Title: Decision Making, Daily Experiences, and Brain Activity in Young Adult Women

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Protocol Title: Decision-Making, Daily Experiences, and Brain Activity in Young Adult Women

Principal Investigator: Kristin Javaras, DPhil, PhD

Site Principal Investigator:

Description of Subject Population: Women ages 18-40

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 are a woman between the ages of 18 and 40, and you might, or might not, be experiencing an eating disorder. We are doing the research to learn more about brain activity during everyday decision making and how it relates to certain daily experiences, including stressful experiences.

If you agree, you will be asked to answer a large number of questions about your medical, psychiatric, and personal history. This will include numerous, detailed questions about stressful experiences (such as sexual or physical assault or abuse and other traumatic experiences) and about suicidal thoughts and behaviors. In addition, you will be asked to do a variety of tasks that include everyday decision making. Some of these tasks involve speaking and doing math out loud. Other tasks involve viewing a large number of food pictures, in order to rate these pictures (e.g., on healthiness) or make choices between them. You will also be asked to get multiple MRI scans of your brain and body. You will be in the study for about 18 hours total, typically over a 1-2 week period, if you decide to stay for the whole study.

The main risks of being in the study are feeling **upset or stressed**, feeling uncomfortable during MRI scans, and feeling tired as a result of participating in the study (especially the all-day Visit 2).

You will be paid up to $425 by check 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.

Kristin Javaras, DPhil, PhD is the person in charge of this research study. You can call her at [redacted] M-F 9:00-5:30. You can also call [redacted], M-F 9:00-5:30 with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call [redacted] or [redacted] at [redacted]

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

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 have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. 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.

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're doing this research to learn more about what happens when people make everyday decisions, like which product you're going to buy, who you're going to spend your free time with, or what you're going to have for a snack. In particular, we're interested in learning more about brain activity during everyday decision making and how it relates to certain daily experiences.

We are asking you to take part in this study because you are a woman between the ages of 18 and 40. You might, or might not, be experiencing an eating disorder.

It is planned that up to 100 people will take part in this study.

The National Institutes of Health (an agency of the U.S. government) is paying for this research to be done.

How long will I take part in this research study?

This research study will take place over multiple weeks. It will usually take up to two weeks to complete this research study.

This research study has two phases, although not everyone will be asked to do the second phase.

Phase 1 (Study Visit 1): This visit can take place at McLean Hospital, but right now you may have the option to do it virtually instead.* Visit 1 will usually be split into two or three sessions, depending on the interview length. However, in some instances, you may be able to schedule Visit 1 as a single session that includes a long break. At the end of this visit, we will schedule Study Visit 2 (if relevant) based on your menstrual cycle.

Phase 2 (Study Visit 2): This visit takes place primarily at McLean Hospital. However, you may be asked to do one of the visit tasks, which can be done virtually, a day or more ahead of time. This visit will usually take place very soon after Study Visit 1. This will depend on your menstrual cycle and on when the scanner is available.

* During this study we may need to make changes to study visits and procedures to comply with public health efforts to address COVID-19 (coronavirus). We may need to adjust the study visit schedule and/or research procedures as a result of study site restrictions on research visits. We may conduct Visit 1 virtually until the restrictions are lifted. Virtual visits will be conducted over Zoom. During these visits, someone from our study staff will contact you via Zoom and conduct all of Visit 1 virtually. Although Visit 2 must take place onsite at McLean Hospital, we may use Zoom to conduct certain parts of the visit virtually, with you in one room and study staff in another.

Study staff will provide you information on how to access the video conferencing platform used during virtual visits. 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. If you do Visit 1, or part of Visit 2, virtually from your home, 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 our study staff if you have any questions about this prior to your video visit.

Also, due to COVID-19, it is possible that onsite research will be temporarily shut down for general health safety reasons. If a shutdown occurs, we may need to postpone Visit 2 after it is scheduled. If this happens, we will let you know as soon as possible, and we will plan to reschedule the visit for the soonest date possible. However, if the visit has to be postponed for

more than six weeks, you will not be asked to do Visit 2, and your participation in the study will end after Visit 1.

