimately go on to die by suicide.[4]

Fig 1. Average daily suicides 5 years after discharge (*n* = 6026).



The risk of suicide is highest in the time immediately following discharge from inpatient psychiatric care.[2,3,21–24] **Fig. 1** shows data from a population-based study[25] that tracked individuals who ultimately died by suicide within 60 months of discharge from inpatient psychiatric care. The risk of dying by suicide was nearly four times greater in the first month after discharge than in any of the next 59 months. Despite this knowledge, and despite recent calls for research on interventions that are effective during the post-discharge period,[26] prior research has fallen short by not examining interventions that can reduce risk during the transition from inpatient to outpatient care. Our study addresses this limitation by specifically targeting individuals who are in this high-risk period.

Fig. 2. Changes in momentary suicidal ideation.
Some participants highlighted to improve clarity.



Research suggests that the four weeks after discharge are so risky because of poor treatment adherence after discharge, as nearly 50% of patients do not attend scheduled therapy after discharge.[4,27] The skills those who do attend therapy learn may be difficult to use during the highly distressing time leading up to and during STBs (i.e., a suicide crisis).[5,6] Suicide crises can emerge suddenly and escalate rapidly. **Fig. 2** shows our real-time monitoring data showing that people with a suicide attempt history often go from no ideation to very severe ideation in just a matter of hours. Indeed, nearly one-third of responses differed by a standard deviation or more from the previous rating 4-8 hours earlier. Because this period of rapid escalation of suicidal ideation is highly distressing, the skills learned in therapy might not be easily accessible. As discussed below, our intervention is highly accessible during a suicide crisis by providing repeated contact throughout the day and by allowing on-demand administration when participants are having suicidal thoughts.

Existing suicide risk interventions are limited in several key ways. The few existing treatments for suicide risk reduction have limited efficacy.[17] Several brief interventions (e.g., caring letters)[28–30] exist, including some that use smartphones.[31] According to a recent meta-analysis, the effects of such interventions are at best weak, and in most cases non-significant when adjusting for publication bias.[32] Four key limitations hinder these interventions' effectiveness, each of which is addressed by the proposed project: **(1) Existing interventions do not provide sufficiently frequent contact.** Most existing brief suicide risk interventions involve one post-discharge contact via postal mail or text message. Those with multiple contacts are still infrequent, ranging from twice weekly[33] to once every other month.[34] Meta-analysis of brief interventions in related areas (e.g., alcohol abuse)[35] suggest that the most effective interventions involve frequent contact over short intervals. Our intervention has at least three daily contacts. **(2) Most interventions are introduced and practiced during calm periods and are not easily accessible during highly distressing suicide crises.**[36–38] In our intervention, patients practice UP skills during exposures with a therapist while distressed (after first learning the skills while calm). On-demand interventions that can be easily initiated whenever needed and Empatica E4-triggered interventions that are presented when there is an indication of distress increase accessibility during a crisis. **(3) Existing interventions do not target the underlying mechanisms of STBs.** A few interventions are specifically designed for use during a suicide crisis (e.g., safety planning).[39]

Although useful to alleviate a suicide crisis, they do address the underlying factors that precipitated the crisis, limiting their efficacy in preventing future crises. Our intervention is designed to both alleviate a suicide crisis in the moment (because of its smartphone and physiological monitoring technology) and to help prevent future suicide crises (because of the UP's therapeutic content). **(4) Existing interventions do not complement outpatient therapy.** Nearly 50% of individuals do not attend planned therapy after discharge.[4] Attending therapy is very important because those who do not are more likely to attempt suicide again.[40] Previous studies of suicidal individuals have found that increased follow-up contact with a patient increases outpatient treatment attendance[41] and decreases suicide risk.[30] We expect that the repeated daily contact will increase outpatient treatment adherence (Aim 2c).

Our intervention overcomes barriers that prevent suicidal people from receiving treatment. (1) Our intervention reduces stigma[42,43] by being private and discrete. Using the smartphone EMI would look to observers no different than any other smart-phone activity (e.g., sending text messages). **(2) Our intervention may reach those who cannot access outpatient therapy.** There is approximately one therapist for every 100 mentally ill individuals with even fewer in some rural areas.[44] **(3) Our intervention is cost-effective.** Many individuals do not begin or continue treatment because of the cost.[45] Our intervention requires fewer face-to-face sessions than typical risk reduction protocols. Whereas traditional cognitive behavioral therapy (CBT) protocols for suicide risk reduction[46] involve 10 face-to-face sessions with a therapist, our UP-based protocol requires only five sessions.

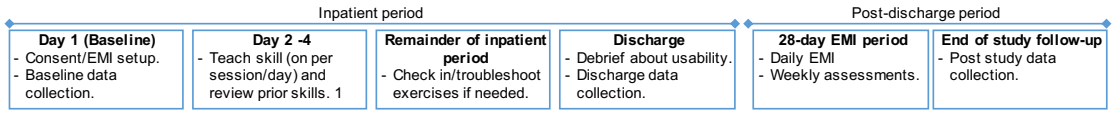
5. STUDY PROCEDURES

5.1 Provide a complete overview of the study:

- Describe the procedures participants will be asked to complete or undergo.
- Explain step by step what participants will be asked to do
- Include how long the procedures will take.

If your study includes multiple variations of the procedures, please make clear which procedures are included in the variations.

Figure 3. Overview of study procedures.



A. Inpatient period. This period will have five components:

(1) Consenting and baseline data collection. Data collection will begin on, or near, the participant's inpatient intake date. Participants will be asked to complete a brief iPad-based baseline survey assessing suicide history, key sociodemographic information, and psychiatric/psychological risk factors. See "Self-report items" in ESTR for the text of these items.

(2) EMI setup and customization. The EMI setup is simple and involves installing and configuring two smartphone apps: LifeData, to enable EMI and active data collection; and Empatica Alert, to transfer data from the wearable biosensor watch to the cloud. The participant will also be introduced to and familiarized with the wearable biosensor watch called Empatica

Embrace. Both apps and the wearable device have been previously approved by the HUA IRB (see IRB 16-0380).

LifeData (http://www.LifeDataCorp.com/) is an Android- and iOS-compatible real-time monitoring program that will be used primarily for administering the intervention and study assessments as well as collecting GPS location at the time the intervention is completed. LifeData is highly secure as the data collected are stored using 256-bit encryption and participant names will not be used on the system (. This EMI platform will allow us to flexibly tailor many aspects of the intervention (e.g., scheduling prompts to be delivered around sleep schedules).

Empatica Alert App is an Android- and iOS-compatible app that is used to sync the wearable device (described below) to the secure cloud server. The device connects to the participant's smartphone to upload data to the smartphone. The data is encrypted and secured on the phone and uploaded as soon as possible (immediately in most cases), and then removed from the phone. It uses the same industry-standard security as other apps in our suite of apps.



Figure 4. The Empatica Embrace

The Empatica Embrace is a wearable biosensor with an appearance similar to current watches/wearables. Most importantly, it is one of the few wearable sensors that can assess electrodermal activity (EDA; also called galvanic skin response). It can also assess physical activity and temperature, which will allow us to reduce false positives from the EDA signal and will allow us to assess a variety of parameters related to sleep. Our team has considerable expertise in using these types of devices. We have used this and similar devices in our prior studies (e.g., IRB 16-0380).

(3) EMI training. Starting on the second day of the study, participants will begin three 30-minute sessions of in-person EMI training (around 1 session per day). The number of sessions can vary depending on the patient's inpatient schedule as the modules are flexibly designed to be able to fit in a dynamic range of sessions. The goal of these sessions is to teach three core UP skills: mindful emotion awareness, cognitive flexibility, and countering emotion-driven behaviors (see attachment "Therapist session outlines" for session outlines and "Demo text for intervention" for examples of what will be presented to participants) and to train participants on how to use the EMI platform LifeData. These in-person sessions are based on the UP protocol previously tested with suicidal inpatients[66] and involve learning a new intervention, reviewing any previous day's content, troubleshooting if needed, and practicing the learned skills using the EMI on the LifeData app. Participants will have access to all previous modules and will be signaled to complete (i.e. practice) them three times daily through the app, in addition to being able to self-initiate the EMI. This pattern of reviewing the past day's intervention, learning a new intervention, and practicing that intervention mirrors an effective component of traditional CBT.[5] The three modules that will be taught in the in-person sessions are summarized below.

