Cover Page for ClinicalTrials.gov

Document: Informed Consent Form

Official Study Title: A One-Arm Open Trial of a Smartphone Delivered Treatment for Suicidal Thoughts and Behavior

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NCT Number: NCT06967545

Mass General Brigham

Subject Name:

MRN or DOB:

Research Consent Form
General Consent Form Template
Version Date: November 2022

Protocol Title: A Randomized Controlled Trial of a Smartphone Delivered Treatment for Suicidal Thoughts and Behavior.

Principal Investigator: Adam Jaroszewski, Ph.D.

Site Principal Investigator:

Description of Subject Population: 20 adults with recent suicidal thoughts

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

We are asking you to be in a research study. This form will tell you what you should expect if you agree to be in the study. You will find more information about each of the following points later in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you recently experienced suicidal thoughts. We are doing this research to test if a treatment offered to you through your smartphone can reduce suicidal thoughts by making suicide seem more negative.

If you agree to participate, you will complete a diagnostic clinical interview, self-report measures, and computerized behavioral tasks. You will be asked to complete brief surveys on your smartphone, both daily and once per week. You may also choose to complete an optional picture-matching game, which will be offered at the end of the daily surveys during the first 30 days of the study. This picture-matching game is designed to make suicide seem more negative,

and includes some images related to suicide. You will also be asked to rate images and complete brief computerized behavioral tasks once per week. You will be in the study for 60 days if you decide to stay for the whole study.

The main risks of being in the study are that your symptoms, such as suicidal thoughts, might not improve, and there could be breaches of confidentiality or privacy. It is also possible that some images we show or questions we ask may cause temporary discomfort.

You might benefit from being in the study because you will be answering questions about your mental health symptoms and suicidal thoughts, which for some people can be helpful.

You will be paid maximum amount of $325.00 for taking part in this research study. You will find more information about the payment amount for each visit and a plan if you do not complete all study visits later in this form.

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Adam Jaroszewski, Ph.D. is the person in charge of this research study. You can call him at 617-724-9149 Monday to Friday 9AM – 5PM.

If you have questions about the scheduling or technology issues, call Heyli Arcese at (617) 726-9634.

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

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

Why is this research study being done?

We are doing this research to test if a smartphone app can reduce suicidal thoughts by making suicide seem more negative.

Who will take part in this research?

We are asking you to take part in this research study because you have recently experienced suicidal thoughts. We expect that about 20 people will take part in this study. The National Institute of Health is paying for this study to be done.

What will happen in this research study?

In this study, you will be asked to complete several tasks, some of which will occur in the treatment period (first 30 days of the study) while other tasks will occur in the 30 days after the treatment period (follow-up period). Today you will provide us with your contact information, at least one "emergency contact," and answer some questions about your mental health symptoms and experiences. If you are eligible for the study, you will then answer some survey questions online and complete brief picture ratings and behavioral tasks, also online. Some of these questions will relate to self-injurious and suicidal thoughts and behaviors. You will also see and rate suicide-related images during the study so that we can assess your perceptions of these images.

Then, we will install some software on your phone that will ask you questions three times per day. These questions will only occur during appropriate hours that you agree to, and they will begin the day you download the software. These questions will ask about how you are feeling in the moment as well as whether you are having any thoughts of suicide or self-injury. These questions will start today. You also have the option to complete a picture-matching game and complete a brief "in-the-moment" survey afterwards.

During the first 30-days you will receive notifications on your smartphone prompting you to answer three "in-the-moment" surveys throughout the day. You will also have the option to play a picture-matching game and complete an additional "in-the-moment" survey after playing. The picture-matching game will include images related to suicide, and is designed to make suicide seem more negative. It is optional to complete this game. In the 30-day follow-up period, you will be asked to complete one daily "in-the-moment" survey. Throughout the entire 60-day study, you will also be asked to complete weekly surveys on your smartphone.

	Day	**Major Activities (Time it takes to complete)**	**Total Time**
Baseline Day 1	Day 1 / today	- Consent (10-20 min.) with a trained clinician - Telehealth/virtual (Zoom) with a trained clinician (30-90 min) - Install/demonstrate smartphone surveys and app (10 min.) - Complete baseline surveys (15-45 min.)	1 - 3 hours
Treatment Period (Days 1-30)	Daily tasks	- Complete 3 brief 'in-the-moment' smartphone surveys per day (3-5 min each, 10-15 min total) - **Optional**: Play the picture-matching game (5 min per game, 15 min total) - Optional: Complete 1 brief 'in-the-moment' smartphone survey after playing the picture-matching game (2 min each, 6 min total)	10 - 36 min per day
	Weekly task	- Complete 1 smartphone survey (5-15min.) - Complete picture ratings (~5 minutes) - Complete a behavioral assessment/compute game (~5 minutes)	15 - 25 min per week
Follow-up (Days 31-60)	Daily tasks	- Complete 1 'in-the-moment' smartphone survey per day (3-5 min)	5 min per day
	Weekly task	- Complete 1 smartphone survey (5-15 min) - Complete picture ratings (~5 min) - Complete a behavioral assessment/compute game (~5 min)	15 - 25 min per week

