Title: Dopaminergic Therapy for Inflammation-Related Anhedonia in Depression

NCT#: NCT04723147

Date: 04/28/2022

Participant Consent

MOD0020-STUDY00000361
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EMORY UNIVERSITY | Institutional Review Board
Research Administration

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 35 people who are being studied at Emory.

Why is this study being done?

This study is being done to answer the question: What is the best dose of an FDA-approved medication, Sinemet (also called L-DOPA), that might be used in the future to treat depressed individuals who have high levels of inflammation and low motivation (anhedonia).

You are being asked to be in this research study because you have the above symptoms of depression (anhedonia or low motivation) and elevated inflammation according to your blood sample.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for a minimum of 8 study visits. The researchers will ask you to do the following: Complete an EKG, physical and psychiatric evaluations, MRI scans and provide blood samples. You will also complete self-report forms intended to measure symptoms pertaining to your mental health and do computerized tests that measure your level of motivation. ALL of these procedures will be paid for by the study.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question: What is the best dose to test the effectiveness of an FDA approved combination medication, Sinemet (L-DOPA), for the treatment of patients with depression, high inflammation and anhedonia?

What are the risks or discomforts I should know about before making a decision?

The study will take time. This study is not intended to treat your depression, and the FDA-approved drug may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include

potential adverse reactions to the FDA-approved study medication, loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study

If you decide not to enter this study, there is care available to you outside of this research study. The study clinician will discuss these options with you. You do not have to be in this study to be treated for depression.

Costs

You WILL NOT have to pay for any of the study procedures.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Take time to consider this, and talk about it with your family and friends.

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Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: **Dopaminergic Therapy for Inflammation-Related Anhedonia in Depression**

Principal Investigator: Jennifer C. Felger, PhD

Sponsor: National Institute of Mental Health (NIMH)

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

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.

What is the purpose of this study?
The purpose of this study is to explore new treatment options for people with depression and high inflammation, a process of immune system activation, and anhedonia or low motivation. This study will help determine the best dose of an FDA-approved medication, Sinemet (also called L-DOPA), that might be used in the future to treat sub-groups of depressed individuals.

Thirty-five male and female participants with depression, between the ages of 25-55 years of age, will be randomized to two study tracks (A and B) to receive both placebo and three doses of L-DOPA, given in different orders. Neither you nor the study team will know which track you are assigned to or in which order you receive the three doses of L-DOPA. Increases or decreases in each dose will occur gradually over 6 weeks of the study. Your participation, should you decide to enter the study, will last about 2 months, including your screening visit(s).

Medications to Avoid:
You will be excluded from the study if you take any of the following medications on a regular basis or if they are prescribed by a physician: psychiatric medication (for example: antidepressants, mood stabilizers, etc.) aspirin or aspirin-like compounds, ibuprofen or naproxen (for example: Advil, Aleve, Motrin IB), antibiotics, topical steroids (i.e. hydrocortisone), herbal medications and omega-3 supplements. Please contact us before starting any new medication

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that your doctor prescribes while you are participating in the study. Please also contact us if you plan on starting any new over-the-counter medications between study visits. Please do not stop taking any prescribed medications. If you take the above medications on an as-needed (prn) basis, we will determine your eligibility to participate in the study based on frequency and necessity of intake and may need to discuss this with the prescribing physician before arriving at this decision

Although it is recommended that you do not drink alcoholic beverages during your participation in the study, you may drink alcohol on occasion (at most 1 glass of wine or equivalent per day). Use of illegal drugs during your participation in the study is not allowed and you will be drug-tested for illegal drugs as part of this study.

If the study doctor (Dr. Miller or his designee) determines that your depression has gotten worse at any time during the study, you may be discontinued from the study. When you have completed or been discontinued from the study, the study doctor will discuss how to best continue your treatment for depression. In addition, the study team will try to find a physician for follow up care if you do not have one.

During this study you will interact with study doctors, research clinicians and nurses who have experience in administering antidepressant medications. You will also interact with a research coordinator and other staff who will help arrange your schedule during the study.

Disclosure

Dr. Treadway is a co-inventor of the EEfRT task software, which is used in this study. Emory University and Vanderbilt University licensed this software to BlackThorn Therapeutics. Under the IP Policies of both universities, Dr. Treadway receives licensing fees and royalties from BlackThorn Therapeutics. Additionally, Dr. Treadway has a paid consulting relationship with BlackThorn. The terms of this arrangement have been reviewed and approved by Emory University in accordance with its conflict of interest policies.