Module name	**Brief description of skills taught in module**	**Suicide-relevant deficit targeted by skill**
Mindful emotion awareness	This skill brings one's attention to the present moment, away from upsetting past events or future possibilities.	Attentional impairments, problem-solving deficits, abnormal stress response, rumination.
Cognitive flexibility	This skill helps individuals be more flexible in their thinking about emotion-provoking situations.	Cognitive rigidity, cognitive distortions.

Countering emotion-driven behaviors	This skill helps individuals counter maladaptive, emotion-driven behaviors with more adaptive, alternative actions.	Low emotion tolerance.

EMI prompts and delivery. As detailed earlier, the EMI will be delivered and practiced through the LifeData app three times a day. Each EMI survey prompt will have three components: (1) pre-intervention assessments of distress and suicidal ideation, (2) UP intervention, and (3) post-intervention assessments of distress and suicidal ideation. The final EMI of the day will assess treatment utilization, negative events, and experience with the intervention. The EMIs will be delivered in: (1) random prompts throughout the day as practice *(although we will evaluate in the pilot study whether patients find this practice helpful and remove it from the full RCT if they do not),* (2) and when initiated by pressing a button on the application (an intervention module will be randomly chosen).

The pre- and post-intervention assessment are identical. We will assess a variety of affect states and mechanisms of change. The assessments of current suicidal ideation will include: the patient's desire to die by suicide, intent to die by suicide, and to resist the urge to die by suicide. All of these items are currently being used in our other real-time monitoring studies and are able to detect variations over very short periods of time.

The final EMI prompt each day will assess participants' daily experiences with the intervention, including any trouble with the LifeData app or with the Empatica Embrace, how much participants believed that the intervention was useful during the day, and if or to what degree the intervention interfered with their daily life.

Assessments. We will send three assessment prompts per day, which will include the same text as the pre-intervention survey. Thus, participants will receive a total of six prompts per day: 3 that include interventions and 3 that include assessments. We are including assessment-only prompts in order to allow us to collect data on participants when they are not receiving an intervention.

(4) Remainder of inpatient period. After all skills have been taught, participants will complete the intervention as they would, described above in "EMI prompts and delivery." Study staff will check in with participants each day to review any of the skills if needed.

(5) Discharge. At discharge, participants will complete an assessment similar to the baseline survey, asking questions about STBs that occurred during the inpatient period and about usability of the intervention See "Self-report items" in ESTR for the text of these items. Nearly all participants will be on the inpatient unit for >7 days and thus we will, in essentially all cases, have ample time to complete all of the study procedures in the timeline specified. If a patient is to be discharged early, we can easily modify the protocol to take fewer days since the intervention was designed to flexibly fit to "real life" conditions as much as possible. As the length of stay varies between participants, we will record information on length of stay, allowing us to examine if a length of stay has an effect on any of the study outcomes.

B. Post-discharge intervention period.

Participants will complete the intervention and assessments as they would, described above in "EMI prompts and delivery." Push notifications asking participants to complete one of the three modules will be delivered in a random order at random times (scheduled to not interfere with sleep).

We will also contact participants weekly to administer self-report measures of specific EMI skills and assess changes in suicidal ideation and behaviors (treatment usage, changes in UP mechanisms. The last weekly assessment will also ask about user experiences with mobile health applications.

We will contact participants again at the end of the post-discharge period to get general opinions about the intervention. See "Self-report items" in ESTR for the text of these items.

C. Evaluation of feasibility and usability.

The primary goal of the pilot study is to assess the feasibility and usability of the intervention. We will assess this in several ways: **(1) Quantitative assessment of experiences.** As mentioned earlier, during discharge and the last weekly assessment we will send a set of self-report measures through LifeData that assess user experiences with mobile health applications (some of which will take from the Mobile App Rating Scale,[6] a measure that evaluates the quality of mobile health interventions). We will also ask participants about the intervention (e.g., which module was their favorite and which seemed most effective). **(2) Qualitative self-report assessment of experiences.** During the discharge assessment, we will present participants with a list of open ended questions asking if any parts of the in-person sessions were confusing or unhelpful and solicit specific opinions for what participants would change about the intervention. For example, we will assess the desired number of prompts during the weekly assessment, and whether these prompts interfered with daily living during the in-app assessment.

The below sections contain additional questions depending on the type of research that you are conducting and is meant to supplement the study overview. Please complete each section, as applicable.

SURVEYS/ QUESTIONNAIRES/PSYCHOMETRIC TESTING

5.2 List the names of all surveys/questionnaires/psychometric tests to be used in this study and a description of any that are not standard/formally named (such as study-specific questionnaires).

Smartphone measures

All smartphone self-report questions are listed in the "smartphone questions" attachment in ESTR.

Self-report measures.

The chart below lists the self-report measures that we will give in various parts of the study: Baseline (BL), Discharge (DC), once per week during the study (Wkly), and at the end of the 28-day monitoring period (Wkly). All of the items and their references can be found in the "Self-report measures" attachment. All of these measures are standard assessments.

Measure name	Items	Used in? BL	DC	Wkly	End	Notes
Demographics	6	X				
Handedness Questionnaire	3	X				
PROMIS Emotional Distress-Depression	4	X	X	X	X	See "PROMIS Depression, Anger Anxiety"
PROMIS Emotional Distress-Anger	5	X	X	X	X	See "PROMIS Depression, Anger Anxiety"
PROMIS Emotional Distress-Anxiety	4	X	X	X	X	See "PROMIS Depression, Anger Anxiety"

PROMIS Self-efficacy for managing emotions	4	X	X	X	X	
Hamburg-Hannover Agitation Scale (H2A)	11	X	X	X	X	
UP Cognitive Skills Usage	8		X	X	X	
Brief experiential avoidance questionnaire	15	X	X		X	
Self-Injurious Thoughts and Behaviors Interview, Self-Report (SITBI-SR)	15	X				
SITBI-SR, Discharge	6		X			
SITBI-SR, Weekly	6			X		
Emotion Reactivity Scale	21	X			X	
PROMIS Alcohol Use	8	X				
Mobile App Rating Scale			X		X	
Usability/Feasibility Questions			X	X	X	Based off of items from Mobile App Rating Scale

5.3 How often will participants be asked to complete the surveys/questionnaires/psychometric tests and how long will it take to complete?

The timeline of the procedures, surveys, and tasks will generally be as follows (however the inpatient intervention modules are flexible to fit into a dynamic range of sessions as they fit into the patient's inpatient schedule and will not interfere with treatment):

Day 1: Participants will go through the informed consent process, complete a baseline data survey, and be introduced to and set-up with the smartphone apps and biosensor watch (60 minutes total).

Days 2 –4: During their inpatient stay, participants will attend three EMI training sessions (30 minutes/day) to learn and practice UP intervention skills. Participants will complete/practice exercises when prompted outside of these sessions (3x/day, 10-15 minutes total) and complete assessment prompts (3x/day, 5-10 minutes total).

Discharge day: Participants will complete an assessment at discharge which will include completing a variety of measures about STBs that occurred during the inpatient period, questions about usability of the intervention, and a qualitative assessment of the participant's experience with the inpatient portion of the study (30 minutes total).

28 days post-discharge period: Participants will practice and use exercises taught during the first days of the study (3x/day, 10-15 minutes total), complete assessment prompts (3x/day, 5-10 minutes total), complete weekly assessments (15-20 minutes each). At the end of the study the participant will complete one last assessment similar to the one on discharge day.

5.4 Will you be using any survey software (such as Qualtrics)?

☒Yes (see question below)

☐No

If "Yes" which survey software will you be using? :

Qualtrics, LifeData, Embrace

INTERVIEWS/ORAL HISTORY/FOCUS GROUPS

Skip this section if not applicable. **N/A (Qualitative questions are open-ended self-report questions)**

5.5 Explain where interviews/focus groups will take place (including possible online venues such as Skype, online chat rooms, etc.)

5.6 Describe any steps you will take to protect the participant's privacy during the interview/focus group.

5.7 Describe the number of interviews/focus group sessions you anticipate for each participant and approximately how long you expect each interview/focus group to last.

OBSERVATIONAL/ETHNOGRAPHIC RESEARCH

Skip this section if not applicable. **N/A**

5.8 If you will be actively participating in the field (as in participant-observation), describe what this will entail.

5.9 Describe what and who will be observed and in what settings (such as public events, religious ceremonies, household activities, work meetings, internet chat-rooms and social media sites, etc.)

