**Consent Form**

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| Study Title: | Improving Attentional and Cognitive Control in the Psychological Treatment of Intrusive Thoughts |
| Principal Investigator: | Ryan J. Jacoby, PhD<br>Assistant Professor<br>Massachusetts General Hospital / Harvard Medical School<br>Boston, MA, United States of America |
| Ethical approval: | Mass General Brigham Institutional Review Boards (protocol # 2019P003768, approved on Approved: 01/21/20) |
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| Document Date: | June 21, 2023 (and annually reviewed thereafter) |
| Author: | Ryan J. Jacoby, PhD |
| Version: | Draft 1.0 |
| Notes: | This version of the consent form is for the randomized controlled trial phase (Phase 2; n=62), which is the data reported on ClinicalTrials.gov. |

Protocol Title: Targeting Attentional and Cognitive Control to Enhance the Transdiagnostic Treatment of Repetitive Negative Thinking

Principal Investigator: Ryan Jane Jacoby, Ph.D.

Site Principal Investigator:

Description of Subject Population: Adults with Repetitive Negative Thinking - Phase II

## 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.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

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

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Partners now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

## Why is this research study being done?

Many people struggle with unwanted intrusive thoughts that are difficult to control and cause them distress. We are conducting this study to learn whether psychological treatment can help people with three types of repetitive negative thinking who have trouble stopping unwanted thoughts and shifting their attention: mental rituals (as seen in obsessive compulsive disorder, OCD), worries (as seen in generalized anxiety disorder), and ruminations (as seen in depression).

## How long will you take part in this research study?

If you decide to participate, it will take you approximately 5 months to complete the study (2 months of active treatment plus a 3-month follow-up visit). During this time, we will ask you to complete a virtual screening/baseline visit, 3 additional; virtual psychological assessment visits (mid-treatment, post-treatment, and 3-month follow-up), 3 in-person visits – including eye-tracking procedures occurring at the Simches Research Building at the MGH main campus and electroencephalogram (EEG) procedures occurring at the Martinos Center at the Charlestown Navy Yard campus (baseline, mid-treatment, post-treatment), and 8 weekly virtual therapy visits. You may opt to complete your screening and baseline visits on the same day if you prefer.

## What will happen if you take part in this research study?

If you decide to join this research study, you would complete a diagnostic clinical interview, self-report measures, and computerized tasks. We would examine attention using an eye tracker, brain activity using an electroencephalogram (EEG) machine, and skin conductance (i.e. the sweatiness of your palms) using electrodes that fit comfortably on your fingers. Participants also will be randomly assigned (like the flip of a coin) to receive one of two 8-week psychological treatments that addresses RNT: (a) Attention Regulation Therapy or (b) Supportive Psychotherapy. Each of the 8 treatment sessions will last 60 minutes. If you are assigned to receive Attention Regulation Therapy, you will learn specific strategies to help you regulate your attention and will practice these skills using imaginal exercises and in real world situations that trigger RNT. If you are assigned to receive Supportive Psychotherapy, you will explore factors that may affect your RNT symptoms (for example, relationships, work, stress) and learn to manage challenges in your life by developing positive coping skills.

## Why might you choose to take part in this study?

We cannot promise any benefits to you from taking part in this research study. However, possible benefits may include a free evaluation with experts in RNT, careful monitoring of your symptoms, and free psychological treatment (which may improve your RNT symptoms). Others with RNT may benefit in the future from what we learn in this study.

## Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully. Important risks and possible discomforts to know about in this study include: (a) feeling bored or tired completing some of the questionnaires or computer tasks, (b) feeling uncomfortable or embarrassed about the interview or self-report questions about your mental health history, (c) mild discomfort if we have to gently scrape your skin to make a good recording of your brain waves during the EEG procedure, (d) distress from the computerized images during the eye-tracking task, and (e) a temporary increase in your anxiety or depression level as you are focusing on these symptoms in treatment. Finally, with any research study, there is always the possible risk of loss of privacy in allowing us to store and use your health information. Other things to consider are the time commitment for this study, as well as travel to our downtown Boston and Charlestown Navy Yard locations. A detailed description of risks and possible discomforts (as well as how we minimize them in this study) can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

## What other treatments or procedures are available for your condition?

Alternative treatments for RNT include: medications called serotonin reuptake inhibitors (SRIs) or cognitive behavioral therapy (CBT). If you choose not to participate in this study, you will be provided with referral resources to seek treatment elsewhere.