What will I be asked to do?

Before you can participate in this study, you will need to complete some virtual assessments by ZOOM, a video service approved by Emory University for patient communications. You will also come in for screening visits on campus to see if you are eligible to enter the study. You are required to wear a mask during the COVID pandemic while on Emory Campus. You will be asked questions, in advance of your appointment and again at Emory University, about whether you are experiencing symptoms suggestive of an infection. You will also have your temperature checked at each visit. If you show signs of an infection, we will cancel your appointment and discuss options for your care. Please alert the study team if you have been exposed to or in quarantine with someone exposed to the COVID virus. The investigator and/or the investigator's staff will ask you questions and run tests that are described below to determine if you are eligible to enter the study. It is important that you answer all of the questions honestly and completely. If your condition or circumstances change during the study, you must tell the investigative team.

If you are currently doing well on antidepressant medication, you will not be eligible to participate in this study. It would not be in your best interest to discontinue medication that is helping you. On the other hand, you may enter this study if you are not currently taking an antidepressant, mood stabilizer or any other psychotropic medication.

If you plan to take any medication or undergo any medical treatment other than taking the study medication given to you, please notify the study team before starting the medication or treatment. This includes medications given to you or recommended by any other doctor, and over-the-counter drugs such as cough treatments, cold treatments, pain medications such as aspirin or ibuprofen, investigational drugs/procedures and sleeping medications (as decribed above in **Medications to Avoid**). If elective surgery or a diagnostic procedure is planned, you must notify us before the procedure is performed.

If you agree to participate, this is what will happen during the study. If you qualify, **the study visits will be spread across ~ 6 weeks**. During this time, you will be asked to take study medication every day. You will begin taking either Sinemet or placebo first, depending on the randomization schedule. Throughout the study, you will take 3 pills a day (morning, noon and afternoon/evening) regardless of whether you are taking Sinemet or placebo.

Table 1. Schedule of Study Procedures and Assessments.

Procedure	Intake Visit(s)	Screen A*	Screen B*	Extra screen (if needed)	Baseline (V1)	Week 1 (V2)	Week 2 (V3)	Week 3 (V4)	Week 4 (V5)	Week 5 (V6)	Week 6 (V7)
Consent**	X										
Self-report forms	X	X	X	[X]	X	X	X	X	X	X	X
Psychiatric assessments	X	[X]	[X]	[X]	X	X	X	X	X	X	X
Vital signs and height and weight		X	X	[X]	X	X	[X]	X	X	[X]	X
Screening labs (rapid CRP finger prick, blood draw, EKG, and urinalysis)		X	[X]	[X]	[X]						
Physical exam			X	[X]							
Urine drug screen		X	[X]	[X]	X	X	[X]	X	X	[X]	X
Urine pregnancy test (if applicable)			[X]	[X]	X	X	[X]	X	X	[X]	X
MRI scan					X	X		X	X		X
Study medication dispensed					X	X	X	X	X	X	X
Computerized and paper tasks (outside scanner)			X	[X]	X	X		X	X		X
Fasting research blood draw			X	[X]							
Non-fasting research blood draw				[X]	X	X		X	X		X
Adverse events	X	X	X	[X]	X	X	X	X	X	X	X

[X]- To be completed if needed
*May be completed within one day if necessary
**- If our consent form is updated you will be notified of any applicable changes. You will be asked to sign the newest version of our consent form.

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Types of Assessments will include:

a. Psychiatric assessments
b. Self-report forms (to assess severity of depression and history of trauma)
c. Motivation and neurocognitive testing
d. Medical history and physical exam
e. Blood sampling
f. MRI scans-completed on 5 of your visits

Intake: As part of the initial screening for this study, you will participate in a virtual pre-screen interview that will take approximately 1-2 hours. This pre-screen will occur online using a virtual conferencing system called ZOOM that is approved by Emory University for patient communication. This interview may also occur by phone if necessary. Once you sign the consent form either virtually or in-person, a study clinician will ask you about your mental health and any medical conditions.

You will then be scheduled for further screening visits, including in-person visits to Emory University as described below.

Screening: Participation in this study requires screening visits at which time your eligibility will be reviewed and verified. The screening process is divided into two visits (**Screen A** and **Screen B**), which will take approximately 2-3 hours each visit. The assessments for both visits may be completed in one day if necessary. A portion of the screening interviews may also be conducted virtually on ZOOM, as described above for the intake pre-screen visit.