5.10 Will any observational data be considered private, according to the standards of that community?

☐Yes ***(see below)***

☐No

If "Yes" describe the information that would be private.

5.11 Will the data you collect contain any information that identifies specific individuals?

☐Yes

☐No

5.12 Do you plan to quote the remarks of participants in your study?

☐Yes
☐No

5.13 Will you notify participants that they are being observed?

☐Yes
☐No ***(see below)***

If "No" explain the circumstances why you would not be able to let participants know they are being observed.

5.14 If permission to observe participants is obtained, how will you ascertain whether there are individuals who do not want to participate, and how you will manage such a situation?

AUDIO-RECORDING/VIDEO-RECORDING/PHOTOGRAPHS

Skip this section if not applicable. **N/A**

5.15 What type of recording will take place? (check all that apply)

☐Audio-Recording
☐Video-Recording
☐Photography
☐Other ***(see below)***

If "Other" describe:

5.16 Explain what types of data will be recorded or photographed.

5.17 If you will be collecting sensitive data, will you use any procedures to de-identify or anonymize the recordings or photographs?

5.18 Explain what will happen to the recordings/photographs at the end of the study.

DECEPTION AND INCOMPLETE DISCLOSURE

Skip this section if not applicable. N/A

Deception is the intentional misleading of a subject about the nature of the study. While withholding of full information is known as incomplete disclosure.

5.19 Describe what information will be withheld from participants or what misinformation will be provided to participants.

5.20 Explain why this research involves no more than minimal risk to participants and why it would be impracticable to carry out the research without the use of deception or incomplete disclosure.

5.21 Describe the plans for debriefing participants after their participation. If you do not plan to debrief participants, explain why.

Please be sure to attach a copy of the debriefing script (if applicable) to the "Local Sites Documents" section in the ESTR SmartForm.

USING PREVIOUSLY COLLECTED DATA

Please complete this section if you are receiving data that has already been collected. This section does not pertain to data that is being collected through interaction or intervention as part of this study. Skip this section if not applicable.

5.22 Indicate the identifiability of the data:

☐Will not contain any direct or indirect identifiers; will be anonymous.

☒Will not be directly identifiable, but there will be a code held by the data source that links to the identities; will be coded.

☐Will contain direct or indirect identifiers, but this research team will remove them upon receipt; will be de-identified data.

☐Will contain direct identifiers; will be identifiable.

5.23 Describe which data sets you plan to analyze, who is providing the data to you, and whether the data are public use data sets, restricted access datasets, or another type of dataset.

We will use information from the participant's Electronic Health Records provided by Partners Healthcare System.

5.24 Provide an overview of the types of variables that are contained in the dataset (for example, identifiable data such as names, dates of birth, addresses, or any data that are considered sensitive).

We will access Electronic Health Records (EHR) data for two reasons: (1) to make decisions about inclusion/exclusion and (2) for data analysis. In the sections below, we describe how our data flow procedures will remove any personal health information (PHI) from any extracted data before they reach non-MGH/Partners researchers. Thus, by the time non-MGH employees access the data, they will no longer be considered PHI.

Use 1: Making decisions about inclusion/exclusion. We will use EHR data to inform the study team about how appropriate a participant is for the study. The person who will be making the initial determination about appropriateness for the study (Michelle Stein) is an MGH employee and would make the determination by reviewing (but not recording information from) the EHR. Any consultation on eligibility would involve study staff who are MGH employees (Kate Bentley or Jeff Huffman) or non-MGH employees who could receive relevant information without PHI (e.g., reason for admission but not date of admission, name, etc.).

Use 2: Data Analysis. We will extract from Electronic Health Records (EHR) coded information about the participant's clinical history, current inpatient treatment, and treatment that occurs 6 months after the end of the study that can be used to aid in our prediction models to understand who will respond best to the intervention. The reason for obtaining this information from the EHR is to decrease participant burden during the study assessments.

The flow of these data will be as follows, which will avoid any non-MGH employee having access to data that are PHI.

(1) MGH/Partners RAs will have access to a linking sheet (stored on a secure SharePoint site accessible only by the MGH study staff) that links participant ID to Medical Record Number (MRN). No non-MGH employees will have access to this linking sheet.

(2) Initial extraction will be performed by Partners/MGH Research Assistants (RA). The MGH RAs will extract from the medical record data such as: chart diagnosis, previous receipt of treatment, and future hospitalizations and treatments. The following identifiers are included in the EHR but will <u>not</u> be included in the data extraction: (1) Name, (2) address, (3) telephone number, (4) fax number, (5) email address, (6) MRN (which will be contained in a linking sheet, described below, and only available to MGH/Partners staff but not extracted for analysis purposes), and (7) healthcare numbers.

(3) MGH RAs will enter this data (linked by study ID, but not MRN) into another MGH secure SharePoint site (that non-MGH staff do not have access to).

(4) MGH RAs will create from PHI data variables that are no longer PHI. The following identifiers will be used to create aggregate, non-identifiable variables (and only the non-identifiable variables will be given to the Harvard study team): (1) birthdate, which will be used to calculate current age at baseline, (2) admission and discharge dates, which will be used to calculate length of inpatient stay, and (3) date of any re-admissions, which will be used to calculate days from initial admission.

(5) MGH RAs will transfer to a SharePoint site accessible by the entire study team only the non-PHI data (including non-PHI data created from formerly PHI data in step 4). These data will be linked by study ID only.

5.25 Was the data you plan to analyze collected in a previous research study?

☐Yes ***(see below)***

☒No

If "Yes" provide the title/name of the previous research study and which institution and researcher collected the data for the previous study. If the data were collected in a previous Harvard University research study, provide the ESTR number assigned to that study.

5.26 Will any of your data be obtained from internet sites (including data mining and data scraping activities)?

☐Yes ***(see question below)***

☒No

If "Yes" what websites will you access to obtain the data?

Please know that it is your responsibility to check the terms of service of any websites from which you plan to collect data to determine whether your planned data collection is compatible with the terms of service.

5.27 Is the data publicly available on the internet (i.e., freely available without permission, sign-in, or other restrictions)?

☐Yes

☒No

5.28 Do you plan to access any data that is Protected Health Information (PHI) under the HIPAA law (for example, data held by a hospital or other healthcare provider or insurer)?

☒Yes

☐No ***(skip to question #5.31)***

5.29 Which organization will provide the HIPAA PHI to you?

We will use information from the participants' Electronic Health Record provided by Partners Healthcare System. The collaborators from MGH will examine all new medical records in the Partners Systems for each participant to determine if the participant revisited the hospital due to suicide ideation or suicide attempt during the follow-up period. This approach has been used in prior studies to measure such outcomes.

5.30 How will permission to allow the use/disclosure of individual's protected health information (PHI) be obtained?

Staff from Partners will obtain participants' permission to disclose these data.

HRP-330 WORKSHEET: HIPAA, which may be found in the ESTR library, provides an overview of items pertaining to HIPAA that may be helpful to the study team.

5.31 Do you plan to access any data that is FERPA protected (data that are held as education records by an educational institution)?

☐Yes
☒No

HRP-331 WORKSHEET: FERPA COMPLIANCE which may be found in the ESTR library provides an overview of items pertaining to FERPA that may be helpful to the study team.

USING PREVIOUSLY COLLECTED BIOLOGICAL MATERIALS

Please complete this section if you are receiving biological material that has already been collected. This section does not pertain to biological material that is being collected through interaction or intervention as part of this study. Skip this section if not applicable. N/A

5.32 Indicate the identifiability of the biological materials:

☐Will not contain any direct or indirect identifiers; will be anonymous.
☐Will not be identifiable, but there will be a code held by the data source that links to the identities; will be coded.
☐Will contain direct or indirect identifiers, but this research team will remove them upon receipt; will be de-identified data.
☐Will contain direct identifiers; will be identifiable.

5.33 How will you obtain the material? (check all that apply)

☐Residual clinical material
☐Material obtained from a vendor
☐Material that was collected as part of another research study ***(please see below)***
☐Other – ***(see below)***

If you chose "another research study" provide the title/name of the previous research study and which institution and researcher collected the specimens for the previous study. If the specimens were collected in a previous Harvard University research study, provide the ESTR number assigned to that study.