By downloading Catalyst by MetricWire, the smartphone app where you fill out 'in the moment' surveys, you are agreeing to the MetricWire Terms of Use (TOU, available at https://metricwire.com/terms-of-use/). The TOU states that when you use MetricWire, you agree to the research team collecting information and data from you through surveys and similar methods. MetricWire may also collect data about how you use their app to improve it. All the information and data that MetricWire collects from you is owned by the research team. MetricWire will not use your data to make money and will not share your data with anyone else

besides the research team. MetricWire may, however, look at your data in case that the research team needs their help with troubleshooting issues with the app. All your data are stored in an encrypted format without any identifying information.

To participate in this study, you must agree to MetricWire's TOU. If you do not want to download this app, you will not be able to participate in the study. If the MetricWire TOU is updated during study participation, you will be informed of any relevant significant changes by the research team. If you become no longer comfortable with the TOU, you are free to remove Catalyst by MetricWire from your smartphone and withdraw from the study at any time.

It is important to note that your survey responses are not monitored in real-time, so you should not rely on your responses to the study surveys to communicate to us that you are having a hard time and may need help. If your responses on the surveys indicate that you are at high risk for suicide, you may see a pop-up message encouraging you to seek help – these messages are automated and not monitored in real-time by our study staff. You may receive follow-up questions from us (by phone call or text message) to ask more questions about your risk, including your current suicidal thoughts and behaviors. If we do not hear from you and are concerned about your safety, we will continue to try to contact you. If we cannot reach you after multiple attempts and are still concerned about your safety, we may get in touch with the person(s) you identify as your emergency contact(s) and use all available study data to make sure that you are safe. If you are experiencing strong urges to hurt or kill yourself, it is your responsibility to contact your clinician (if you have one), call 911, or bring yourself to the nearest emergency room. You can also call 988 (the Suicide & Crisis Lifeline) 24 hours a day, 7 days a week for support from a trained lifeline specialist. Because we are not able to monitor your responses in real-time, you should not rely on the survey app or the research team to send help to you during the study. Remember, if you experience discomfort or distress at any point during this study you can stop taking part in the study at any time.

When you report *high* levels of suicidal thoughts, you may receive a phone call or text messaging from a member of the study team. All interventions will encourage you to use your personalized safety plan or specific strategies from your safety plan. When you report high levels of suicidal thoughts, we may ask you some more questions about your current suicidal thoughts and behaviors (which **may come over text message** if you agree to receive unencrypted text messaged for this study). Up to 15 minutes after each completed survey, we may also send you another briefer survey to check-in on how you are doing. We may also reach out to you to check how you're doing if you report experiencing high levels of suicidal thoughts on one of these brief follow-up surveys.

Early Withdrawal

You will be removed from the study if we determine that participating in the study is causing you significant distress (for example, you inform us that you are in distress because of your study participation or the study intervention), or if you request to be withdrawn. We will not remove you from the study if you make a suicide attempt, unless the rare case arises that the suicide attempt is determined to be due to your study participation (for example, if you or your provider reports this to the research team). You may withdraw from this study at any time by requesting to be withdrawn. There is no penalty for withdrawing from the study.

Contact with study staff

A member of the study team may contact you over the phone, text or email to discuss study procedures during the treatment and follow-up periods of this study. A staff member will provide you with the phone numbers we will use to contact you into your phone's contacts so that we can easily communicate with one another.

