Gamified Approach to Maximizing Biobehavioral Inhibition in Trauma-related Conditions (GAMBIT)

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## STUDY INFORMATION:

**Study Title:** Gamified Approach to Maximizing Biobehavioral Inhibition in Trauma-related Conditions (GAMBIT)

**Study site(s):** Icahn School of Medicine at Mount Sinai

**Lead Researchers (Principal Investigators):** Jonathan DePierro, PhD & Laurel Morris, PhD

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## SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you might be interested in joining. Participation in the study is voluntary. You can agree to join or not. Your decision will not limit your ability to receive care at Mount Sinai. You should only agree to take part if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

The purpose of this research study is to test a new digital training task called GAMBIT in a group of people with posttraumatic stress disorder (PTSD). Many people with PTSD experience unwanted flashbacks and memories of their traumatic experience and have difficulties suppressing traumatic memories. Current research about PTSD suggests that people with PTSD have issues with “inhibitory control,” which is the inability to stop, change, or delay behaviors that are inappropriate given the current context or environment, including traumatic memory suppression. While there are multiple therapies and medications designed to decrease the symptoms of PTSD, they are sometimes not very effective or require the patient with PTSD to engage with traumatic reminders. The GAMBIT task is designed to train people with PTSD to exercise their inhibitory control skills in a setting that does not require exposure to traumatic reminders.




Effective Date: 10/28/2024
End Date:9/16/2025

If you choose to participate in this study, you will be asked to complete the GAMBIT task, mental health assessment, an inhibitory control task, and fMRI scans on multiple days. While some portions of the study require you to come to the Depression and Anxiety Center and Mount Sinai Biomedical Engineering and Imaging Institute (BMEII), other portions of the study will be completed remotely over a HIPAA-compliant telehealth platform. The requirements to participate in the study are described here:

- Complete and sign this consent form.
- Complete all study visits (approximate study participation of up to 81 days)
- Complete multiple mental health assessments during each study visit.
- Complete a urine toxicology screen during two study visits.
- Complete an fMRI scan during two study visits.
- Complete the internet-based GAMBIT task on your home computer a total of 18 times: 3 times per week for 6 weeks.
- Complete inhibitory control tasks (e.g.,the Go/No-Go and the Facestroop tasks during the fMRI scans at two study visits.
- Complete inhibitory control tasks in the lab during two study visits (e.g., the combined Think/No-Think and Go/No-Go).

Please note that by participating in this study, your current standard of care will not change or be affected in any way. There are no costs associated with participating in this study. If you choose to participate in this study, you will be compensated for each task you complete.

If you choose to take part, the main risk to you is potential discomfort while completing the mental health assessments and/or the fMRI scans. The mental health assessments ask about current PTSD-related symptoms and about trauma exposure, which may cause some negative feelings to arise. The study team does not foresee any major risks to those who participate in this study.

You may benefit from taking part in this research. Since the GAMBIT task is designed to exercise your brain's inhibitory control network, there is a possibility that participating in this study will increase your inhibitory control skills.

If you are interested in learning more about this study, please continue to read below.



## STUDY PARTICIPATION:

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you meet the diagnostic criteria for current PTSD according to the Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition (DSM-5), **OR** if you have no lifetime history of any psychiatric diagnosis. Your eligibility to participate and your study group placement will be determined during the screening visit(s).

Your participation in this research study is expected last up to 81 days, until the final follow-up assessment (Visit 4) is complete. *If you are a pilot participant, you will only complete Visits 0-1.*

There are 50 people expected to take part in this research study at The Depression and Anxiety Center.

Funds for conducting this research study are provided by the Icahn School of Medicine at Mount Sinai.