If "another research study" or "Other" please specify:

5.34 Will the material consist of any of the following? (check all that apply)

☐Embryonic tissue
☐Embryonic stem cells
☐Stem cells
☐Fresh human fetal tissue
☐None of the above

5.35 Provide an overview of the types of variables that will accompany the biological materials (for example, identifiable data such as names, date of birth, addresses, or any data that are considered sensitive).

DEVICES

5.36List the device(s) that you plan to use in this study (add additional lines as necessary):

NOTE: We will be using these devices that have been previously tested in other work (i.e., we are not evaluating the efficacy, safety, etc. of this device).

Device Brand Name	Generic/Common Name	Manufacturer	Purpose	Function/Operation
Empatica Embrace	Empatica Embrace	Empatica	Physiological monitoring	Senses skin conductance, movement, and skin temperature

5.37 Is the device(s) that you plan to use FDA-approved/cleared?

☒Yes
☐No

This device is FDA-approved for seizure detection (https://www.empatica.com/embrace/).

5.38 If any of the devices that you plan to use require a certified professional to operate, please explain who is certified to operate this device and whether they are on your study team.

This device does not require a certified professional to operate.

Please complete HRP-307 WORKSHEET: DEVICES which may be found in the ESTR library and attach to the "Local Site Documents" section in the ESTR SmartForm.

DRUGS

Skip this section if not applicable. **N/A**

5.39 List the drug(s) or biologic(s) that you plan to use in this study (add additional lines as necessary):

Drug/Biologic Brand Name	Generic/Common Name	Manufacturer	Purpose	Function/Operation

5.40 Is the drug(s)/biologic(s) that you plan to use FDA-approved/cleared?

☐Yes

☐No

5.41 Please explain who is qualified to dispense this drug/biologic and whether they are on your study team.

Please complete HRP-306 WORKSHEET: DRUGS which may be found in the ESTR library and attach to the "Local Site Documents" section in the ESTR SmartForm.

6. RISK AND BENEFIT ASSESSMENT

6.1 Describe the foreseeable risks associated with your study. Please include discussion of any physical risks and non-physical risks, such as economic, psychological, social, and legal harms.

There are several risks associated with this study. Although we believe them to be no more than minimal, we take these risks seriously and have carefully considered their occurrence and potential impact and have taken steps to minimize their occurrence.

1. **Some survey questions may be distressing.** It is possible that participants may experience psychological distress when reporting their thoughts, feelings, and behaviors related to self-injury. Addressing this concern, several studies have demonstrated that asking questions about suicidal behaviors does not result in detectable increases in psychological distress or increases in one's suicidal thoughts/behaviors.[25,26]

2. **We may need to break confidentiality.** We will inform participants that all information they provide as part of this study is confidential; however, there is a risk that we will need to break confidentiality if the participant indicates that they are at imminent risk of harming themselves. Participants will be informed during the consent process that this may involve the research team contacting them, contacting any collateral contact that they provide, calling their clinician (also with a number provided by the participant), or us calling emergency services (e.g., 911).

3. **Study participation may be learned by others because of the wearable device or completion of surveys, or by a breach of data security.** Regarding the wearable device, we selected the Embrace device because of its well-matched scientific capabilities (given the focus of this project and our prior data on the use of EDA to predict distress), but

also because it has the appearance of commercially available wearable devices commonly worn by non-participants in research (e.g., Fitbit, Apple Watch, etc.). We believe this will minimize the likelihood that study participation will be known by others while increasing compliance in the study. Regarding the surveys, we encourage discrete completion of the surveys. Regarding data security, we have taken significant steps involving data completion, transfer, and storage to minimize the likelihood of (a) data breach, and (b) a hacker being able to link the data stored on the server with a participant's identity (detailed below). We believe we have taken every step possible to minimize these concerns.

4. **Physical discomfort.** There is a risk that the biosensor watch will feel uncomfortable. Some people have also experienced skin irritation from wearing the biosensor.

6.2 Describe the steps that you will take to minimize risks to your participants (for example, using pseudonyms or a coding system, etc.)

Protections Against Risk

1. Risk: **Some questions may be distressing.** Protection: To decrease the likelihood of being distressed by the nature of the survey questions: (1) we will inform participants of this possibility during the consent procedures; (2) we will inform patients that they may skip questions that they find distressing; (3) we will inform participants that they may withdraw from the study at any time without penalty and (4) we will not approach participants determined by clinical staff to be in a level of psychiatric distress that would preclude participation in this study. All potential participants will have recently participated in a clinical evaluation with hospital staff, and any individual not satisfying the aforementioned inclusion/exclusion criteria will not be approached for participation in this study.

2. Risk: **We may need to break confidentiality.** Protection: We will inform participants during the consent process of all procedures that involve breaking confidentiality. We will also tell participants that in some cases there may be a delay in receiving a risk assessment response from us, so they cannot expect an immediate response and should not use their research responses as a substitute for requesting immediate help from other sources (e.g., their therapist, suicide hotline). We will not remove participants from the study because of elevated suicide ideation or intent in itself, only for suicide attempts or significant distress determined to be the result of their participation (i.e., they inform the research team that they are in distress because of their participation). If a participant is experiencing severe suicide ideation, he or she will be presented immediately with a pop-up screen that offers resources and suggests they may wish to follow up with a clinician regarding their thoughts or feelings. At baseline, all participants will be provided with a list of resources in case they would like to use them in the future.

5. Risk: **Participants' identity and data will become known due to data breach or to wearing a sensor**. Protection: Participant data will be linked with a research ID number. All identifiable information we collect (i.e., phone numbers or email addresses to contact participants to remind them about study assessments and for payment) will be kept separately from other research data, and all study data will be listed only by research ID number. The devices we will use to collect active, passive and physiological data during the 28-day daily monitoring period is fully HIPAA compliant and offers key features to protect the privacy of participants: 1) All data collected via LifeData and Empatica will be

coded by linking a unique identifying code (no personally identifying information is collected) and 2) all data are encrypted before they are stored on cloud-based databases (no data are stored on the server's file server). Further details can be found below in Section 12. As for the risk of wearing the sensor, as noted above, the sensor selected for this study is small and similar in appearance to commonly worn smartwatches/sensors.

3. Risk: **Physical Discomfort.** Protection: Study staff are trained to show participants how to reduce physical discomfort caused by the biosensor watch. They will show patients how to move the sensors around on the arms until comfortable, how to clean the sensors (with a damp cloth and, if needed mild soap, once per week) and how to carefully remove them if necessary. Patients will be informed they do not have to wear the sensors if they do not want to. The sensor should not hurt in any way. The sensor provided is similar to commercially available smartwatches that the participants may already be familiar with (e.g., Fitbit).

6.3 Are provisions needed for medical and/or psychological support resources (for example, in the event of research-related distress or incidental findings)?

☒Yes

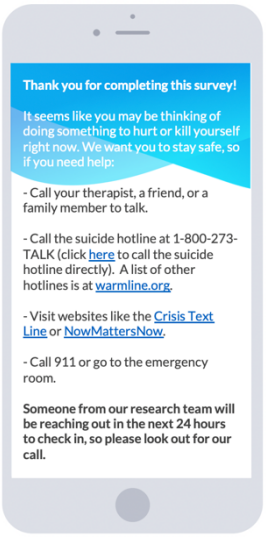
☐No

6.4 If applicable, what steps will you take if a participant becomes distressed during your study or reports intent to harm themselves or others?

Overview

Because the purpose of this study is to test an intervention to reduce suicidal thoughts among those at risk, we expect that every participant will experience distress (not as a result of participation) and desire/intent to harm themselves.

Our risk monitoring plan is based off of our prior experience in these types of studies (e.g., IRB 15-1975) and in consultation with experts in the field (e.g., other researchers, lawyers, clinicians). Our risk assessment will be triggered based on responses to the item assessing intent to act on suicidal desires ("right now how strong is your intention to die right now?"). We will use three thresholds for triggering a risk assessment: (1) Low, defined as any score 1-5 (on a 0-10 scale), (2) moderate, defined as 6-9 out of 10, and (3) high, defined as 10 out of 10. When participants report any non-zero score on the item assessing suicide intent, the software will display a pop-up message. The content of this message will vary based on the level of risk and the study period (i.e., inpatient vs. outpatient, because the resources available during each period differs). A demo screenshot of the pop-up message is shown to the right.



Inpatient period

Low risk (1-5 out of 10): At the conclusion of the survey, participants will receive a message thanking them for doing the survey and reminding them to contact a member of their treatment team if they need assistance. This will not involve breaking confidentiality since it will be fully automated.