You will be asked to do Study Visit 1:

____ At McLean Hospital ____ Virtually

What will happen in this research study?

You'll be asked to do several tasks during each phase of this study. In some research studies, the investigators cannot tell you exactly what the study is about before you participate in the study. Below, we describe the tasks you'll be asked to do in a general way, but we can't explain the specific goals of the study until after you complete these tasks.

Because this study involves important questions about your health history, we will use your electronic and health records to confirm certain key details of your health history.

When you're done, we will explain why we are doing this study, what we are looking at, and any other information you should know about this study. You'll also be able to ask any questions you might have about the study's goals and the tasks you did. Although we may not be able to explain the specific goals of the study until after you complete the tasks, there are no additional risks to those that have been described in this consent form.

Phase 1 (Study Visit 1):
The goal of this visit is to assess whether the study is a good fit for you. We cannot predict exactly how long the visit will last. However, it will generally last at least 5.5 hours and may last up to 8 hours for some people. The visit may occur across two or three sessions, or as a single session with a long break. You may be asked to split Visit 1 across three sessions depending on the length of the interviews.

During this visit, we'll ask you a number of questions. First, we'll ask you to complete a questionnaire about your demographics (for example, gender and race). Then, we'll ask you a large number of questions about your health, by interviewing you and also by asking you to complete several more questionnaires. For example, we'll ask about your medical and mental health history and current symptoms, and about any medications you've taken recently. We will also ask about your history of suicidal thoughts or behaviors, and your history of trauma. In addition, we will ask about your daily life, things like sleep, exercise, diet, and use of drugs and alcohol.

During your visit, we will also ask you to rate a large number of food pictures. You'll be asked to rate whether each food is familiar to you and whether you can safely eat it. You will do this on the computer.

Depending on the results of these assessments, you may not be eligible to continue with the remainder of the study. In this case, we may stop the visit early, without doing all of the assessments described above.

If you are eligible to continue, we will schedule Visit 2. We will give you instructions on how to prepare for your next visit. We will ask you not to take any over-the-counter medication or herbal supplements for 24-48 hours prior to Visit 2. We will also ask you not to use alcohol or unusually large amounts of caffeine for 24-48 hours prior to Visit 2. In addition, we'll ask you to get enough sleep the night before your visit and not to exercise the morning of your visit. We will also give you recommendations for eating breakfast before you leave home on the morning of your visit.

Before you leave, Dr. Javaras will review your responses to some of the questions we've asked during the visit. She will also ask you some additional questions and check how you're doing, in case any part of the visit has been upsetting. This will include questions about thoughts or urges to harm yourself or others.

Phase 2 (Study Visit 2):
This visit will last about 12 hours and occurs on a Saturday or Sunday. During this visit, you'll be asked to perform a variety of tasks, including decision-making tasks. You will get to take a complete break from all study activities once every four hours or so.

Morning Activities:
We will ask you to rate a large number of food pictures. You'll be asked to rate the healthiness and tastiness of each food. You will do this on the computer. Please note that we may ask you to do this task virtually ahead of Visit 2, to reduce the time you are at McLean for Visit 2.

Also, we'll interview you and ask you to complete several questionnaires. The interview and questionnaires will focus on your daily life, things like sleep, exercise, diet, and use of drugs and alcohol. They will also focus on your health, including your mental health and recent suicidal thoughts or behaviors, as well as your menstrual cycle.

In addition, we will take some measurements, including your height and weight.

We'll also ask you to complete a urine drug screen. We will do this urine test in the office and discard the test material immediately.

Depending on the results of some of these assessments, you may not be eligible to continue with the remainder of the study. For example, if the drug test is positive, you may not be able to continue with the study.

Next, you will have a lunch break. We will provide you with a standard lunch. You'll be asked to choose from several options. You should pick an option that you like and can safely eat without feeling sick or having an allergic reaction.

Early Afternoon Activities:
After lunch, you will get a break. During your break, you will have an opportunity to engage in your choice of activities and will also watch the movie Happy Feet. However, it is important that you do not exercise, eat, or do anything that might cause you to become stressed or excited during your break. This is because these activities could affect the data we get from your MRI scan.