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

## DESCRIPTION OF WHAT IS INVOLVED:

If you agree to participate in this research study, here is what may be involved during each study "visit". Note: while each phase of the study is called a study "Visit", some portions of the study will be completed remotely by phone or Zoom (the phone screening, Visit 0, and Visit 2) while others will be completed at the Biomedical Engineering and Imaging Institute (BMEII) at Mount Sinai (Visit 1, Visit 3, and Visit 4) or Depression and Anxiety Center office. A member of the study team will coordinate with you to schedule your study visits. Additionally, a member of the study team may email and/or text you to remind you of your upcoming study visits. All emails and text messages will comply with MSHS policy. A timeline of the study visits is shown and described below.



| | **Pre-Screening** (Pre-consent) | **Visit 0** Screening | **Visit 1 (Day 1)** Pre-assessment (0-28 days after Visit 0) *HC Pilot's Last Visit* | **Days 2-44** (6 weeks) | **Visit 2 (Day 23)** (3 weeks) | **Visit 3 (Day 45)** Post-assessment | **Visit 4 (Day 52)** Follow-up assessment |
|---|---|---|---|---|---|---|---|
| Eligibility Phone Screen | X | | | | | | |
| Informed Consent | | X | | | | | |
| **Assessments** | | | | | | | |
| SCID-5 | | X | | | | | |
| CAPS-5 (past week version) | | X | X | | X | | X |
| CAPS-5 (past month version) | | X | | | | | |
| PCL-5 | | X | X | X | X | X | X |
| MADRS | | X | X | | X | X | X |
| WTAR | | X | | | | | |
| MoCA | | X | | | | | |
| CTQ | | X | | | | | |
| TLEQ | | X | | | | | |
| SDS | | X | X | | X | X | X |
| C-SSRS | | X | | | | | |
| DERS | | | X | | X | X | X |
| QIDS-SR | | | X | | X | X | X |
| ACS | | | X | | X | X | X |
| ATQ-EC | | | X | | X | X | X |
| BIS/BAS Scales | | | X | | X | X | X |
| Addiction/Craving Scales | | | X | | X | X | X |
| ERRI | | | X | | | | |
| RRS | | | X | | | X | |
| Urine Toxicology Screen | | | X | | | | X |
| **Study Tasks*** | | | | | | | |
| GAMBIT Task Practice (PTSD Group only) | | | X | X | | | |
| Combined Think/No-Think and Go/No-Go Task | | | X | | | | X |
| | | | | | | | |



| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **FMRI*** | | | | | | | |
| Structural scan | | | X | | | | X |
| Resting state functional connectivity | | | X | | | | X |
| Go-No-Go task | | | X | | | | X |
| Facestroop Task | | | X | | | | X |
| | | | X | | | | X |
| Adverse Event Reporting | | | X | X | X | X | X |
| Study Exit Meeting and Forms | | | | | | | X |

*** Note: the tasks listed in the "Study Tasks" and "FMRI" sections above are representative of inhibitory control tasks that may be administered both in and outside of the fMRI scan.

Eligibility Phone Screen and Informed Consent:

- You will complete a phone screening with a member of the research team to determine if you are eligible to participate in the study.
- You will complete and sign this informed consent form before you participate in the rest of the study.

Mental Health Symptom Assessments and Self-Report Forms:

- At the screening visit (Visit 0), you will complete two mental health assessment interviews with a trained member of the Depression and Anxiety Center study team. The first assessment asks about your current mental health symptoms, mental health history, work history, and treatment history and takes approximately 90 minutes to complete. The second assessment asks about your current PTSD symptoms and takes 45-60 minutes to complete. You will also complete multiple questionnaires that will assess your PTSD and depressive symptoms. In total, Visit 0 will take 3-4 hours to complete. You will complete the screening visit (Visit 0) remotely via HIPAA-compliant Zoom.
- At Visits 1, 2, 3, and 4, you will also complete a mental health assessment interview that will assess your PTSD symptoms from the past week. You will also complete multiple mental health questionnaires about your present PTSD and depressive symptoms. You will complete the assessments at Visits 1 and 4 in person at the Depression and Anxiety Center office or the Center for Stress, Resilience, and Personal Growth office, and complete the assessments at Visits 2 and 3 remotely via HIPAA-compliant Zoom.
- Additionally, you will complete a mental health survey that asks about your current PTSD symptoms after you complete the GAMBIT Task remotely. You will complete this assessment once a week for 6 weeks during Days 2-44 of the study. This survey takes about 5-10 minutes to complete and will be done remotely via a weblink link sent to you via email from the study team.