## If you have questions or concerns about this research study, whom can you call?

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

Ryan Jane Jacoby, Ph.D. is the person in charge of this research study. You can call her at 617-724-4167 Monday through Friday 9am-5pm with questions about this research study. She can also be reached or by her pager at 617-726-2000 24 hours/day in the event of a psychiatric emergency.

If you have questions about the scheduling of appointments or study visits, call Sara Velazquez at 617-726-5592.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. 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?

Many people struggle with unwanted intrusive thoughts that are difficult to control and cause them distress. We are conducting this research study to learn more about the cognitive and attentional processes among individuals with three types of repetitive negative thinking (RNT): mental rituals (as seen in obsessive compulsive disorder, OCD), worries (as seen in generalized anxiety disorder, GAD), and ruminations (as seen in major depressive disorder, MDD). Specifically, we are investigating whether psychological treatment can help people with repetitive negative thinking who have trouble stopping unwanted thoughts and shifting their attention. We are studying two treatments: "Attention Regulation Therapy" and "Supportive Psychotherapy." We would like to find out whether one treatment is more effective than the other for helping people with RNT.

In order to answer this question, participants will complete a diagnostic clinical interview, self-report measures, and computerized tasks. We will examine attention using an eye tracker and brain activity using an electroencephalogram (EEG) machine. Participants also will be randomly assigned (like the flip of a coin; a 50-50 chance) to receive one of two 8-week psychological treatments that addresses RNT (Attention Regulation Therapy or Supportive Psychotherapy). Attention Regulation Therapy is a promising new treatment, and we will test its effectiveness for reducing RNT. The study will also test the effectiveness of Supportive Psychotherapy, which is the most widely used therapy in the community to treat anxious/depressed mood and related problems.

## Who will take part in this research?

We expect to screen up to 93 participants, in order to include 62 subjects at Massachusetts General Hospital (MGH) in this phase. We are asking you to take part in this research study because you have repetitive negative thoughts that you find bothersome and distressing.

The National Institute of Mental Health (NIMH) is paying for this research study to be done.

## What will happen in this research study?

If you decide to participate in this study, the following will take place:

**Screening/Baseline Visit**
First, you will complete a virtual screening/baseline visit, which can be done as one visit or broken into two. The screening visit will take about 2-2.5 hours and will be completed virtually through an encrypted and HIPAA-compliant video conferencing platform called Healthcare Secure Zoom™ (see Virtual Visits below for more information). At the start of this visit, you will be asked to read and sign this consent form. Then the following procedures will be done to see if you qualify to participate in this research study:

- You will be interviewed by a doctoral-level psychologist who will ask you questions about your psychological (mental and emotional) history, mood (how you feel), and your medical history.
- You will complete some self-report questionnaires online, which will take about 5 minutes to complete.

If you are not eligible for the study, we will provide you with referral resources for alternative treatment options.

If the results of the screening visit show that you are eligible to participate in the study, you will then complete a virtual baseline clinical assessment visit, which will take about 1-1.5 hours. During the baseline assessment:

- You will be interviewed by an independent evaluator (who is an advanced doctoral student or doctoral-level psychologist) about your symptoms (60-90 minutes).
- You will complete some online questionnaires about your anxiety, mood, thought processes, daily functioning, and quality of life that will take about 20-30 minutes to complete. Although it is hoped that you will answer all of the questions, you may skip over any questions you do not wish to answer.

**Mid, Post, & 3-Month Follow-Up Assessment Visits**
You will also complete three additional clinical assessment visits via Healthcare Secure Zoom™ at mid-treatment (week 4), post-treatment (week 8), and 3-month follow-up (week 24).

During these clinical assessment visits, the following will occur:

- You will be interviewed by an independent evaluator (who is an advanced doctoral student or doctoral-level psychologist) about your symptoms (45-60 minutes).

- You will complete some online questionnaires about your anxiety, mood, thought processes, daily functioning, and quality of life that will take about 20-30 minutes to complete. Although it is hoped that you will answer all of the questions, you may skip over any questions you do not wish to answer.
- At the post-treatment assessment, you will also be asked to provide your feedback about the intervention.

These clinical assessment visits will each take about 1-1.5 hours to complete.

**In-Person Visits**

In addition, you will complete 3 in-person visits, which will include eye tracking and EEG procedures. The first in-person visit will take place right after the baseline visit (and prior to starting treatment; week 0), the second midway through treatment (week 4), and the third after you complete treatment (week 8). The eye tracking and EEG procedures can be combined into one visit or broken up into two visits, depending on your preference and room/equipment availability. Please see below for more detailed information about the eye tracking and EEG procedures.