After your break, you will get to lie inside a fake scanner, to help you see what it is like to be inside a (real) MRI scanner. The fake scanner is not actually collecting any information about your brain or other parts of your body.

We will also help you prepare for your MRI scans. To do so, we will ask you a series of questions that help us be sure it is completely safe for you to get an MRI scan.

MRI Scanning Session #1 (Brain Imaging):
MR imaging will take place at the McLean Imaging Center at McLean Hospital. This will be the first of two MRI scanning sessions during Visit 2. You will spend up to 90 minutes in the MRI scanner during the first session.

Because the scanner contains a strong magnet, you will be asked to remove all metal objects from your person including, but not limited to: watches, rings, necklaces, bracelets, earrings and other body piercings, belts, loose change, wallet (with credit cards), items of clothing containing magnetic materials (for example, underwire bras, certain types of zippers), and shoes. These items will be secured in a safe place until your scan is completed. We will provide you with clean hospital scrubs to wear during your MRI scan.

You will be scanned in an MR machine that has a field strength of 3 Tesla. The scanner looks like a large cylinder with an opening running down the center. You will be asked to lie down on your back on a foam-padded table and place your head into a special holder. The table will slide you inside the "hole" of the scanner. Soft foam rubber sponges may be placed on both sides of your head for comfort and to help keep your head from moving.

Once you are positioned in the scanner, you will undergo a series of scans. Some of these will take place while you are resting, and others will take place while you are doing various activities (described below). During the scanning procedure, you will hear a number of different sounds. Some of these sounds are loud, and they are part of the normal operation of the scanner. These noises vary with the type of scan being performed and include: sounds like a hammer hitting a piece of wood, repetitive buzzing noises, and long series of loud beeps. Some scans are silent. These sounds, or combinations of them, may be repeated several times. To reduce the noise of the scanner, you will be fitted with earplugs and/or headphones. The longest continuous scanning run may be up to 15 minutes, and you will be given breaks between scanning runs. You are free to talk during the preparation time and during breaks, but you should not talk during the actual scanning process. During scans, you should try to remain as still as possible.

At several points throughout the scanning session, we will collect various measurements of your current "state." This includes asking you to fill out surveys about how you are feeling. We will also collect blood pressure and heart rate readings, as well as saliva samples, from you. For the saliva samples, you will be asked to keep a hygienic cotton swab in your mouth for about 120 seconds. We will repeat these "state" measurements up to four more times over the next two hours. Also, we will audio record you during certain parts of this scanning session. These recordings will help us understand whether people are able to complete the activities as instructed. They will also help us understand how people react to the activities.

Next, we will ask you to complete either a speaking or a talking activity through a virtual platform. In the speaking activity, you will be told what topics to cover when you speak. In the talking activity, you will get to talk about a topic of your choice. You will also be asked to do some counting in both activities. You will undergo scans during certain parts of the activity.

Next, you will be asked to complete a task related to your preferences for different foods. Specifically, we will show you two pictures of different foods and ask you to pick between the two. Instructions for this task will be provided to you before you enter the scanner and again while you are lying down in the scanner. You will undergo scans while doing this task.

Afterward, you will undergo multiple scans that provide information on the structure of your brain. You can rest during these scans. The scans usually include a standard clinical brain MRI scan to look at the overall structure of your brain. This brain scan will be reviewed by a radiologist, and a report will be generated. If you have received a clinical brain MRI scan within the past year for another study at McLean Hospital, you will not need to receive one for the present study. However, if you have not received one in the past year, one will be obtained for the present study.

If you feel uncomfortable at any time during the scan, you may tell us to stop. The MRI scanner has a microphone and you can ask us to stop the scanning procedure at any time.

When your session is over, the technician will move you out of the scanner and assist you up from the table.

Late Afternoon Activities:
Afterward, you will fill out a questionnaire before getting an afternoon snack that includes foods you chose earlier.