Receiving unencrypted text messages for this study

Text messages by mobile/cell phones are a common form of communication. This research study involves sending you text messages that are relevant to the research study. These text messages will include checking in about any issues you might have, troubleshooting any problems you might have with the study technology, as well as sending personalized links to complete the study surveys. They may also include following up about your smartphone survey responses, as we mentioned earlier. Specifically, text messages may include **questions about your current suicidal thoughts and behaviors** as well as suggestions for coping strategies. The research team will use Televox, a secure MGB-approved texting platform, to send you texts containing sensitive information. You will receive all texts as normal SMS messages to your cell phone. Text message conversations may be de-identified, and saved and stored with the rest of the de-identified information you provide in this study. Texting over mobile/cell phones carries security risks because text messages between mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by someone other than staff involved with this research study, or by your mobile/cell phone provider or carrier. You can expect these text messages every few days if we do not regularly receive data from you. We may also text you if we are having trouble getting in touch with you or are concerned about your safety. Texting over mobile/cell phones carries security risks because text messages between mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by someone other than staff involved with this research study, or by your mobile/cell phone provider or carrier.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore carry security risks. This research study and MGB are not responsible for any interception of messages sent through unencrypted text

message communications.

- You will be responsible for all fees charged by your carrier's service plan for text messaging. This study and MGB are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.
- Your text messages will only be read during regular business hours. Texts sent on nights or weekends will not be read until the next business day.
- Text messaging should not be used in case of an emergency. If you experience a medical or psychiatric emergency, call 911 or go to the nearest hospital emergency department.
- You may decide to not send or receive text messages with staff associated with this research study at any time. You will still be able to participate in the study if you decide not to receive texts. You can do this in person or by sending the research number a text message that says "Stop Text."
- Your agreement applies to this research study only. Agreeing to other texts from MGB, for example appointment reminders, is a separate process. Opting out of other texts from MGB is a separate process as well.
- It is your responsibility to update your mobile/cell phone number with this research study in the event of change.

I have had the chance to ask questions about texting with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communications associated with this research study.

Please initial: YES: _____ NO: _____

Receiving unencrypted emails for this study

The MGB standard is to send email securely. This requires you to initially set up and activate an account with a password. You can then use the password to access secure emails sent to you from MGB. If you prefer, we can send you "unencrypted" email that is not secure and could result in the unauthorized use or disclosure of your information. If you want to receive communications by unencrypted email despite these risks, MGB will not be held responsible. Your preference to receive unencrypted email will apply to emails sent from this research group/study only.

Below are some important points about emails in this research study.

- Unencrypted emails carry security risks. This research study and Mass General Brigham are not responsible for any unauthorized use or disclosure of your information.

- Emails should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.
- You may decide to not send or receive emails with staff associated with this research study at any time. You can do this in person or by sending the research email address an email that says "Stop Research Email."
- Your agreement to email applies to this research study only.
- It is your responsibility to update your email with this research study in the event of a change.

I have had the chance to ask questions about sending and receiving unencrypted emails with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted email communications associated with this research study.

Please initial: YES: _____ NO: _____

Preferred contact method
If you prefer to receive communications by email, there are two options: encrypted or unencrypted. If you prefer unencrypted email despite the risks, your preference will apply to emails sent to you from our research team. To access encrypted emails, you will need to create an account. Encrypted emails can only be accessed using a computer, not a smartphone or tablet.

☐ Phone [consent to voicemails on this line]
☐ Email [encrypted]
☐ Email [unencrypted]

Emergency Contact Information
As a reminder, if we cannot reach you after multiple attempts and are concerned about your safety, we may get in touch with the person(s) you identify as your emergency contact(s) and use all available study data to make sure that you are safe. Do you agree to provide an emergency contact?

☐ Yes
☐ No

Emergency contact name:_____
Emergency contact relation:_____
Emergency contact phone number:_____

National Institute of Mental Health Data Archives

This research study is funded by the National Institute of Mental Health (NIMH). As part of this research award, we will share de-identified versions of the demographic, self-report, and clinical data that you provide during this project with the NIMH Data Archives (NDA). The NDA is an NIMH operated platform which allows researchers to contribute data to a large data repository. Data shared with the NDA will be used only for research purposes and shared in a restricted online database accessible only to other approved researchers with special permissions following the guidelines of the NDA. Summary level data of contributions from research projects, such as this one, will be available "open access" through the online database.

As part of your participation in this study, a unique subject number will be assigned to you that will allow researchers with access to the study's data in the NDA to see if you have been involved in more than one research study in the database. If you have participated in more than one study or database, this unique subject number will help connect information across studies. This subject number will allow your de-identified data to be combined with data from other research studies to increase the likelihood of meaningful analysis. Only this subject number and not your personal identifiable information will be accessible to other investigators. This unique subject number may make it possible for a study doctor who used this unique subject number in another study that you took part in to identify you.

Audiotaping:

All assessments and interviews sessions will be digitally audiotaped so the study team can monitor and ensure the quality of study assessments, and to assist with development of future tools and research. These audiotapes will be kept confidential and will be listened to only by research team members. Names will not be included in the digital recordings, in computerized data files, or in any published reports. The recordings will be stored electronically on a secure server at MGB. The audiotapes will be securely stored in perpetuity; however, we will destroy the recording of your interview if you express this wish to the study team by calling any of the contact people listed later in this form, under "If I Have Questions."