Urine Toxicology Screen:

- You will complete a urine toxicology screen before you complete the fMRI scans at Visit 1 and Visit 4. The urine toxicology screen will test for illicit drugs or dis-allowed concomitant medications as per study protocol. Intermittent cannabis use that does not meet criteria for a substance use disorder may be permitted under the protocol. The test will be administered at the Depression and Anxiety Center office.

Neuroimaging (fMRI) Scans:

- You will complete an fMRI scan during Visit 1and Visit 4. The fMRI scan will focus on capturing activity your brain's inhibitory control network. Approximately 10-minutes of resting state and 10- minutes of structural fMRI data will be collected before you complete the inhibitory control tasks (described below). The entire fMRI scan will take approximately 1 hour to complete. You will complete the fMRI scans at the Mount Sinai Biomedical Engineering Imaging Institute.

The GAMBIT Task:

- The GAMBIT Task is an experimental game that depicts an underwater scene. The underwater scene includes a fish, which will appear on either the left or right sides of the screen. Depending on which side of the screen the fish is on, you will be instructed to hit a specific key on a keyboard to make the fish swim away. If you hit the correct key fast enough, you will win a gold coin which is added to a pot of gold. However, if you don't choose the correct key fast enough, you will lose a gold coin from your pot of gold. While you play the game, you may hear a sound that means a shark is approaching. When the shark is approaching, or if you see the shark itself, you must not hit any keys on the keyboard. If you don't hit any keys while the shark is approaching, you will be rewarded with another gold coin. However, if you hit any keys while the shark is approaching, when the shark is on the screen, you will lose gold coins. Other times during the game, the water may change colors to indicate that a shark may be approaching, or you may see floating objects in the water. Again, if you don't hit any keys when the shark is approaching, or when the shark is on the screen, you will be rewarded with gold coins. However, if you incorrectly hit a key when the shark is approaching or present, you will lose gold coins. The GAMBIT task takes approximately 8 minutes to complete.
- You will complete the GAMBIT task 18 times in total throughout the study. You will complete the task remotely three times a week for six weeks on your home computer. You will be provided instructions for how to complete the GAMBIT task remotely via the PsychoPy/Pavlovia platform.
- For the first three weeks, a member of the study team will meet with you via HIPAA-compliant Zoom call to observe as you complete the GAMBIT Task. These meetings are to ensure that you are completing the GAMBIT Task correctly and to provide any technical support if needed.

Study Tasks:



The study team will administer multiple tasks that test inhibitory control skills both in and outside of the fMRI scan. The tasks described below are representative of the types of tasks that you may complete:

- The Go/No-Go task is a measure of inhibitory control requiring withholding of a response based on a salient visual cue (e.g., alphabetical letters). This task takes about 15 minutes to complete will be done at the first and fourth study visit (Visits 1and 4) during the fMRI scan.
- The Face-Stroop task assesses reaction time between congruent and incongruent stimuli. You will be simultaneously presented with images of emotional faces and emotional words (e.g., “Happy”, “Sad”), with some trials presenting matching stimuli (happy face + “Happy”) and other trials presenting mismatched stimuli (happy face + “Sad”). You will then be asked to identify the faces and words separately. You will complete 2 runs of the Facestroop Task at the first and fourth study visit (Visits 1and 4) during the fMRI scan, which takes approximately 10 minutes to complete.
- The combined Think/No-Think and Go/No-Go task assesses inhibitory control. You will be asked to learn 35 cue-target word pairs (for approximately 15 minutes). Then, you will be asked to alternatively suppress, recall, or think about the cue-target word pairs, when prompted. This task takes approximately 20 minutes to complete. You will complete this task at the first and fourth study visit (Visits 1 and 4).
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Research Results

- The study team intends to publish the results of this study. Any published research results will not include any identifiable information. If you wish to access your individual study results, please contact the Principal Investigator, Dr. Jonathan DePierro.

## Future Contact:

The researchers may wish to use your personal contact information to contact you in the future. Do you give the researchers permission to **contact you** in the future to request the collection of additional information about you, discuss how your private information, study data and/or samples might be used, or discuss possible participation in another research study?