After the snack, you will get a break. During your break, you will have an opportunity to engage in your choice of activities and will also watch the movie Happy Feet. However, it is important that you do not exercise, eat, or do anything that might cause you to become stressed or excited during your break. This is because these activities could affect the data we get from your MRI scan.

Also, we'll ask you to complete some additional interviews and questionnaires. These will ask about life experiences, mental health symptoms, and your personality.

MRI Scanning Session #2 (Brain & Body Imaging):
The second MRI session will involve some brain imaging and also body imaging. This will, again, take place at the McLean Imaging Center at McLean Hospital. You will spend up to 90 minutes in the MRI machine for this second scanning session.

Once you are positioned in the scanner, you will undergo a series of scans. Some of these will take place while you are resting, and others will take place while you are doing a variety of activities (described below).

At several points throughout the scanning session, we will collect various measurements of your current "state." This includes asking you to fill out surveys about how you are feeling. We will also collect blood pressure and heart rate readings, as well as saliva samples, from you. For the saliva samples, you will be asked to keep a hygienic cotton swab in your mouth for about 120 seconds. We will repeat these "state" measurements up to four more times over the next two hours. Also, we will audio record you during certain parts of this scanning session. These recordings will help us understand whether people are able to complete the activities as instructed. They will also help us understand how people react to the activities.

Next, we will ask you to complete either a talking activity or a speaking activity (whichever one you did not do during Scanning Session #1) through a virtual platform. In the talking activity, you will get to talk about a topic of your choice. In the speaking activity, you will be told what

topics to cover when you speak. You will also be asked to do some counting in both activities. You will undergo scans while doing certain parts of the activity.

Next, you will be asked to complete the task related to your preferences for different foods again. You will undergo scans while doing this task.

Afterward, you will undergo a body scan. During the scan, we will ask you to hold your breath for short periods of time. We will provide you with instructions on how to do this. This scan can provide information related to metabolic health, such as measures of adipose (fat) tissue.

If you feel uncomfortable at any time during the scan, you may tell us to stop. The MRI scanner has a microphone and you can ask us to stop the scanning procedure at any time.

When your session is over, the technician will move you out of the scanner and assist you up from the table.

Study Visit Wrap-Up:
Before you leave at the end of Visit 2, we will ask you to complete a few more questionnaires and an interview about your experiences during the study. The interview will be audio recorded so that we can capture your responses as accurately as possible. You will also be given the chance to eat a snack that includes foods you chose earlier.

At the end of the visit, study staff will explain more about the study and its goals. They will also answer any questions you have.

Also, Dr. Javaras will review your responses to some of the questions we've asked during the visit. She will also ask you some additional questions and check how you're doing, in case any part of the visit has been upsetting. This will include questions about thoughts or urges to harm yourself or others.

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

General Risks of Study Visits
You will likely feel very tired — both physically and mentally — after completing study visits, especially Visit 2. You can choose to stop the study at any point, for any reason, including fatigue.

Risks of MR Scans
Magnetic resonance technology uses strong magnetic fields and radio waves to collect

images and data. Unlike X-rays or CAT scans, it does not use ionizing radiation. There are no known risks from the magnetic fields and radio waves used in MRI scans. However, there could be adverse effects that have not yet been recognized because they are delayed or very mild.

The 3T scanner is approved by the FDA for routine clinical studies in children or adults. Although we will take numerous precautions to avoid all known risks associated with MRI (see below), this procedure may involve risks to you that are currently unforeseeable.

Risks Related to Magnetic Fields:
Because the scanner contains a strong magnet, there are significant risks associated with metal objects and other material affected by magnetism. Significant risks may exist for people with:

- Cardiac pacemakers
- Metal clips on blood vessels (also called stents)
- Artificial heart valves
- Artificial arms, hands, legs, etc.
- Brain stimulator devices
- Implanted drug pumps
- Ear implants
- Eye implants or metal fragments in eyes
- Exposure to shrapnel or metal filings (wounded in military combat, sheet metal workers, welders, and others)
- Other metallic surgical hardware in vital areas
- Certain tattoos with metallic ink (please tell us if you have a tattoo)
- Certain transdermal (skin) patches such as NicoDerm (nicotine for tobacco dependence), Transderm Scop (scopolamine for motion sickness), or Ortho Evra (birth control), or certain metal-containing IUDs

If you are unsure whether you have any of these items in your body, you should know that most would have been implanted as part of a surgical procedure. So, trying to remember any past operations may help you remember. You will be asked whether you have any implanted devices or history of exposure to shrapnel or metal filings, and if so, you will not be able to participate in this study.