Pop-up text: Thank you for completing this survey! Just a reminder, if you find yourself having thoughts of suicide, you should tell a member of your treatment team immediately.

Moderate risk (6-9 out of 10): At the conclusion of the survey, participants will receive a message thanking them for doing the survey and telling them that if they are feeling unsafe, they should contact a member of their treatment team if they need further assistance. This will not involve breaking confidentiality since it will be fully automated.

Pop-up text: Thank you for completing this survey! It seems like you may be thinking of doing something to hurt or kill yourself right now. We want you to stay safe, so if you need help, please tell a member of your treatment team immediately.

High risk (10 out of 10): At the conclusion of the survey, participants will receive a message telling them that they should contact a member of their treatment team immediately if they are having suicidal thoughts. We will also tell participants that we will be following up with their treatment team. A study RA will review the research data nightly to assess if any participants are at imminent risk for suicide. In these cases, the study RA will contact the staff on site (e.g., Dr. Huffman) who will take further clinical action (e.g., alerting the attending physician, conducting a detailed risk assessment). Research data will only be shared with the clinical team only if the participant is at imminent risk for suicide (i.e., if their intention of acting on their suicidal thoughts is 10 out of 10 or higher on the momentary prompt about suicide intent).

Pop-up text: Thank you for completing this survey! It seems like you may be thinking of doing something to hurt or kill yourself right now. We want you to stay safe, so please tell a member of your treatment team immediately. We will be reaching out to them to check in within the next 24 hours.

Rationale: Taking clinical action when participants are at high levels of suicide risk may bias participants' responding to the suicide risk questions. In this case, however, introducing the chance for bias reduces the risk for negative ethical and medico-legal outcomes that may be associated with having important clinical information about a participant's wellbeing and not sharing that information with the clinical team. Because inpatient units have such close monitoring of patients, we expect that in almost all cases the clinical staff will already be aware that a patient is at imminent suicide risk when we communicate with them. Thus, because the study information will be largely redundant with what is known by the clinical team, we expect the information to have no role in stay/discharge decisions. There may be rare cases where the participant is reporting to the study that they are at imminent suicide risk but not reporting to the clinical staff the same level of risk. In this case, the clinical staff would conduct additional clinical interviews, which are still part of routine clinical care.

Outpatient period

Low risk (1-5 out of 10): At the conclusion of the survey, participants will receive a message thanking them for doing the survey and providing some on-line resources if they feel unsafe (e.g., links to nowmattersnow.org). This will not involve breaking confidentiality since it will be fully automated.

Pop-up text: Thank you for completing this survey! Just a reminder, if you find yourself having thoughts of suicide, you can:

- Visit websites like the Crisis Text Line (link to https://www.crisistextline.org/)
- Call the suicide hotline (1-800-273-8255) or any of the other hotlines listed here (warmline.org).

Moderate risk (6-9 out of 10): When participants report any non-zero score on the item assessing whether the participant is considering acting on their suicidal thoughts, the software will display at

the end of the survey a pop-up message. This pop-up includes information such as a button to call the suicide hotline and a reminder to go to the ER if needed. We will not need to break confidentiality in this situation.

> **Pop-up text:**
>
> Thank you for completing this survey! It seems like you may be thinking of doing something to hurt or kill yourself right now. We want you to stay safe, so if you need help:
>
> - Call your therapist, a friend, or a family member to talk.
> - Call the suicide hotline at 1-800-273-TALK (click here to call the suicide hotline directly). A list of other hotlines is at warmline.org.
> - Visit websites like the Crisis Text Line or NowMattersNow.

High risk (10 out of 10): We will instruct participants that 10 out of 10 on the item assessing whether the participant is considering acting on their suicidal thoughts at that very moment means they are at imminent risk (i.e., "hours away from attempting suicide"). In these cases, in addition to the pop-up message, participants will receive a message that we will be following up via phone call within 24 hours to conduct a more thorough risk assessment and take further action if needed (e.g., suggesting they go to the ER, calling the suicide hotline, or calling 911 for the participant). Some of these actions (e.g., calling 911 for the participant) could involve breaking confidentiality. We expect, however, for these cases to be quite rare since our studies on this unit have only ~2% of responses at 10/10 and we consider actions like calling 911 a measure of last resort. Thus, we would need to take this action few, if any, times. The other actions we may take during the follow-up phone assessment (e.g., suggesting the participant go to the ER) would not involve breaking confidentiality. In cases where we suggest taking some action in the future (e.g., going to the ER at that time, seeing their therapist in the morning), we will call the participant again to determine whether they have done so.

> **Pop-up text:** Thank you for completing this survey! It seems like you may be thinking of doing something to hurt or kill yourself right now. We want you to stay safe, so if you need help:
>
> - Call your therapist, a friend, or a family member to talk.
> - Call the suicide hotline at 1-800-273-TALK (click here to call the suicide hotline directly). A list of other hotlines is at warmline.org.
> - Visit websites like the Crisis Text Line or NowMattersNow.
>
> Someone from our research team will be reaching out in the next 24 hours to check in, so please look out for our call.

Collateral contact: As a requirement for being enrolled in the study, participants must provide at least one verifiable collateral contact (and more than one if the participant wishes). During the consent process, we will obtain permission from the participant to reach out to the collateral contact if we cannot reach the participant (e.g., if we need to do a risk assessment [as mentioned above], if we need to contact the participant regarding compliance). When we contact the collateral contact, we will only do so to request the participants' contact information (if there is new contact information) or to ask the collateral contact to ask the participant to get in touch with the research team. We will do this in a way that does not reveal the nature of the study (e.g., by saying that we are calling from Massachusetts General Hospital/Harvard University with some information for the participant but not saying what that information is). As part of the consent process, we will inform participants how we will use the collateral contact information (to get in touch with them) and how we will not use the collateral contact information (to enlist the contact's help in assessing risk).

To collect the collateral information, we will give participants a paper form they can write the contact info on (in ESTR called "Back-up contact sheet"). After the baseline session, study staff will enter this information into the secure SharePoint site and shred the contact form.

Rationale: As with our plan for the inpatient period, taking action when participants are at high levels of suicide risk may bias participants' responding to the suicide risk questions. In this case, however, introducing the chance for bias reduces the risk for negative ethical and medico-legal outcomes that may be associated with not taking further action when participants are at elevated risk for suicide.

6.5 Describe any potential direct benefits to participants in the study. If there are no individual benefits, indicate as such.

There is no guarantee of direct benefits to participants in this study. However, participants in this study may receive benefit in the form of suicide risk reduction given that the aims of the study are to create an intervention that can be used to reduce suicide risk among suicidal inpatients during their hospitalization and immediate discharge.

6.6 Describe any potential benefits to society.

The proposed study has the potential to help people in the future through improvement of existing treatments and development of an effective and accessible interventions for people who experience suicidal thoughts and behaviors. The data gleaned from this study will also provide useful real-time monitoring data that can be used to inform our understanding of the imminent prediction of suicidal thoughts and behaviors.

7. CHARACTERISTICS OF THE STUDY POPULATION

7.1 Indicate the estimated number of participants, by subgroup if applicable. *If it is not possible to estimate the number of participants (e.g., open online survey), please indicate that it is not possible and provide an explanation of why it is not possible.*

Participants in the pilot study will be 25 adult (18+ years) patients from Massachusetts General Hospital (MGH) Inpatient Psychiatric Service (IPS).

7.2 Describe the criteria for enrollment – Will you be limiting your enrollment to a certain age range, gender, people with certain health conditions, etc.? Please also describe any criteria that will exclude people from enrollment.

Inclusion criteria include a recent suicide attempt or serious suicidal ideation (i.e., ideation with at least 70% intent or a suicide plan with access to lethal means), the ability to speak and write English fluently, access to an internet-capable smartphone (e.g., an iPhone or Android phone), and providing at least one collateral contact in cases where we cannot reach the participant. Inclusion criteria will be assessed by the research staff reviewing information from the clinical intake interview that is given by hospital staff to all individuals upon admission as well as a brief conversation during recruitment to gather information not assessed during the clinical intake interview (e.g., what type of phone the participant owns).