**Eye-Tracking Procedures**

The eye-tracking procedures will occur at the Simches Research Building at the MGH main campus. During this part of the visit, you will complete two computer tasks in which you view a series of images (i.e., faces, scenes), and we will measure where on the screen you are looking using an eye tracker and the sweatiness of your palms using electrodes that fit comfortably on your fingers. These tasks will take about 60-90 minutes to complete.

**EEG Procedures**

The EEG procedures will occur at the Martinos Center at the MGH Charlestown Navy Yard campus and will take approximately 2 hours to complete. EEG recordings are very safe and are generally painless. They measure brain activity by recording the electrical activity on your scalp caused by your brain. We will use an EEG "cap" to record this electrical activity. The cap is constructed from cloth and sensors, which will be placed on your head. We will then use a new, sterile blunt syringe to apply gel to your scalp. The gel allows us to record the brain signal. Application of the gel can sometimes cause minor irritation because it can be necessary to rub the scalp to get a good signal. If at any time during the study you are uncomfortable, please tell the researcher so that we can make things more comfortable for you. Once the EEG cap is on, we will record your brain waves as you complete the computer task. You can ask us to pause or stop the EEG session at any time, for any reason.

**Treatment Sessions**

After the baseline visit, you will be randomly assigned (by chance, like the flip of a coin) to receive one of two 8-week psychological treatments for RNT. Half of the study participants will be assigned to receive Attention Regulation Therapy, and the other half will be assigned to receive Supportive Psychotherapy. You will have an equal chance of receiving either treatment. You and your therapist will be told to which treatment group you have been assigned. However, the independent evaluator doing the psychological assessments with you (described below) will not know which treatment you are receiving, and it is important for you not to tell this person what kind of treatment you are receiving.

In both groups, treatment will be provided by a doctoral-level psychologist or advanced doctoral student who is knowledgeable about RNT via Healthcare Secure Zoom™. Each session will take 60 minutes. If you are assigned to receive Attention Regulation Therapy, you will learn specific strategies to help you regulate your attention and will practice these skills using imaginal exercises and in real world situations that trigger RNT. If you are assigned to receive Supportive Psychotherapy, you will explore factors that may affect your RNT symptoms (for example, relationships, work, stress) and learn to manage challenges in your life by developing positive coping skills.

In addition to the scheduled sessions, you will be permitted two Adjunctive Services and Attrition Prevention (ASAP) sessions in the event of any urgent psychiatric concerns. An ASAP session is an additional treatment session with your study therapist to address any crises, unusual circumstances, and/or needs that may arise. These sessions are optional and available in the case of a psychiatric emergency.

**Virtual Visits**

As described above, the majority of the study visits (assessment and therapy sessions) will take place **virtually** via Healthcare Secure Zoom™ (or you can opt to have visits by phone if you prefer). Some study-related procedures (e.g., eye-tracking and EEG), however, will take place **in-person** at either the MGH Center for OCD and Related Disorders at the MGH main campus or the Martinos Center at the MGH Charlestown Navy Yard campus.

All virtual visits will be conducted through an encrypted and HIPAA-compliant video conferencing platform called Healthcare Secure Zoom™. Study staff will provide you information on how to access the video conferencing platform. We will launch the video conferencing in a private and secure area. To protect your privacy, we ask that you do not take screenshots, photographs, or recordings of any kind with any electronic equipment.

We would like to remind you that a video meeting is similar to us visiting you at home. We may learn more about your home and the people living with you than we would during a visit at the hospital. For example, we may learn information from you that must be reported to public health

or public safety authorities. We are required by law to report known or suspected child or elder abuse. If we make such report, the public health and safety authorities can use the information as they see fit and may end up sharing it with other government agencies. Please ask the research staff if you have any questions about this prior to your video visit.

**Confidentiality of Your Study Information**

All your responses and study information will be kept completely confidential. To ensure that your information is kept confidential we will do the following: We will label your study information with a code instead of your name. We will keep the key to the code that connects your name with your study information in a password-protected database. Your responses to the questionnaires and assessments will be coded and used in data analysis along with the information obtained from other participants, so at no time will data be linked to individual subjects. The information we gather from these questionnaires, assessments, and eye-tracking tasks will be used for research purposes only and will not become part of your medical record. However, if your responses on questionnaire or interview items indicate that there are safety concerns, then a clinician will further assess the degree of risk.

We will not keep any formal medical record of your taking part in this study at Massachusetts General Hospital. Instead, your study information will remain in the study doctor's files. If you have previously participated in studies at our clinic, some of your answers from that study may be used for this study so that you do not have to repeat questionnaires or assessments. Your de-identified data may also be shared with other researchers in our group as well as used across our studies for research purposes only.