Significant risks also can arise if certain materials (many types of metal objects) are brought into the scanning area, as they can be pulled into the scanner at great speed because it contains a strong magnet. Such items can cause serious injury if they hit you. Therefore, these types of items are not permitted in the scanning area. You will not be allowed to bring anything with you into the scanning room.

Risks Related to Pregnancy:
Women who are pregnant cannot have MR scans for research. Women are considered to be of childbearing potential from their first menstrual period until they are post-menopausal or have been surgically sterilized and there has been no menstrual period for more than 6 months.

Other Physical Sensations:
The MR exams are painless, and except for pulsating sounds, you will not be aware that scanning is taking place. Most people experience no ill effects from MR scans. However, some people do report dizziness, mild nausea, headaches, a metallic taste in their mouth, double vision, or sensation of flashing lights. These symptoms, if present, disappear shortly after leaving the scanner.

The MRI has the potential, during normal routine use, to cause localized warming of your skin and the underlying tissues. You should immediately inform us if you experience discomfort due to warming, and the procedure will be stopped.

In rare cases, a very slight, uncomfortable tingling of the back is induced in some people undergoing certain types of scans. If you experience this sensation, you are asked to report this immediately so the scan can be changed to avoid this.

Some people have also reported tingling or tapping sensations, or muscle twitches in different parts of their body during the MRI scanning procedure. These sensations are not dangerous and are not likely to cause you any serious discomfort.

You may become fatigued (tired) and/or have physical discomfort from lying still on your back during the scanning session.

Some people do become very anxious during scans. You shouldn't have an MRI if you have claustrophobia (fear of small spaces) or severe anxiety.

The top and sides of the machine will be very close to your body. Because of this, you may feel anxious while inside the MRI machine. If you feel anxious during the procedure, you can ask us to stop the MRI at any time.

Risks of Finding Potential Medical Problems:
In some cases, MRI scans can reveal a medical problem. Whenever possible, we will ask a radiologist (a doctor who specializes in x-rays, scans, and test results of this sort) to review the results of your scans. In this study, a radiologist will review certain MRI scans of your brain and write a report, which Dr. Javaras will review. It is fairly common for the radiologist to note

something in their report that our study physician, Dr. James Hudson, will contact you to let you know about, usually by phone. However, we won't typically ask a radiologist to review scans of your other body parts, because those scans aren't comprehensive protocols designed for detecting medical problems.

If the radiologist thinks there might be a problem based on the results they review, we will tell you and help you get follow-up care. It's important to note that this can lead to unnecessary tests and unnecessary worry if it turns out that you don't actually have a medical problem. Also, even if the radiologist does not see any potential problems in the scans, this does not guarantee that your brain is in perfect health. There could be a problem that the radiologist did not see in the scans.

Risks Associated with Saliva Samples
Few risks are expected during saliva collection, from which various hormone levels will be extracted. You may find it slightly uncomfortable. The main concern for this portion of the study is confidentiality, since these are biological samples that contain your DNA. To protect confidentiality, saliva samples will be labeled with an anonymous study ID.

Risks Associated with Eating
You will be eating lunch and snacks during some of the study visits.

We will always give you several food options, and you should choose one that you can safely eat. If you have any concerns about eating a food, please don't eat it. If you feel sick or are have any other negative reaction to a food, please stop eating and let us know immediately.

As you know, certain foods (like peanuts) can make people feel sick or cause an allergic reaction. Because of this, we'll ask you about any known food allergies, intolerances, or sensitivities during Study Visit 1. It's very important that you share this information with us. For store-bought food, we'll ask you to read the package information carefully, to make sure it's safe for you to eat.