Screening visits that will occur at the Emory Behavioral Immunology Program on the 4thh Floor of the Woodruff Memorial Research Building, located at 101 Woodruff Circle. At these visits, you may be asked to have one or two drops of blood collected by a trained research staff from a finger prick to measure C-reactive protein (CRP), a marker of inflammation. If your inflammation level is high (CRP>1.5 mg/L), approximately 5 teaspoons of your blood will be drawn to check for any abnormalities that would disqualify you for study participation. This includes testing for the human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV). You will be excluded from the study and referred to your primary care physician should you test positive for any of these viruses. If your inflammation levels are low, you will not qualify for the study.

Your blood will also be evaluated by Emory Medical Labs for CRP and other tests to assess your general medical status including tests to assess your blood, kidney, thyroid and liver status. You will also receive a pregnancy test if you are a female. You will be disqualified from the study if you are pregnant. If you are a woman of childbearing age, we will ask you for documentation of adequate birth control during the study period. The study doctor or a nurse practitioner will also conduct a physical examination. You are strongly encouraged to ask the study doctor or a member of the study staff if you have questions about the results of your lab tests and other diagnostic procedures. During these screening visits you will also provide about 5 tablespoons of blood while you have been fasting. You will be asked not to eat or drink anything but water after midnight the night before your visit, planning for blood to be drawn first thing in the morning. This blood will be used to look at levels of your inflammation and markers of metabolism in your blood and immune cells. You will also practice the neurocognitive and motivation tasks that that you will complete during the study.

If you qualify for the study and choose to enroll you will participate in at least 9 visits (including the screening visits) across ~ 8 weeks. All study visits will take place either at Woodruff memorial Research Building or the Atlanta Clinical Translational Science Institute (ACTSI) outpatient research unit in the Emory University Hospital on the main Emory campus. At all visits you will fill out several self-report questionnaires that will ask about depressive symptoms and about the quality of your life. At screening and each visit, you will be asked to supply approximately 4 tablespoons of urine in a special cup that will test for the presence of drugs of abuse, such as marijuana, cocaine or heroin. A positive test for any of these drugs at screening will prevent you from participating in the study. A positive test at any other visits may be a reason for withdrawing you from this study.

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Vital signs, including pulse and blood pressure will be measured at every visit. Height, weight and waist circumference will be measured at screening. You may be asked to come in for additional screening visits to repeat any lab work or assessments.

Study Visit Descriptions

Visit 1 (Baseline) (Duration approximately 4 hours)
You will arrive to Emory Woodruff Memorial Research Building in the morning of your visit. You will be called within 72 hours of your appointment and given instructions about anything to avoid eating or drinking and for how long depending on the time of your appointment. You will be asked to give a urine sample in order to test for any signs of drugs of abuse and a pregnancy test if you are female. You will have your vital signs checked.

You will then be escorted to the scan room where you will undergo MRI scan for about 1 hour (1 hour and 15 min maximum). The MRI scan is being done to identify brain changes resulting from high inflammation in the body. You will be walked by study staff to the BITC neuroimaging center and you will sit in a waiting area until the MRI technician and study team are ready to escort you into the room where the MRI scanner is located. This scanner uses a very strong magnet to take pictures of your brain.

MRI scans are painless and contain no radiation. You will be asked to remove all jewelry and other metal-containing objects. You will then be placed on a narrow table, which will slide into the MRI scanner. The scanner is a large closed box with a tube in the middle. You will lie in the tube while the scan is being done. The tube is about 6 feet long and 25 inches wide. You will then be asked to lie still during the scan for about 60 minutes. You may be asked at some times during the scan to lay with your eyes open, to complete tasks that you have practiced outside of the scanner using a response button, or to rest with your eyes closed. During this first scan only, you may be asked to view a series of human faces showing a range of expressions and emotions. As part of the scanning process, you will be fit with a head coil, which resembles a larger frame football helmet for the entire duration of the scanning period. You will be able to communicate with the scanning personnel using a microphone and speaker in the scanner bore. You will hear some loud noises as the scanner takes pictures of your head. You will be offered earplugs to wear while you are being scanned to decrease how loud the noise seems to you. Occasionally, people have an extreme fear reaction (claustrophobia) to being in the scanner. If this occurs, you will be removed from the scanner and the experiment will be stopped. After the scan you may eat and drink snacks and drinks provided by the study investigative team.