Exclusion criteria include the presence of any factor that impairs an individual's ability to comprehend and effectively participate in the study including: an inability to speak or write English fluently, the presence of gross cognitive impairment due to florid psychosis, intellectual disability, dementia, acute intoxication, or the presence of extremely agitated or violent behavior. Decisions

about these inclusion/exclusion criteria will be made by the attending psychiatrist at the time and primary consideration will be given to ensuring the safety of all participants and research staff involved. Additionally, patients who are on involuntary hospitalization status will be excluded. Individuals younger than 18 years old will also be excluded.

There will be **no study-initiated withdrawal** for participants who are noncompliant of the EMI or study assessments. For the purpose of increasing feasibility and acceptability of the intervention through this pilot study, we are interested in capturing as many participants' experiences of the intervention as possible including those who are noncompliant. Participants will have the option of partially withdrawing (e.g. only withdrawing from the EMI components but not the weekly/monthly study assessments or vice versa) or completely withdrawing. During withdrawal, we will also ask for permission for us to continue following their medical record.

If a participant returns to a higher level of care (e.g., visits the psychiatric emergency department or is re-hospitalized) we will make every effort to keep these participants in the study. If a participant indicates (via the questions on the smartphone survey) that they have visited the psychiatric ED or have been re-hospitalized, we will contact them to assess whether they should remain in the study. We will withdraw participants if: (1) Their ED visit or re-hospitalization triggers other withdraw criteria (e.g., if the participant is on a unit where they cannot use their phone). (2) The worsening of symptoms is related to the intervention. (3) The clinical team has concerns with the participant's involvement in the study. Upon withdrawal (and if necessary when contacting the participant to troubleshoot before withdrawing them), we will conduct a thorough risk assessment and will help with a referral if needed.

7.3 Are there any potential vulnerable populations or individuals proposed for involvement in the research? (check all that apply)

- ☐Children
- ☐Wards of the State
- ☐Prisoners/Detainees
- ☐Pregnant Women
- ☐Adults not Competent to Consent
- ☐Non-English Speaking
- ☐Employees of Harvard University (as a focus of the study)
- ☐Undergraduate Students of Harvard University (as a focus of the study)
- ☐Staff or students that are part of your lab or for whom you provide oversight
- ☐ Other – ***(see below):***

If "Other" please specify:

CHILDREN

Skip this section if not applicable. **N/A**

7.4 What is the age range of children participating in your study?

7.5 Are there any special considerations that need to be taken into account? For example, do the children have a learning disability?

PRISONERS

Skip this section if not applicable. N/A

7.6 Describe any advantages that prisoners may accrue through their participation in the research, especially in comparison to the general living conditions, medical care, quality of food, amenities, and earning opportunities in the prison.

7.7 Explain whether the risks of the research are commensurate with risks that would be accepted by non-prisoner research participants.

EMPLOYEES OR STUDENTS OF HARVARD UNIVERSITY

Skip this section if not applicable. N/A

7.8 Explain how you will minimize the potential for employees and/or students of Harvard University to feel coerced or experience undue influence to participate in the research.

8. RECRUITMENT

8.1 Will potential participants be provided with information about the study?

☒Yes ***(see below)***
☐No ***(skip to next section)***

If "Yes" indicate how, when, where, and by whom participants will be recruited. If you are recruiting from a Harvard University Study Pool, describe how you meet their requirements.

Study staff will obtain explicit permission from patients in the IPS at MGH to be approached about the research study. A study research assistant (RA) working within MGH will check in with the inpatient clinical staff each day to inquire about whether any new admitted patients meet the study inclusion criteria and have agreed to be approached. If so, the RA will check in with that patient's attending psychiatrist to receive their permission to approach the patient and double-check whether the patient will have access to his or her mobile device throughout the stay. Once the patient's inclusion criteria are confirmed, the RA will approach the patient, briefly describe the study and ask if they are interested in learning more about it. If the potential participant declines to know more about the study, no further attempts will be made to enroll. If the patient agrees to participate, the RA will describe the study more fully and walk the patient through the informed consent procedure and obtain their written informed consent to participate. Following informed consent, the RA will go through the baseline data collection procedures with the patient and introduce them to the real-time monitoring and EMI procedures. The participant will then begin the in-person intervention sessions during their inpatient stay.

The attached recruitment outline "Clarifications 3.0_R34_IRB_Enrollment Outline" in ESTR describes this process. Only research team members who are affiliated with MGH will be reviewing medical records during this process.

8.2 Are there any materials that will be used to recruit participants (e.g., websites, emails, posters, oral scripts)?

☒Yes ***(see below)***
☐No

If yes, list the materials by document name here, and be sure to attach copies to the "Consent and Recruitment Materials" portion of the "Local Site Documents" section in the ESTR SmartForm.

Oral recruitment process (see outline in Local Site Documents)

HRP-315 WORKSHEET: ADVERTISEMENTS which may be found in the ESTR library provides an overview of items pertaining to advertisements that may be helpful to the study team.

9. SCREENING

9.1 Will you be screening participants for eligibility?

☒Yes
☐No ***(skip to next section)***

9.2 Explain what your screening criteria will be and how you will conduct the screening process.

Clinical staff at MGH will know about the inclusion/exclusion criteria (outlined above) and will work with the Study RA to determine whether someone is appropriate for the study.

9.3 Do you plan to destroy the data from people who participate in the screening process and do not qualify to be in the study as soon as the screening process is over?

☐Yes
☒No ***(see below)***

If "No" explain why you will keep the data collected in the screening process for people who are not eligible to participate in this study.

We will collect no identifying information about persons who are identified as not meeting screening criteria for the study. We will, however, collect the age, gender, and reason for refusal for persons approached about the study but who decide not to participate. This will allow us to report differences in basic demographics between those who do versus those who do not agree to study participation.

10. INFORMED CONSENT PROCESS

If you plan on having more than one consent process (such as signed, written consent for one population and use of an online "click" consent script for another population), please explain which variations of the study will use which types of consent process with each of these questions.

ADULT PARTICIPANTS

If you will not include adults in your study, please skip this section.

10.1 Will you be obtaining informed consent or an agreement to participate (for Exempt studies) from participants that take part in your study?

☒ Yes, I will be obtaining informed consent or an agreement to participate.
☐ No, I will not be obtaining consent or an agreement to participate **(skip to next section after answering below)**

If you will not be obtaining consent or an agreement to participate, please explain:

- ***why this research involves no more than minimal risk to participants and***
- ***why it would be impracticable to carry out the research with consent or an agreement to participate***

10.2 Will the consenting or an agreement to participate process involve obtaining a signature?

☒ Yes
☐ No ***(see below)***

If a signature is not obtained, explain why:

10.3 Where will the consent or an agreement to participate process take place?

☒In-person
☐Online
☐Over the telephone
☐Other ***(see below)***

If other, please describe:

A research member will guide and consent the participant in person using a paper consent form. After the consent process is completed, the consent form will be copied and given to the participant for their records.

10.4 Who will obtain consent or an agreement to participate from participants? *Will the Principal Investigator, other members of the Harvard University research team, collaborating researchers from other institutions, or another third party (such as a survey firm) obtain consent?*

Members of the research team including trained RAs and PI/Co-Is (on both the Harvard team and the MGH/Partners team) will be obtaining consent from the participants. In no cases will the potential participants' physician be involved in consenting the participant. All of the study staff (who are approved study team members) who could see patients at MGH and might complete consents in some rare cases (e.g., if Dr. Bentley filled in for an RA who is not in that day) typically do not actually see patients on the unit. Drs. Huffman, Bentley, and Stein are all involved in supervisory/administrative roles on the unit. In the very rate case of these study team members was having direct patient contact, we would make sure they are not involved in the study consent process. The study therapists described in section 2.11 will not be involved in consent and the other study staff at MGH (RAs) are not able to provide care to patients. Moreover, we will make clear during our introduction to the potential participant that the research study is not associated with their treatment.

10.5 Describe the process that will be used to obtain consent or an agreement to participate.

We will thoroughly and comprehensively inform participants of all study details, all risks involved with this study, that their participation is completely voluntary, that their responses are confidential (unless we learn of significant imminent risk of harm to the participant or someone that they identify), and that they can skip questions and can stop participating at any time. We also will inform participants that their participation in the study will have no effect on any clinical care that they may receive at MGH. Finally, we will inform the participants that the study is not the sole route to keep them safe during times of imminent suicide risk and we will use the collateral contacts only to get in touch with the participant (if we cannot get a hold of them), and not to enlist the contact's help in risk assessment or safety planning.