**Audiotaping**

All treatment sessions and assessment interviews will be audiotaped so that the study investigators can monitor and ensure the quality of your study sessions. The purpose is to evaluate the performance of the study staff, not you. These recordings will be kept confidential and labeled with your study code number, not your name. The recordings will be stored electronically on a secure server at MGH and will only be listened to by study personnel. The audio recordings will be kept for 5 years after the conclusion of the study, at which time they will be destroyed.

**Early Withdrawal**

You decide whether or not you want to be in the study. Participation is voluntary. If you decide not to participate, you can change your mind later and stop participating in the study. If you exercise your right to be withdrawn or refuse to participate in this study, it will in no way affect your clinical care at MGH or other Partners Healthcare institutions. You will also be reimbursed for your time spent in the study. The study doctor may need to take you out of this study if the doctor deems the study unsafe for you for physical or mental health reasons. As soon as it

becomes available, the researcher will give you new information about the study that may or may not affect your decision to stay in the research study.

You may stop participating in the study early for any of the following reasons: 1) Any changes in your symptoms that require a need for hospitalization; 2) Thoughts of harming or hurting yourself that the treatment team determines makes it unsafe for you to remain in the study; 3) Responses to questionnaires indicating that your symptoms are worsening and that it is not in your best interest to continue in the study; 4) Your therapist decides that stopping your participation in the study would be in your best interest; 5) You decide to stop participating for any reason. If you stop the study early, the reason for your discontinuation will be explained to you. You will be referred for treatment at Massachusetts General Hospital or in the community, for which you will need to pay. Pharmacotherapy (medication) may also be discussed with you as an alternative to study participation.

In addition, the NIMH may choose to end the study at any time, for reasons unrelated to health care.

**Other Treatment**

During the 5 months of the study, regardless of the group to which you are assigned, we strongly encourage you not to begin any other form of psychiatric or psychological treatment (such as new psychiatric medications, individual therapy or counseling, family therapy, or group therapy). If you are on psychiatric medications at the time you begin the study, we also strongly encourage you to keep your dosage stable for the duration that you are enrolled in the study. You are free to begin other medications or other forms of treatment after you have finished the study (including after you have completed the 3-month follow-up visit).

**Release of Information**

If you are currently taking psychiatric medications or are currently (or recently) receiving psychotherapy, we ask you to share the name and contact information of your provider who we can contact as needed to coordinate your care.

☐ **N/A** – I do not have a current (or recent) psychiatric provider

☐ **YES**, I consent to having my psychiatric provider notified by the study staff of my participation in this study in order to coordinate my care.

Initials _____

Name of provider: _____

Address of provider: _____

_____

Office number: _____

Office fax number: _____

**Taking Part in Future Studies**

We would like to contact you in the future about other research studies. This is optional (not required). The choice is yours. You can change your mind about being contacted at any time, by calling any of the contact people listed later in this form, under "If I Have Questions."

☐ Yes ☐ No Initials _____

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

The samples and 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 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.

## Will you get the results of this research study?

The research study we are doing is only a stepping stone in understanding repetitive negative thinking. Therefore, no information about the results of your individual participation in the research study will be given to you or your doctor. Tests done for the research using your samples will not be useful in directing your medical treatment. The results of the tests will not be placed in your medical record.

You can choose to get an email that will tell you about the results of our study and next steps with research studies we are doing. This newsletter will not announce your individual results or anyone else's, but it will tell you some information about what we are learning about RNT from our research.

☐ Yes ☐ No Initials _____

We will also publish what we learn in medical journals using the data obtained from all participants (so at no time will data be linked to individual subjects).

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

**Assessments and Questionnaires**
Completing the questionnaires and computer tasks may be tiresome, and answering questions about your personal history, anxiety, or depressive symptoms may cause discomfort or embarrassment. You will have as much time as needed to complete these questionnaires, and you may skip any questions you do not want to answer. The independent evaluator will make every effort to help you feel comfortable throughout the study.

**EEG Procedures**
The EEG procedures are very safe and there are no known or foreseeable risks or side effects. The EEG sensors (Brain Products GmbH, Gilching, Germany) have been approved by the FDA for research purposes and will be operated within the standards reviewed and accepted by the FDA. The only risk is that you may experience some discomfort because we may have to gently scrape your skin to make a good recording of your brain waves. We will make every effort to keep the EEG procedure entirely painless. If you experience any discomfort, please tell us and we will adjust our approach to ensure your comfort.