After the scan you will then return to the research clinic. You will have about 5 tablespoons of blood collected, then you will have a ~ 15-minute break and you will be given a snack. You will then complete a computerized test that measures your level of motivation. On this test, you will have the opportunity to earn additional payment based on your choices and performance. You will receive this payment by Clincard (see below). This test will take about ~15 minutes. You will also complete additional computer or pen and paper neurocognitive tests that will take 20-30 minutes. After this you will be given another snack. You will be asked questions about how you are feeling to measure the current level of emotional distress and other symptoms pertaining to mental health. You will complete self-report behavioral assessments. These evaluations will take about 30-40 minutes.

As part of Visit 1, you also will be given placebo or L-DOPA in a blister pack. Whether you start with L-DOPA or placebo will be random like the flip of a coin. The pills will look the same, so you and the study staff will not know which medication you have received. You will be told how to take the medication and when and what side effects to expect. Your total time commitment for this visit will be approximately 3-4 hours with breaks.

Visit 2 (Week 1) (Duration approximately 3-4 hours)
This visit will be very similar to the Baseline visit the week before. You will arrive to Emory Woodruff Memorial Research Building in the morning of your visit. You will be called within 72 hours of your appointment and given instructions about when to take your medicine and anything to avoid eating or drinking and for how long depending on the time of your appointment. Any side effects that you may have experienced from the medication will also be discussed. Upon arrival

at your visit, you may be asked take the first dose of your medication for the day along with a snack and drink provided by the study investigative team. You will be asked to give a urine sample in order to test for any signs of drugs of abuse. You will have your vital signs checked along with an inspection of your medication container. Any pills that you have not taken will be counted. You will be asked about any adverse events or potential side effects.

You will then be escorted to the scan room where you will undergo MRI scan for ~45 minutes (1-hour maximum). The MRI scan will take place in the same building as before and will be performed just like your first MRI scan. After the scan you will then return to the research clinic. You will have about 5 tablespoons of blood collected, will have a ~ 15-minute break and be given a snack. You may also be asked to take the next dose of your medication, depending on the time of your visit. You will then complete a computerized test that measures your level of motivation. On this test, you will have the opportunity to earn additional payment based on your choices and performance. You will receive this payment by Clincard (see below). This test will take about ~15 minutes. You will also complete additional computer or pen and paper neurocognitive tests that will take 20-30 minutes. After this you will be given another snack. You will be asked questions about how you are feeling to measure the current level of emotional distress and other symptoms pertaining to mental health. You will complete self-report behavioral assessments. These evaluations will take about 30-40 minutes. At the end of your visit, if you are tolerating your study medication without significant side effects, you will be given a new medication packet.

Visit 3 (Week 2) (Duration approximately 30 min to 1 hour)
Just like Baseline and Week 1 visit, you will arrive at the Emory Behavioral Immunology Program in the Woodruff Memorial Research Building. You will have your vital signs checked along with an inspection of your medication container. Any pills that you have not taken will be counted. You will be asked questions about how you are feeling and fill out questionnaires intended to measure the current level of emotional distress and other symptoms pertaining to your mental health. At this visit, if you are tolerating your study medication without significant side effects, you will be given a new medication packet. If the event that you are unable to attend this visit in person, your visit will occur virtually and we will arrange for you to receive your medication by an alternate method, for example by mail.

Visit 4 (Week 3) (Duration 3-4 hours)
This visit will be very similar to the Baseline and Week 1 visits before. You will arrive to Emory Woodruff Memorial Research Building in the morning of your visit. You will be called within 72 hours of your appointment and given instructions about when to take your medicine and anything to avoid eating or drinking and for how long depending on the time of your appointment. Any side effects that you may have experienced from the medication will also be discussed. Upon arrival at your visit, you may be asked take the first dose of your medication for the day along with a snack and drink provided by the study investigative team. You will be asked to give a urine sample in order to test for any signs of drugs of abuse. You will have your vital signs checked along with an inspection of your medication container. Any pills that you have not taken will be counted. You will be asked about any adverse events or potential side effects.