How may we use and share your samples and health information for other research?

The information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these

uses. If we share your data and/or health information with other researchers outside of Mass General Brigham, we will label the samples and information with a code instead of your name or other directly identifying information. The key to the code connects your name or other identifiers to your sample and/or information. We will keep the code on a secure server at MGB.

Will you get the results of this research study?

Subjects will not receive results from their individual participation in the research study. It could take many years before we know the results of this research. However, when findings from the study become available, we will make the results of the research available through our lab website(s). Subjects who request information regarding published products from this research will be added to a list and sent research articles when published. We will share results of this research with the scientific community in peer-reviewed publications, presentations, and in follow-up grant applications. When we make research findings available to the public, all data will be completely deidentified, meaning nothing will be directly linked to your name or other identifying information.

What are the risks and possible discomforts from being in this research study?

Psychological Risk - If you choose to participate, there is a risk that you might feel distress or discomfort when responding to personal or sensitive questions, completing questionnaires, viewing or rating suicide-related images, or having clinician interviews audiotaped. In rare cases, repeatedly responding to questions about suicidal thoughts may increase peoples' thoughts of suicide or self-injury. Also, the smartphone intervention we are testing as part of the study is not guaranteed to reduce your risk for suicidal thoughts and behaviors. There is a risk of a person feeling uncomfortable around other people if answering survey questions and/or playing the picture-matching game in public. You can choose to not answer questions if you feel uncomfortable.

Reviewing suicide-related images before agreeing to participate:
As we mentioned, during the study you will see and rate images depicting suicide-related content. Therefore, we would like to show you the 5 suicide images that you will see during the study before you decide to participate.

As mentioned above, seeing these pictures of suicide may cause temporary discomfort in some people. Seeing these images before deciding to participate is required, but the choice to see them now is yours. If you decide to see them now, you will be able to skip any image or stop viewing

them at any time you wish by informing the study team member who is showing you the pictures.

_____ _____ ☐ YES, I wish to see the 5 suicide-related images now before deciding to participate in the study

_____ _____ ☐ NO, I do NOT wish to see the 5 suicide-related images now before deciding to participate in the study, and I understand that this will exclude me from participating in the study.

Initials Date

Breaking Confidentiality – All of the information you provide to us will be confidential, meaning that all of your data will be identified by a number, and not directly linked to your name or other identifying information (e.g., your email address). We will not link your data to any of your identifying information UNLESS your responses during the study suggest to us that you are at imminent risk of killing yourself. In this case, we may take steps to keep you safe that involve informing others about your level of risk (e.g., calling a person you identify as an emergency contact) and/or using any available study data. Only a few people on our team will ever be able to link your data to your identifying information.

Loss of data privacy – Loss of privacy may occur due to a data breach. We protect your privacy by referring to you by a number (rather than your name) throughout our study materials, and by keeping all collected data on secure and encrypted computer servers. Although we have taken numerous steps to ensure the security of your data, as with all data, we cannot guarantee that a breach will not occur (for instance, by someone hacking into the study's computer servers). Additionally, if you consent to receiving unencrypted text messages, it is possible these texts will include content related to your suicidal thoughts or behaviors, or your participation in the study more generally. Like any text messages sent to/from your phone, it is possible someone could see this content.

Clarification about Managing your Risk of Injury or Death - Please note once again that we will not be actively monitoring your responses to surveys in real-time so you should not rely on the research team to send help to prevent you from harming yourself based on your survey responses. Therefore, if you are having uncontrollable urges to make a suicide attempt, or if you actually make a suicide attempt, you should call 988 (the Suicide & Crisis Lifeline) for help, call 911 or go to your nearest emergency room.

You can stop taking part in this study at any time. If we learn during the course of one of our evaluations that you or someone else is at immediate risk of harm, we will take appropriate

measures. This may involve contacting people you identify as your emergency contacts, or, in rare cases, contacting emergency services to send you help.

What are the possible benefits from being in this research study?

You may not benefit from taking part in this study. However, you might benefit because you will be answering questions about your mental health symptoms and suicidal thoughts, which for some people can be helpful. The knowledge gained from this research will hopefully help other people in the future. Your participation in this research will result in greater knowledge about the factors that contribute to, or protect against, suicidal feelings, thoughts, and behaviors. This understanding will be important in helping individuals who think about suicide or act in a manner to end their own lives.