**Computer Tasks**
Some of the scenes you will view during the eye-tracking visit involve emotionally evocative images of violence, death, blood/gore, and sex that may generate distress. It is alright to look away if you find these images too disturbing.

**Treatment**
It is possible that treatment exercises that address RNT may temporarily increase your anxiety or depression level as you are focusing on these symptoms. However, you will be able to manage the intensity of these exercises along with your therapist.

**Privacy**
The main risk of conducting assessments and treatment visits online and allowing us to store and use health information for research is a possible loss of privacy. However, as previously described, we will protect your privacy by removing identifying information from your file. In addition, both Healthcare Secure Zoom™ and REDCap™ are secure, encrypted and HIPAA-compliant platforms.

The information from this study will not be shared with anyone not involved in this study, except with your permission. However, if we believe you are at serious risk of harming yourself or any other person, we are obligated to take steps to ensure safety. For example, we may recommend that you visit the emergency room, or we may connect you with a suicide hotline or request a wellness check for you. Throughout the study, we will be monitoring safety based on weekly self-report assessments completed before each therapy session and certain assessments. If there is any concern about your safety, a study clinician will speak with you further at your visit. Please note that these safety assessments are not always viewed by study clinicians in real-time, and therefore, they cannot replace the need to visit the emergency room or call 988 or 911 if you experience a clinical emergency. Additionally, in order to ensure your safety, we ask you to give us the name and contact information of a local relative or friend who can serve as an emergency contact throughout your participation in the study (whom we can contact if we have concerns about your wellbeing). We also may contact these individuals if we lose contact with you during the study.

**Contact #1:**
Name: _____

Relation to you: _____

Phone number: _____

**Contact #2 (optional):**
Name: _____

Relation to you: _____

Phone number: _____

If we learn information from you during this study that indicates ongoing abuse or neglect of a child, disabled, or elderly person, we also may be required by law to share that information with third parties, including public safety or law enforcement authorities, and may take other precautions to protect against such harm. It is also possible, but unlikely, that unforeseen and uncontrollable circumstances could result in the disclosure of your health information outside the context of the research study (for example, in the event of a court order).

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

Your participation may or may not benefit you. The benefits to you include a free evaluation with experts in RNT, free psychological treatment, and careful monitoring of your symptoms.

Participation has the potential benefit of improving your RNT symptoms. However, we cannot guarantee or promise that you will receive any benefits from this study. Information gathered from this study may benefit people with RNT in the future, as we may learn more about the treatment of these symptoms.

## What other treatments or procedures are available for your condition?

Alternative treatments for RNT include: medications called serotonin reuptake inhibitors (SRIs) or cognitive behavioral therapy (CBT). Available data indicate that both are often effective in treating OCD, generalized anxiety, and depression. A member of the study team will be glad to talk to you about these other treatments. If you choose not to participate in this study, you will be provided with referral resources to seek treatment elsewhere. If you wish to receive treatment in the Psychiatry Department at MGH or in the community, you could be referred to clinicians that provide Supportive Psychotherapy or CBT. As Attention Regulation Therapy is a newer approach, it may not be available in the community.

## Can you still get medical care within Partners 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 Partners 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?

You will be paid $20 for each of the 4 clinical assessment visits (baseline, mid-point, post-treatment, and 3-month follow-up), and $40 for each of the 3 in-person visits. Thus, you will be paid $200 total if you complete this study. You will be compensated at a rate of $20/hour if you are ineligible at the screening visit. If you terminate your participation early, you will be compensated for the completed visits. If you drive to the clinic, you will be given a voucher to cover the cost of parking.

You will receive payment by check approximately one month after completion of your final study visit. We will pay for the cost of your parking in the hospital garage for the in-person study visits. We will not compensate for public transportation fees.

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. Massachusetts General Hospital 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 Social Security Number 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?

You will not incur any costs for participating in this study. Study funds will pay for the equipment, assessments, and procedures. The initial eligibility interview and all study procedures will be provided at no cost to you. Your insurance company will not be charged.

Charges for any ongoing or routine medical care and services you receive outside this study will be billed to you or to your insurance company in the usual way. 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 Partners 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:**

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

**Who may see, use, and share your identifiable information and why:**

- Partners 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 Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners 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 researchers within or outside Partners, for use in other research as allowed by law.

## 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 Partners, 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 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.

## 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 identifiable information to be used and shared as described above.

| Subject | Date | Time |
|---|---|---|

## 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.

| Study Doctor or Person Obtaining Consent | Date | Time |
|---|---|---|

Consent Form Version Date: 6/21/2023