Psychological Risks and Discomforts
Some of the questions in the interview or questionnaires may make you feel **uncomfortable or upset**. This will include numerous, detailed questions about stressful experiences (such as sexual or physical assault or abuse and other traumatic experiences) and about suicidal thoughts and behaviors. You can choose not to answer a question at any time for any reason. You can also choose to stop the study at any point for any reason.

In addition, viewing large numbers of food pictures may make you want to eat, or make you feel upset.

Also, you will likely find some of the activities during Visit 2 to be **upsetting or stressful**. In addition, you may find some of the activities during study visits to be tedious or boring. You can choose to stop these tasks at any point for any reason. You can also choose to stop the study at any point for any reason.

Some people may find that they feel upset or distressed after a study visit. If you experience any of the following things after you leave, please call 911 or go to your nearest emergency room. If you have a psychiatrist or therapist, you can also contact them to let them know what is going on.

- **Serious distress**
- **Serious struggles with eating**
- **Thoughts of hurting yourself or others**
- **Any other serious medical or mental health problem**

_____ Please initial to indicate that you agree with the following statement:
I acknowledge that portions of this study will likely be stressful or upsetting, and that the study involves numerous, detailed questions about stressful experiences, such as physical or sexual assault or abuse and other traumatic experiences.

Confidentiality Risks

Another potential risk of participating in this study is the loss of confidentiality. Loss of confidentiality refers to situations where someone outside our research team gets access to the information we collect from you. Depending on what information they access, there could be legal, psychological, social, or financial consequences for you. Also, even if this doesn't happen, you might worry about it happening.

Serious efforts will be made to protect the information collected from you. We have chosen devices and computer software designed to minimize any risks related to breach of privacy, confidentiality, or data security. The information collected via these devices and software will be "de-identified." In other words, it won't contain any personal information (like your name) that links the data to you. In general, we will store your data without any personal information, like your name, that could link the information to you. Instead, we'll label your data with an anonymous study ID, a combination of letters and numbers that tells nothing about your identity.

However, there are two exceptions. First, as noted above, a radiologist will review some of the MRI scans of your brain. These scans, and the report from the radiologist reviewing the scans, will become part of your Partners electronic health records. The record will include a disclaimer stating that the scans were collected as part of a research study, without giving any information about the research study.

Second, the audio recorded during certain parts of the study will include your voice, which is personal information because it reveals your identity. For this reason, we will store the audio recordings separately from the other data, without any information linking the recordings to this study or to your other data. To help protect your confidentiality, only approved members of the study staff will have access to the recordings, and the recordings will not be shared with other researchers within or outside of Partners. The audio recordings will provide a record of what happens during portions of our study visits. This can help us assess how participants are adhering to study instructions and also how they are reacting to study procedures. Recording the interview about your experiences during the study helps us ensure we transcribe your experiences as accurately as possible. The recordings will not be used for any other purpose, or shown to anyone else, without getting additional permission from you. For example, after listening to the recordings, we might contact you to request permission to use your audio as an example when presenting our study results to other researchers. You should always feel free to deny our request, for any reason. After the research study ends, we will store the recordings for 7 more years and then destroy them. If you wish to have your recording destroyed sooner, you can contact Dr. Kristin Javaras at [redacted] with a written and signed request.

Even with these serious efforts to protect the information we collect from you, no method for storing information is 100% secure. This means that there's always a chance that someone outside our study team could access the information we collect from you.

Further, confidentiality has ethical and legal limits. **There are some circumstances where we may have to release information that would identify you.** Our study has a Certificate of Confidentiality from the Department of Health and Human Services, which means that, in most circumstances, we can't be forced to share research information that identifies you. This includes research information about your health or other sensitive activities collected during this study. **However, even with a Certificate, there are still some circumstances where we would have to release information that would identify you.** This could occur if you express a clear and credible threat or intention to do serious harm to yourself or some other identifiable person. Under state law and our professional ethics codes, we would have to take all reasonable steps to protect both you and/or the intended victim. This usually involves notifying the police or others who could intervene to prevent harm from being done. A similar situation would exist if you tell us that a child or elder in your care is being abused and/or neglected. There is a mandatory reporting law where we would be required by state law to report admitted or suspected child or elder abuse and/or neglect to the Department of Social Services. In these cases, we would release only the minimal necessary information.