What other treatments or procedures are available for your condition?

Alternative treatments for suicidal thoughts and behavior include: antidepressant medication (for example: fluoxetine [Prozac], paroxetine [Paxil], bupropion [Wellbutrin]); antidepressant medication with a second antidepressant or another psychiatric medication (for example: aripiprazole [Abilify], quetiapine [Seroquel], risperidone [Risperdal]); and non-medication treatment, such as therapy or alternative forms of treatment (for example: cognitive behavioral therapy [CBT]; Electroconvulsive Shock Therapy [ECT]]. If you choose not to participate in this study, you will be provided with referral resources to seek treatment elsewhere.

Can you still get medical care within Mass General Brigham if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

Maximum Compensation

Assessment Component	**Frequency**	**Compensation**	**Total**
Baseline assessment (day 1)	Once	$50.00	$50.00
End of treatment assessment (day 30)	Once	$15.00	$15.00
Follow-up assessment (day 60)	Once	$15.00	$15.00
'In the moment' surveys			
Days 1-30 (*treatment phase*)			
Survey	3x/day	$1.00	$90.00
Daily Bonus (if 2 surveys completed)	1x/day	$0.50	$15.00
Days 31-60 (*follow-up phase*)			
Survey	1x/day	$1.00	$30.00
Bonus (if 80% (24/30) surveys completed)	once	$10.00	$10.00
Weekly target & symptom assessment	nine	$10.00	$90.00
Bonus (if 89% (8/9) assessments completed)	once	$10.00	$10.00
Total			$325.00

In total, if you complete all study assessments and receive all bonuses, you can receive $325.00. You can receive $50 for completing the Baseline visit at the start of the study. You can receive $15 for completing the End of Treatment assessment at day 30. You can receive $15 for completing the Follow-up assessment at day 60. You can receive up to $3 per day for answering surveys during the treatment phase (Days 1-30), you will receive $1 for each survey you complete, up to 3 per day; and you can receive a maximum bonus of $15 for completing ≥ 2 surveys per day. You can receive up to $1 per day for answering surveys during the follow-up phase (Days 31-60). You will receive $1 for each survey you complete, 1 per day. You can receive a bonus of $10 for completing ≥ 80% (24/30) surveys. You can receive $10 per week for completing weekly symptom surveys (Days 1-60). You can receive a $10 bonus for completing ≥ 8 weekly symptom surveys.

You will receive payment by check approximately one month after completion of your final study visit.

If you participate in this study, we will ask for your Social Security Number (SSN) as part of the payment process. Your SSN is needed as an identifier for internal auditing purposes. MGB must inform the Internal Revenue Service (IRS) of any payments greater than $600 given to you for taking part in research in a calendar year. If that happens, you will receive a 1099 form at the end

of the year. No information regarding why you received payment is communicated to either the Hospital accounting department or the government. Your SSN will be kept strictly confidential.

We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples or information are used for this purpose.

What will you have to pay for if you take part in this research study?

The only direct cost that you will incur is if the data used by the application on your smartphone exceeds your data limit. The data requirements of the program are extremely small (e.g., only about the size of data required for a few minutes of web browsing), so it is very unlikely that the data from this program will have a measurable impact on your bill. Additionally, if you do not want the study phone applications to use your data plan at all you may choose to have it run exclusively through Wi-Fi in the app settings. In the event that we text or call you, standard text messaging or call fees would apply. You may inform us that you would like to opt out of text messages at any time throughout the study.

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why they may need to do so:

- Mass General Brigham researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Mass General Brigham who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)

- Other: If we are unable to reach you and are concerned about your risk, we may contact the individual(s) who you identify as your contact person(s) to see if they can help us reach you. In an emergency situation in which you have indicated that you are at imminent risk for suicide and/or we are unable to reach you, we may use any information available to us to keep you safe, which may involve sending help to your location.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Please respond to the following items by circling *True* or *False*

1. Taking part in this study is completely voluntary and does not affect your clinical care.	True / False
2. You can stop taking part at any time by letting us know you would like to withdraw.	True / False
3. In this study, we will install an app on your smartphone that will ask you survey questions at random times throughout the day.	True / False
4. When you report having suicidal thoughts on a study survey, you will **always** receive a phone call or text message from the study team.	True / False
5. The study team may not see your responses to the survey questions right away, so you cannot rely on them to keep you safe during this study.	True / False

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Print Name

Subject Signature Date Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Print Name

Signature of Study Doctor or Person Obtaining Consent Date Time (optional)

Consent Form Version: 12/30/2025