Please initial your choice: Yes_____No_____

If “Yes”, please indicate your preferred method of contact: (initial all that apply)

[ ] Email [ ] Phone [ ] Letter [ ] Text



## USE OF YOUR DATA:

The researchers would like your permission to keep your personal information (such as, name, address, date of birth, social security number), study data to use or share in future studies. You can still be part of the study if you do not allow us to use or share them. Please select Yes or No to each of the questions below. To decline all future uses/sharing please select 'No' each time.

**(1)** Will you allow the researchers to store your data to use in future research studies?

**Please initial your choice:** Yes_____No_____

If you select No, please stop here and move to the next section, **'Your Responsibilities If You Take Part in This Research**' section below."

If yes, please continue to the next question and tell us how your personal information, study data may be used in future research studies.

**(2)** The researchers can store your data in one of two ways:

a) Anonymously (no one will know who the data and/or samples came from). If you choose this option, you can't change your mind. So, if you wanted to have your data destroyed in the future, the team could not do it as they would not know which data were yours.
b) Linked to your identity (using a code that can show the information came from you personally). In this case you could ask for your data to be destroyed in the future if you want that to happen.

How would you like your data stored? Please initial **ONE** choice below:

I would like my data stored anonymously _____

I would like my data stored with a link to my identity through the use of a code_____

**(3)** Do you give the researchers permission to keep the data, so they could use them in future studies that are **directly related** to the purpose of the current study?

Please initial your choice: Yes_____No_____

**(4)** Do you give the researchers permission to keep the data indefinitely, so they could use them for



future studies that are **not related** to the purpose of the current study (for example a different area of research)?

Please initial your choice: Yes_____No_____

**(4.1)** From time to time, researchers outside of medicine and related sciences would like to use data. This might be in the fields such as anthropology, human origins, mapping human migration patterns. Do you give permission for researchers **outside the field of medicine** to use your data?

Please initial your choice: Yes_____No_____

**a.** If the future research in a different area can be done without having to know that the data came from you personally, that will be done.
**b.** If the future research in a different area requires that it is known specifically who the data came from, then one of the following will be done:
   I. If you allowed the researchers to contact you in the future, they may be able to contact you to explain why your data is needed and what will be done with it. Your permission will be asked to use your data in that research project.
   II. If you do not give permission to be contacted in the future, or if it is found that contacting you is not practical (for example, because you have moved), your data may still be used. The Institutional Review Board (IRB) will be asked for permission to use the data linked to your identity. The IRB can give permission for researchers to use and share identifiable health information without contacting you, but only if it determines that sharing the data will not be more than minimal risk to you or your privacy. The IRB is a committee of doctors and scientists and nonscientists, including people not associated with this hospital or medical school, whose job it is to protect people who participate in research.

**(5)** Do you give permission to have your data given **to other researchers, including those at Mount Sinai, other medical or scientific institutions and for-profit companies, for use in research within the limits you have chosen above?**

Please initial your choice: Yes_____No_____

## YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for the following things:
1. Complete the study assessments (e.g., clinical interviews, mental health symptom assessments and the fMRI scans) at the proper study visits.
2. Complete the GAMBIT task remotely 3 times a week for 6 weeks on your home computer



3. Complete the Go/No-Go, IFT, and Hariri tasks at the two in-person site visits (Visits 1 and 4) during the fMRI scan.
4. Complete the combined Think/No-Think and Go/No-Go task, as well as the Face-Stroop Task at three in-person site visits (Visits 1 and 4).
5. Be stabilized on your current medications for three months before participating in the study, and do not change your current medication or therapy regimen during the study.

## COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

*Being in this research study will not lead to extra costs to you.*

If you agree to take part in this research study, you will be paid for your time and effort, based on the table below.

| **Procedure** | **Payment** |
|---|---|
| ***Visit 0:*** *Screening* | *$25* |
| ***Visit 1:*** *Clinical Interview and Self-Report Forms* | *$45* |
| ***Visit 1:*** *fMRI Scan* | *$75* |
| ***Visit 1****: Study Tasks* | *$25* |
| ***Days 2-44 (6 weeks):*** *GAMBIT Task Sessions* | *$20 per week* |
| ***Bonus Compensation****: 14 of 18 GAMBIT sessions completed by the end of week 6* | *0* |
| ***Visit 2:*** *Clinical Interview and Self-Report Forms* | *$45* |
| ***Visit 3:*** *Clinical Interview and Self-Report Forms* | *$45* |
| ***Visit 4:*** *fMRI Scan* | *$75* |
| ***Visit 4****: Study Tasks* | *$25* |



| | |
|---|---|
| ***Visit 4:*** *Clinical Interview and Self-Report Forms* | *$45* |

*Note, if you complete 80% or more of the at-home GAMBIT sessions, equating to 14 or more of the 18 intended sessions, you will receive bonus compensation of $50 at your Visit 2 assessment*

*You will receive all payments via check after you complete each study visit. If you wish to be reimbursed for travel expenses, please submit the receipts of your travel costs to the research coordinator (shely.khaikin@mssm.edu).*

*Checks require some time to be prepared and will be given to you once processed and available.* ***It can take up to 6 weeks to prepare and give you a check for study participation.*** If you do not get a check by then, you can first contact the research team. If further assistance is needed, please contact Mount Sinai's Program for the Protection of Human Subjects at (212) 824-8200.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this reporting will take place if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

Electronic Medical Record: Because this research study involves the use of fMRI imaging, a note must be included in your electronic medical record (stored in Epic) that you are taking part in this research study. This way, anyone involved in your medical care at Mount Sinai will know that you are a study participant, and they can work to avoid any problems or negative outcomes that could arise if they do not know. Additionally, having a note of this study in your medical record will ensure that you are not erroneously billed for the fMRI scans that are part of this study. If you have accidentally been billed for an fMRI scan, please let the study team know immediately so they work to resolve the error.

## POSSIBLE BENEFITS:



There is a chance this study may benefit you, but this is not guaranteed. Others may benefit from what researchers learn from the study. Others may not benefit either. However, possible benefits may be that you will increase your inhibitory control skills, which many people with PTSD struggle with. Plus, the data collected during this study will provide valuable information about the GAMBIT task and its potential effectiveness with PTSD patients. Since this is a pilot study of the GAMBIT task, there is no guarantee that you will experience any benefits to your inhibitory control skills or your PTSD symptoms during the study or after the study has ended. If the GAMBIT task becomes available for marketing in the future, there is no guarantee that you will be able to access GAMBIT for no cost after completion of the study.

## POSSIBLE RISKS AND DISCOMFORTS:

- The mental health assessments (the interview and the survey), you will be asked about your current mental health symptoms, your mental health history, and your exposure to traumatic events. The questions during the assessment can occasionally cause feelings of discomfort, including embarrassment, anxiety, or shame. You can refuse to answer any questions that are upsetting to you.
- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- The fMRI procedure is very safe and are commonly conducted as part of routine medical treatment. However, there are known risks when completing an fMRI scan. These risks include the physical risk posed by the presence of metal objects, tissue burns, dizziness, physical discomfort, stress, claustrophobia, and fatigue. However, the study team will take steps to ensure your safety while completing the fMRI scan. For instance:
    - The fMRI machine uses a magnetic field to capture images. In order to ensure your safety, you will be asked if you have any metal in or on your body, including implanted metal, jewelry, etc.
    - Since the fMRI machine is loud, the study team will provide you with headphones to protect your hearing.
    - A study team member will be present for all scanning sessions in case of any unexpected complications. In addition, you will remain in verbal contact with a study team member (via intercom) throughout the scan so that you may communicate any problems immediately or express a desire to terminate the scan at any time.
- In addition to these risks, this research may hurt you in ways that are not known. The unknown risks might be minor.
- Privacy Risks - Your name and other information that could directly identify you (such as address, date of birth or social security number) will never be placed into a scientific database. However, because your information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small but may grow in the future.