You will then be escorted to the scan room where you will undergo MRI scan for ~45 minutes (1-hour maximum). The MRI scan will take place in the same building as before and will be performed just like your first MRI scan. After the scan you will then return to the research clinic. You will have about 5 tablespoons of blood collected, will have a ~ 15-minute break and you will be given a snack. You may also be asked to take the next dose of your medication, depending on the time of your visit. You will then complete a computerized test that measures your level of motivation. On this test, you will have the opportunity to earn additional payment based on your choices and performance. You will receive this payment by Clincard (see below). This test will take about ~15 minutes. You will also complete additional computer or pen and paper neurocognitive tests that will take 20-30 minutes. After this, you will be given another snack. You will be asked questions about how you are feeling to measure the current level of emotional distress and other symptoms pertaining to mental health. You will complete self-report behavioral assessments. These evaluations will take about 30-40 minutes. At the end of your visit, if you are tolerating your study medication without significant side effects, you will be given a new medication packet.

Visit 5 (Week 4) (Duration 3-4 hours)
This visit will be very similar to the Baseline and Week 1 and 3 visits before. You will arrive to Emory Woodruff Memorial Research Building in the morning of your visit. You will be called within 72 hours of your appointment and given instructions about when to take your medicine and anything to avoid eating or drinking and for how long depending on the time of your appointment. Any side effects that you may have experienced from the medication will also be discussed. Upon arrival at your visit, you may be asked take the first dose of your medication for the day along with a snack and drink provided by the study investigative team. At your visit, you will be asked to give a urine sample in order to test for any signs of drugs of abuse. You will have your vital signs checked along with an inspection of your medication container. Any pills that you have not taken will be counted. You will be asked about any adverse events or potential side effects.

You will then be escorted to the scan room where you will undergo MRI scan for ~45 minutes (1-hour maximum). The MRI scan will take place in the same building as before and will be performed just like your first MRI scan. After the scan you will then return to the research clinic. You will have about 5 tablespoons of blood collected, you will have a ~ 15-minute break and you will be given a snack. You may also be asked to take the next dose of your medication, depending on the time of your visit. You will then complete a computerized test that measures your level of motivation. On this test, you will have the opportunity to earn additional payment based on your choices and performance. You will receive this payment by Clincard (see below). This test will take about ~15 minutes. You will also complete additional computer or pen and paper neurocognitive tests that will take 20-30 minutes. After this you will be given another snack. You will be asked questions about how you are feeling to measure the current level of emotional distress and other symptoms pertaining to mental health. You will complete self-report behavioral assessments. These evaluations will take about 30-40 minutes. At the end of your visit, if you are tolerating your study medication without significant side effects, you will be given a new medication packet.

Visit 6 (Week 5): (duration 1-2 hours)
Just like Baseline and Week 1 visit, you will arrive at the Emory Behavioral Immunology Program in the Woodruff Memorial Research Building. You will have your vital signs checked along with an inspection of your medication container. Any pills that you have not taken will be counted. You will be asked questions about how you are feeling and fill out questionnaires intended to measure the current level of emotional distress and other symptoms pertaining to your mental health. At this visit, if you are tolerating your study medication without significant side effects, you will be given a new medication packet. If the event that you are unable to attend this visit in person, your visit will occur virtually and we will arrange for you to receive your medication by an alternate method, for example by mail.

Visit 7 (Week 6) (Duration approximately 3-4 hours)
This visit will be very similar to the Baseline and Week 1 and 3 visits before. You will arrive to Emory Woodruff Memorial Research Building in the morning of your visit. You will be called within 72 hours of your appointment and given instructions about when to take your medicine and anything to avoid eating or drinking and for how long depending on the time of your appointment. Any side effects that you may have experienced from the medication will also be discussed. Upon arrival at your visit, you may be asked take the first dose of your medication for the day along with a snack and drink provided by the study investigative team. You will be asked to give a urine sample in order to test for any signs of drugs of abuse. You will have your vital signs checked along with an inspection of your medication container. Any pills that you have not taken will be counted. You will be asked about any adverse events or potential side effects.

You will then be escorted to the scan room where you will undergo MRI scan for ~45 minutes (1-hour maximum). The MRI scan will take place in the same building as before and will be performed just like your first MRI scan. After the scan you will then return to the research clinic. You will have about 5 tablespoons of blood collected, have a ~ 15-minute break and you will be given a snack. You may also be asked to take the next dose of your medication, depending on the time of your visit. You will then complete a computerized test that measures your level of motivation. On this test, you will have the opportunity to earn additional payment based on your choices and performance. You will receive this payment by Clincard (see below). This test will take about ~15 minutes. You will also complete additional

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computer or pen and paper neurocognitive tests that will take 20-30 minutes. After this you will be given another snack. You will be asked questions about how you are feeling to measure the current level of emotional distress and other symptoms pertaining to mental health. You will complete self-report behavioral assessments. These evaluations will take about 30-40 minutes.