Research Consent to Receive Unencrypted Text Message Communications

Text messages by mobile/cell phones are a common form of communication. With your permission, the Decision Making research study may involve sending you text messages to schedule your study visits. You may still participate in the study even if you decide not to receive text messages. In this case, we would schedule your visits via phone call and/or email instead of texting.

Texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, 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 Mass General Brigham 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 research study and Partners Healthcare are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.
- Text messages will be read based on the availability of the research staff. It is possible that texts sent on nights, weekends, holidays, or during vacation periods may not be read for several days.
- Text messaging 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 text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says "Stop Research Text."
- Your agreement applies to this research study only. Agreeing to other texts from Mass General Brigham, for example appointment reminders, is a separate process. Opting out of other texts from Mass General Brigham 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 a change.

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

You will not directly benefit from taking part in this study. We hope that what we learn from this study may be beneficial to understanding everyday decision making and how it relates to a variety of daily experiences.

Can I still get medical care within Partners if I don't take part in this research study, or if I 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.

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. 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 I do if I 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 I be paid to take part in this research study?

You could earn up to $425 in compensation for completing all phases of the study.

Phase 1 (Study Visit 1)
- $125 for completion

Phase 2 (Study Visit 2)
- $300 for completion

There is a chance you might not complete all of the phases you are asked to, either because you decide to drop out or we ask you to drop out. If this happens, you will not be paid for any phases after you drop out. Also, if you complete only part of a study visit, your pay for that visit will typically be a prorated amount based on how many hours you spent at the visit. However, in certain circumstances (e.g., if we experience problems with technical equipment), we will pay you for completing the entire study visit even if you do not actually complete it.

Additionally, due to COVID-19 (coronavirus), it is possible that onsite research will be temporarily shut down for general health safety reasons. If the shutdown occurs before you have

Visit 2 and the visit has to be postponed for more than six weeks, your participation in the study will end after Visit 1, and you will be paid only for Visit 1.

We will not reimburse travel expenses. This includes parking, since parking at McLean is free.

Your payment will be sent to you in the form of a check. It will be sent after you complete the study.

For tax purposes, we will ask you for your social security number in order to process your payment. McLean Hospital is required to inform the IRS if any participant receives over $600 in a given calendar year. If that occurs, you will receive a 1099 form at the end of the year. No information identifying why you received this payment will be communicated to either the Hospital's accounting department or the government. This information is kept confidential and will not be recorded in your medical records.

What will I have to pay for if I take part in this research 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 copayments 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 I am injured as a result of taking part in this research study?

If you are injured as a direct result of taking part in this research study, we will assist you in obtaining the medical care needed to treat the injury. This means arranging for (but not paying for) transportation to an acute care center for treatment of the injury. McLean Hospital is a psychiatric care facility and does not provide general health care services.

The care provider may 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 next section of this consent form.

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

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

Kristin Javaras, DPhil, PhD is the person in charge of this research study. You can call her at [redacted], M-F 9:00-5:30. Outside of business hours, you can reach Dr. Javaras on her pager. To page Dr. Javaras, call [redacted], enter [redacted] when prompted for the 5-digit ID, and then follow the instructions to leave the phone number where Dr. Javaras should call you back. You can also call [redacted] or [redacted] at [redacted] M-F 9:00-5:30 with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call [redacted] at [redacted] or [redacted] at [redacted].

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

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my 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 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 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 (optional)

Consent, Assent, and Permission for Text Messaging

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 described above and I consent to the use of unencrypted text communications associated with this research study.

Signature of Subject:

_____	_____	_____
Subject	Date	Time (optional)

Consent for Recontact

Are you interested in being contacted for other related research projects?

(If so, we will securely store your contact information so that we can contact you later.)

☐ Yes

☐ No

Signature of Subject:

_____	_____	_____
Subject	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.

_____	_____	_____
Study Doctor or Person Obtaining Consent	Date	Time (optional)

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