To ensure that participants understand the informed consent procedure, we will have a series of true/false questions about the study that they must answer before they can begin participating. We have used this approach in numerous studies with clinical participants and have found that it is an effective way to ensure that participants fully understand the study, and to screen out those who cannot.

10.6 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.

To ensure that participants understand the informed consent procedure, we will have a series of true/false questions about the study that they must answer before they can begin participating:

1. We will reach out to (one of) your backup contact(s) if we can't get ahold of you but will only ask the backup contact to give you a message and will not tell them about the study.
2. In this research study, we are going to ask you to complete surveys sent through your smartphone during the time you are in the hospital and for 28 days after.
3. We will not be monitoring your survey responses in real time. If you are in distressed or feeling unsafe, it is your responsibility to contact your clinician, call 911, or visit the nearest emergency department.

CHILDREN PARTICIPANTS

If you will not include children in your study, please skip this section. **N/A**

If you are including children in your research study, know that consenting or requesting an agreement to participate from a child is comprised of two parts: child assent and parent permission.

10.7 Will you be obtaining assent or an agreement to participate (for Exempt studies) from child participants that take part in your study?

☐ Yes, I will be obtaining assent or an agreement to participate.
☐ No, I will not be obtaining assent or an agreement to participate ***(skip to next section after answering below)***

If you will not be obtaining assent or an agreement to participate, please explain:

- ***Why this research involves no more than minimal risk to participants and***
- ***Why it would be impracticable to carry out the research with assent or an agreement to participate:***

10.8 Will the assenting or an agreement to participate process involve obtaining a signature?

☐ Yes
☐ No ***(see below)***

If a signature is not obtained, explain why:

10.9 Where will the assent or an agreement to participate process take place?

☐In-person
☐Online
☐Over the telephone
☐Other ***(see below)***

If other, please describe:

10.10 Who will obtain assent or an agreement to participate from child participants? *Will the Principal Investigator, other members of the Harvard University research team, collaborating researchers from other institutions, or another third party (such as a survey firm) obtain the assent?*

10.11 Describe the process that will be used to obtain assent or an agreement to participate from children.

10.12 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.

PARENT PERMISSION

If you will not be including children in your research, please skip this section. N/A

10.13 Will you be obtaining parent permission or an agreement to participate (for Exempt studies) from parents whose child takes part in your study?

☐ Yes, I will be obtaining parent permission or an agreement to participate.

☐ No, I will not be obtaining parent permission or an agreement to participate ***(skip to next section after answering below)***

If you will not be obtaining parent permission or an agreement to participate, please explain:

- ***Why this research involves no more than minimal risk to participants and***
- ***Why it would be impracticable to carry out the research with parent permission or an agreement to participate:***

10.14 Will the parent permission or an agreement to participate process involve obtaining a signature?

☐ Yes

☐ No (see below)

If a signature is not obtained, explain why:

10.15 Where will the parent permission or an agreement to participate process take place?

☐In-person

☐Online

☐Over the telephone

☐Other ***(see below)***

If other, please describe:

10.16 Who will obtain parent permission or an agreement to participate from the parents? *Will the Principal Investigator, other members of the Harvard University research team, collaborating researchers from other institutions, or another third party (such as a survey firm) obtain the permission?*

10.17 Describe the process that will be used to obtain parent permission or an agreement to participate from parents.

10.18 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.

OTHER TYPES OF PARTICIPANTS

If this section is not applicable, skip to next section. N/A

10.19 If you will be including **Wards of the State**, explain how consent of legal guardian(s) of ward(s) will be obtained. How will you ensure that the appropriate person granted permission for each ward to participate?

10.20 If you will be obtaining consent from special populations such as **non-English speaking participants**, **illiterate participants**, or **adults not competent to consent**, please explain how you will obtain consent from those individuals.

10.21 Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.

Please be sure to attach copies of all informed consent/parent permission/assent materials to the "Local Site Documents" section in the ESTR SmartForm.

11. PARTICIPANT COMPENSATION AND FINANCIAL OBLIGATION

11.1 Will your study offer any compensation/incentive to participants (including cash, gift cards, course credit, etc.)? *Please refer to the Harvard University Financial Policy on Human Subject Payments.*

☒Yes
☐No ***(skip to next section)***

11.2 What type of compensation will you provide to participants?

☐Cash
☐Check
☒Gift Card/Gift Certificate
☐Course Credit
☐Lottery/Raffle
☐Other ***(see below)***

If you chose "Other" please specify:

11.3 What amount will the compensation be worth?

All participants will be compensated as detailed below:
For each completed EMA prompt (6x/day), participants will be compensated $0.50 for a total of up to $105. For wearing the Empatica Embrace each day, participants will be compensated $1 for a total of $35. For completing weekly surveys, participants will be compensated $5 per survey, totaling to $25. For completing the end of study follow up assessment, participants will be compensated $15.

If participants complete more than 4 EMA prompts per day, the participant will earn an additional $2 every day for a total of $70. If participants wear the Empatica Embrace for 4 days out of the week, participants will earn an additional $5 per week, totaling $25. In total the participants will be able to earn up to $275.50 by the end of the study. (This total number may change slightly due to variance in inpatient stay.) The following table summarizes the compensation schedule.

Item	Compensation	Frequency	Weekly $ per participant	Total $ per participant
Completing each EMA prompt	$ 0.50	6x/day	$ 21.00	$ 105.00
Wearing wearable monitor	$ 1.00	1x/day	$ 7.00	$ 35.00
Completing weekly survey	$ 5.00	1x/week	$ 5.00	$ 25.00
Completing follow-up surveys	$ 15.00	1x/study	N/A	$ 15.00
			SUBTOTAL	**$ 180.00**
Bonuses				
Completing 4+ assessments/day	$ 2.00	1x/day	$ 14.00	$ 70.00
Wearing monitor for 4 days/wk	$ 5.00	1x/week	$ 5.00	$ 25.00
			SUBTOTAL	**$ 95.00**
			GRAND TOTAL	**$ 275.50**

11.4 Describe which participants will receive compensation and when the compensation will be given.

All participants will be eligible for compensation. We will use Amazon electronic and physical gift cards depending on the participant's preference. Physical gift cards will be sent to participant's preferred addresses and electronic gift cards will be sent to the participant's preferred email address. Email addresses recorded in Amazon will not be linked to participants' personal identifying information and participants will be encouraged to use non-identifying email addresses.

The gift cards will be sent at three points: at discharge, two weeks after discharge (50% through post-discharge period), and after we receive confirmation that the Embrace has been shipped back to us (we will send participants a pre-paid envelope with a tracking number before the end of the study).

Participants will receive notifications via email that they will be/have been compensated for completing the study element. In line with Harvard's Human Subjects Payment Policy, none of the single payments will exceed $100 but combined over the course of the study, they will exceed $100.

11.5 Will you provide partial compensation for participants who do not complete all the study procedures?

☒Yes **(see below)**

☐No

If "Yes" please explain how partial compensation will be managed:

The compensation will be managed as described above.

HRP-316 WORKSHEET: PAYMENT which may be found in the ESTR library provides an overview of items pertaining to payment that may be helpful to the study team.

11.6Will participants incur any financial costs by taking part in this study?

☐Yes ***(see below)***

☒No

There are no direct costs to the participant. The applications run primarily through Wi-Fi and can be set to run exclusively through Wi-Fi. The participants may choose to run the applications through Wi-Fi at the outset of the study, or they may change the application settings to run through Wi-Fi at any time. They will be notified of this during the application set-up. If there is an instance where the participant has exceeded their personal data plan during a single month and the participant has not already done so, the participant can change the application settings to connect only through Wi-Fi and continue with participation in the study at no cost to the participant.

If "Yes" please explain.

12. DATA SECURITY AND MANAGEMENT

12.1 Describe the identifiability of the data when first obtained/collected:

☐Will not contain any direct or indirect identifiers (Anonymous)

☐Will not be directly identifiable but there will be a code held by the data source that links to the identities (Coded) – *i.e., if receiving data from another site*

☒Will contain direct identifiers (Identifiable)

12.2 Describe the identifiability of the data when stored:

☐Will be directly labeled with personal identifying information (identifiable)

☒Will be labeled with a code that the research team can link to personal identifying information (Coded)

☐Will not be labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information (Anonymous or De-identified)

☐Other - explain here:

12.3 Which category of information best describes the data according to the Harvard Research Data Security Policy? ***Please know that it is the researcher's responsibility to ensure compliance with the Harvard University Data Security Policy at all times.***

☐LEVEL 1 - Data that is publicly available or not identifiable. Examples:

- Research data that has been de-identified in accordance with applicable rules;
- Published research data; published information about the University;
- Course catalogs;
- Directory information about students who have not requested a FERPA block;
- Faculty and staff directory information.