Potential for Abnormal Medical Findings in fMRI Scans: A limited research report will be sent to a radiologist for all fMRI scans. The scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators for this project may not be trained to perform a medical diagnosis. However, on occasion the investigator may notice a finding on an MRI scan that seems abnormal. When this occurs, a physician will be consulted as to whether the findings warrant further investigation, in which case the investigator will contact your primary care physician to inform them of the finding. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The investigators, the consulting physician, and Mount Sinai are not responsible for any examination or treatment that the participant undertakes based on these findings. Since the images collected in this study may not comprise of a proper clinical fMRI scan, these images will not be made available for diagnostic purposes.

## OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study. If you decide not to take part, this will not affect the clinical care you receive at Mount Sinai. The choice is totally up to you. Instead of being in this research study, your choices may include:

- *Psychotherapy, including cognitive behavioral therapy, with a licensed therapist.*
- *Medication, including (but not limited to) antidepressants, mood stabilizers, antianxiety medications, and alpha-1 blockers, prescribed by your primary care doctor or a psychiatrist.*

*If any of the above alternatives interest you, please consult with your primary care physician, the Principal Investigator (Dr. DePierro), or the Depression and Anxiety Center for more information.*

## IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you believe that being in this research study has harmed you, you should contact the Lead Researcher (Dr. DePierro). Their contact information is listed at the beginning of this consent form.

This does not prevent you from seeking payment for injury related to malpractice or negligence. You can contact the Lead Researcher for more information.

## ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted.

If you decide to stop being in the study, please contact the Lead Researcher (Dr. DePierro) or the research staff.



You may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you decide you don't want your data and/or samples to be used for research anymore, you can contact the researcher and ask to have your data and/or samples withdrawn or labeled so that they will not to be used in additional projects or shared. If your data and/or samples have already been shared with researchers, those researchers will be asked to stop using them. However, if any data and/or samples have already been shared without your identity or a linking code, it won't be possible to retrieve them. Data and/or samples that have already been used will not be affected by your decision. If your data and/or samples have already been deposited in an external repository, the study team will request that your data and/or samples be removed.

Withdrawal without your consent: The Lead Researcher, the funder or Mount Sinai may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent.

## CONTACT INFORMATION:

If you have any questions, concerns or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher at phone number

- Dr. Jonathan DePierro (PI): 646-877-5885; jonathan.depierro@mssm.edu.
- Dr. Laurel Morris (Co-PI): 212-241-2774; laurel.morris@mssm.edu

If there is an emergency, please call 911 or go to the emergency room. Let the emergency room staff know you are in a research study so they can contact the Lead Researcher if needed.

## DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.



The research team has no financial conflicts of interest to disclose relevant to this study.

## MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?

As part of this study, the research team at the hospital(s) involved in the research will collect your name, address, telephone number, birthdate, and e-mail address.

During the study, the researchers will gather information by:

- Reviewing and/or taking your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.

Why is your PHI being used?
Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.



The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers at Mount Sinai who are involved in your care or treatment. The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example:

- The Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants and may need to see your information.
- If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai, might receive your PHI?

As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).
- A Data Safety Monitor (Dr. DePierro) that will monitor the study on an ongoing basis for safety.

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Lead Researcher will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB**,** *OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access.* The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose your PHI?



Your authorization for use of your PHI for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will have access to your medical record and any study information that is part of that record. The research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?
NO! If you decide not to let the research team obtain, use or share your PHI, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment, or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
If you decide to stop being in the study, please contact the Lead Researcher or the research staff. The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your PHI.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

**Notice Concerning HIV-Related Information**
If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted



to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 416-0197. These agencies are responsible for protecting your rights.

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## How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.



## ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

| _____ | _____ | _____ | _____ |
|---|---|---|---|
| Signature of Participant | Printed Name of Participant | Date | Time |

## PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

| _____ | _____ | _____ | _____ |
|---|---|---|---|
| Signature of Consent Delegate | Printed Name of Consent Delegate | Date | Time |

## *WITNESS SECTION:*

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

| _____ | _____ | _____ | _____ |
|---|---|---|---|
| Signature of Witness | Printed Name of Witness | Date | Time |