How will my medicine be provided?
The medicine that you will take will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on his/her research team will provide the medicine to you. If you have questions about the medicine, you should ask the study doctor or study nurse. You may also call the pharmacy at (404) 712-4718 if you have questions about the medicine. The number for the pharmacy is included on your medicine package.

Who owns my study information and samples?
If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that we already collected may be still be used for this study.

Storage of Specimens for Future Research*:*
De-identified plasma samples, immune cells and Tempus tubes for mRNA collected in this study. Samples will be analyzed by the PI and the Laboratory Research Associate or other laboratory personnel that are approved on this protocol, or sent to core laboratories within Emory University for analysis (i.e. the Genomics Core lab, Biomarker Core Laboratory). Samples will remain stored indefinitely to allow completion of all planned or future analyses. By storing samples for future analyses, we can do research for a long time without needing to ask for fresh samples from new patients.

What are the possible risks and discomforts?
There may be side effects from the study drug or procedures that are not known at this time. The most common and less common risks and discomforts expected in this study are:

Study Medication:
The **most common risks and discomforts** expected from the study medication, Sinemet (L-DOPA), include:

- nausea (involving occasional, mild vomiting), dizziness/lightheadedness and mild headache that responds to Tylenol. At least one of these common discomforts occurs in up to ~30% of individuals the first time they take the medication. These symptoms normally decrease over time of taking L-DOPA, and can occur in less than 10% of individuals after several days to two weeks of use.
- **Other transient and mild side effects** that may occur following administration of the doses used in this study include: increased sleepiness or trouble sleeping, increased eye blinking/twitching, fainting, and mental/mood changes.
- **Rare but possible risks (less than 1% for most symptoms) include:** easy bleeding/bruising, signs of infection (e.g., fever, persistent sore throat), tingling of the hands/feet, vision changes (e.g., blurred/double vision), chest pain, seizures, vomit that looks like coffee grounds, black/tarry stools, unusual muscle stiffness, severe confusion, sweating, fast/irregular heartbeat, rapid breath or trouble breathing, painful or prolonged erection in males, rash, itching/swelling (especially of the face/tongue/throat), and severe dizziness.
- **In patients with Parkinson's Disease,** L-DOPA can cause worsening of involuntary movements/spasms. These symptoms may be specific to this illness. In a recent study using the same doses of L-DOPA to be used in this study given to aged persons with depression, 0% of individuals experienced involuntary movements.

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- **To reduce the risks associated with the study medication, you will be monitored carefully for the any adverse events as well as for worsening of your depression. If you are not able to tolerate dose increases from one week to the next, you will be provided 3 days of pills to take to taper off of the study medication.**

Blood Draws: Collecting blood from a vein in someone's arm is a standard medical procedure, although sometimes there may be some minor pain or bruising. Fainting and infection at the site of the blood draw are also known risks. Up to ~2.5% of individuals are at risk of fainting during blood draw, but no participants in our previous studies have experienced infection at the site of blood draw. Because we will be looking at biochemical information in your blood, there may also be other risks that we currently don't recognize or expect. Results that are considered important for your safety such as signs of infection, changes in blood glucose or electrolyte concentrations will be provided to you or your primary care provider, after obtaining a consent from you by obtaining your signature on the form for release of information. The research information that is learned from studies of your samples may be used scientifically and may be used by the sponsor in other research. The results of the analysis of your samples WILL NOT be made available to you or to your referring health care professional. A research lab, not by an Emory Healthcare lab, will do the testing. Some samples may be sent to other labs for additional analysis. The results of the biochemical analysis will not be recorded in your medical record, nor will they be provided to third parties. As for the blood drawing, standard sterile procedure for blood withdrawal will be used. In addition, the volume of blood withdrawn for this study will not exceed 300 ml (about 20 tablespoons).

Psychiatric Assessments: The psychiatric assessments may involve detailed questioning regarding memories or feelings. Discussing mental symptoms may bring up emotions that distress some people. To minimize this, you will be able to discuss any disturbing memories or feelings you may experience with the study staff. Research personnel will be careful not to cause psychological distress during any part of the psychiatric assessment. There is a possible social risk involved if sensitive information related to previous mental health treatment is accidentally released. To guard against this risk, we will use a number and not your name to identify personal information included in the database. All documents will be kept in a locked area, and only the researchers will have a key. The study has been designated as sensitivity study and the information will not be included in your regular Emory Healthcare Chart.