☐LEVEL 2 - Information the University has chosen to keep confidential but the disclosure of which would not cause material harm. Examples:

- Research data that is identifiable but is not considered sensitive;
- Patent applications and work papers, drafts of research papers;
- Building plans and information about the University physical plant.

☒LEVEL 3 - Information that could cause risk of material harm to individuals or the University if disclosed. Examples:

- Information protected by the Family Educational Rights and Privacy Act (FERPA) to the extent it is not covered under Level 4 including non-directory student information and directory information about students who have requested a FERPA block;
- HUIDs associated with names or any other information that could identify individuals;
- Harvard personnel records (employees may discuss terms and conditions of employment with each other and third parties);
- Institutional financial records;
- Individual donor information;
- Other personal information protected under state, federal and foreign privacy laws not classified as Level 4 or 5.

☐LEVEL 4 - Information that would likely cause serious harm to individuals or the University if disclosed. Examples:

- High Risk Confidential Information (HRCI) and research information classified as Level 4 by an IRB;
- Personally identifiable financial or medical information;
- Information commonly used to establish identity that is protected by state, federal, or foreign privacy laws and regulations;
- Individually identifiable genetic information that is not Level 5;
- National security information (subject to specific government requirements);
- Passwords and Harvard PINs that can be used to access confidential information.

☐LEVEL 5 - Information that would cause severe harm to individuals or the University if disclosed. Examples:

- Research information classified as Level 5 by an IRB or otherwise required to be stored or processed in a high security environment and on a computer not connected to the Harvard data networks;

- Certain individually identifiable medical records and genetic information, categorized as extremely sensitive.

12.4 In what format will the research data be **collected**?

☒ Paper
☒Electronic
☐Other – ***(see below)***

If "Other" please specify:.

12.5 In what format will the research data be **stored**?

☒ Paper
☒Electronic
☐Other – ***(see below)***

If "Other" please specify:.

12.6 Explain **where** the research data will be stored while the study is active (e.g., personal laptop, thumb drive, departmental computer server, office file cabinet, etc.).

Coded data will be collected on Qualtrics, LifeData, and Empatica servers hosted on Amazon Web Services, the global leader in cloud-based solutions. AWS is ISO 27001 certified to comply with gold standard "security management best practices and comprehensive security controls" and SOC 3 certified to be protected against "unauthorized access, use, and modification." This data will then be synced to our secure Level 4 Microsoft SharePoint site for cleaning, analysis, archiving, and sharing. A separate Level 4 SharePoint site will be made to house any enrollment information that links the participant's personal identifying information with their respective study datasets. This includes the participant's: name; age; sex; race; medical record number; email; phone number; address; collateral contact information (name, email, phone number, and relationship to participant); smartphone application usernames and passwords for LifeData and Alert; and their study ID number.

Paper consent forms will be stored separate from any research data in a locked cabinet, in a locked room near the inpatient unit at MGH.

12.7 Will the data be managed by Harvard researchers either remotely or housed at Harvard (e.g., physically or Harvard Cloud Storage)?

☒Yes
☐No

12.8 Do you anticipate that the research data will be transferred or transported from your possession to another at any time?

☐Yes
☒No ***(skip to question #12.10)***

12.9 Explain what methods you will use to transfer/transport the data and how you will minimize the risks of a data breach during the transmission process.

12.10 Will data be transferred from the EEA* to Harvard or another non-EEA location?

☐Yes

☒No

**** The EEA includes the 28 states of the European Union and four additional countries: Iceland, Liechtenstein, Norway and Switzerland.***

12.11 Will (or has) a Certificate of Confidentiality (CoC) be (been) obtained for this study? *If your study meets the definition of a clinical trial according to the NIH, a CoC will be automatically issued with your funding.*

☒Yes

☐No

12.12 What will happen to the data at the conclusion of the study? (check all that apply)

☐Direct identifiers* and/or the key to the codes will be destroyed upon completion of the research (all data will be stripped of identifying information and/or the key to codes destroyed, identifiable paper documents shredded, identifiable electronic files purged, Identifiable electronic media securely erased).

☒Retained for study record keeping purposes per institutional policy

☒Retained by the investigator for future research use.

☐Retained for future research use (create repository/bank).

☐Restricted use data will be destroyed or will be returned to the source.

☐No direct or indirect identifiers* are being collected. This anonymous data will be retained at the discretion of the investigator.

☐This research is a clinical trial conducted under FDA regulations. Direct identifiers* and/or the key to the codes will be destroyed as directed by the sponsor (IND/IDE holder) in accordance with FDA regulations.

☐Other – ***(see below)***

**** Direct identifiers.*** *These are variables that point explicitly to particular individuals or units. Examples include: names, addresses, including ZIP and other postal codes, telephone numbers, including area codes, Social Security numbers, other linkable numbers such as driver's license numbers, certification numbers, etc.*

Indirect identifiers. *These are variables that can be problematic as they may be used together or in conjunction with other information to identify individual respondents. Examples include: detailed geographic information (e.g., state, county, province, or census tract of residence), organizations to which the respondent belongs, educational institutions (from which the respondent graduated and year of graduation), detailed occupational titles, place where respondent grew up, exact dates of events (birth, death, marriage, divorce), detailed income, offices or posts held by respondent.*

If "Other" please specify:.

13. SHARING DATA WITH OTHERS

13.1 Will the data be released to anyone who is not on the Harvard University Area research team?

☒Yes

☐No ***(skip to question #13.4)***

13.2 Other than the Harvard University Area research team, who will have access to the data?

☒Colleagues/Collaborators at other institutions

☒Transcribers/coders hired by the research team

☒Sponsor/Funding Agency

☒Other ***(see below)***

If "Other" please specify:.

We plan to share all raw, coded data, as well as summary variables created during the data cleaning and coding process, with the other awardees, NIH, and ultimately with the scientific community more broadly. Raw data will be shared as participants begin completing their study involvement (i.e., data from individual participants would be shared only after they complete their 28 days of post-discharge study involvement), and coded variables created from the raw data would be shared after all data are collected and coded variables are created. We would be pleased to consider other timelines for data sharing. As a general principle, our team strongly values openness, transparency, and sharing of scientific data and products. All data will be coded with an NIH-supplied GUID (https://data-archive.nimh.nih.gov/guid) that will not be personally identifiable.

Data that are shared with other members of the research team who are not affiliated with Harvard primarily or have other appointments in addition to Harvard (MGH, Rutgers) will have access to the secure SharePoint site mentioned in 12.6 and will thus be able to access coded (see 13.3) data there.

13.3 How will the data be shared/disclosed beyond the Harvard University Area research team?

☐Without any identifiers

☒Coded

☐With Identifiers

13.4 Will you be sharing research findings with study participants?

☒Yes ***(see below)***

☐No

If "Yes" please describe which findings will be shared, when they will be shared, and how they will be shared with participants (in-person, over the telephone, etc.):

We will share study results as requested, or as available, or at the end of the study through email.

13.5 Does the study include establishing a repository for sharing data or specimens with other researchers?

☐Yes ***(If so, please know that a separate IRB submission will be needed if a data or specimen repository will be created)***

☒No

GENOMIC DATA SHARING

13.6 Will you be submitting data to a national data repository (dbGaP, GEO, etc.) or other type of repository for broad sharing of data?

☐Yes

☒No ***(skip to next section)***

13.7 Will you require a Genomic Data Sharing (GDS) Institutional Certification per NIH GDS policy?

☐Yes

☒No

13.8 Include a description of all fields to be submitted to the repository:

13.9 Describe the plan for de-identifying data for inclusion in the repository, including how the key linking the identity of participants will be maintained and who will have access:

If data will be prospectively collected, specific elements are required to be included in the informed consent form that you will be using in this study. Please see the NIH guidance document.

If data that will be submitted have already been collected under another IRB or other collection protocol, please be sure to attach a copy of the IRB approval and approved consent form(s) used to collect the underlying data/specimens to the "Local Site Documents" section in the ESTR SmartForm.

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