Computer Testing: There are no known risks for the tests of your motivation.

MRI: The MRI scanner contains a very strong magnet. Therefore, you may not be able to have the MRI if you have any type of metal implanted in your body, for example, any pacing device (such as a heart pacer), any metal in your eyes, or certain types of heart valves or brain aneurysm clips. Metallic objects implanted in the body may move or heat due to force from the magnet in the scanner. Therefore, someone will ask you questions and carefully screen you for any type of metal objects in your body prior to receiving the MRI scan. If you have metal objects/implants in your body that are considered risky by Federal Government MRI safety guidelines, you will not receive the scan. If you are a woman of childbearing potential, there may be unknown risks to the fetus. Therefore, you will not be allowed to participate in the study if you are pregnant. Because the MRI is performed in an enclosed narrow space, some people may experience extreme fear, shortness of breath, rapid heartbeat or claustrophobia. This occurred in ~3-4% of patients in our most recent study. If this happens to you, you may ask to stop the scan immediately. No other known risks are associated with receiving the MRI scan.

Incidental Finding-MRI Scan

You will be getting a scan for research purposes only. The research does not require health professionals to read the scan. The researchers are not qualified to interpret the images for healthcare purposes. Do not rely on the scan for clinical or diagnostic purposes. However, if the researchers have a question about something they see on the scan they will tell you, and ask you if you want the scan sent to a qualified health professional for review and any further medical treatment. You or your insurance company may have to pay for the review and any such treatment.

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Risks with Pregnancy

If you are a woman: The study medication may involve currently unforeseeable risks to pregnant women, the embryo or fetus, or to children of nursing women. If you are a woman who is pregnant, breast feeding, or planning to become pregnant within the period of the study, you must not participate in the study. In addition, all women of childbearing potential are required to undergo pregnancy testing before entering the study. A woman of childbearing potential is defined as one who is biologically capable of becoming pregnant.

All women of child bearing potential must use a medically acceptable contraceptive throughout the study. This includes oral (birth control pills), double-barrier method, injectable or implantable, or mechanical contraception; women whose sexual partners have had a vasectomy or have received or are using mechanical contraceptive devices. Condoms plus spermicide should be used in addition to other contraceptive methods to provide protection against sexually transmitted diseases and to provide additional protection against pregnancy.

If you miss a period or think you might be pregnant during the study, you must notify the investigator immediately so that you can be withdrawn from the study.

For women of childbearing potential, if you (a) plan to become pregnant, (b) become pregnant, (c) think you may have become pregnant, or (d) plan to discontinue contraception, you are required to notify the study doctor immediately.

If you will be taking the study drug home, keep it out of the reach of children or anyone else who may not be able to read or understand the label. Do not let anyone else take the study drug besides you.

If you are a man: Men who are participating in this research study need to understand the possible danger of taking a drug whose effects on the fetus are unknown. You and the study doctor should agree on a method of birth control to use throughout the study.

If you will be taking the study drug home, keep it out of the reach of children or anyone else who may not be able to read or understand the label. Do not let anyone else take the study drug besides you.

The study medication taken in this study may also have unknown risks.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. Your depression may improve while you are in this study but it may not, and it may even get worse. This study is designed to learn more about novel treatment strategies for individuals with depression with high inflammation and anhedonia. The direct benefits of study participation will include receiving a psychiatric and medical evaluation, including standard blood and urine-based laboratory tests. If you participate you will also have the chance to contribute to a scientific investigation, which may be of benefit to future patients.

Will I be compensated for my time and effort?

Our preferred method of compensation will be the use of Clincards. All payments are made using a personal payment card. We issue this to you for free. The payment card is a prepaid debit card. It can be used exactly like a MasterCard. We load money onto your card electronically every time you need to be paid. The card scheme is run by Greenphire, an independent company specializing in payments for research studies and clinical trials. To issue your card, we need to

give Greenphire some of your personal information. Banks and other financial institutions can access this information if they need to verify your identity when you use your card.

Emory University is required by law to report any payments we make to the IRS. Research payments in cash or cash equivalents that exceed $600.00 per calendar year must be reported to the Internal Revenue Service (IRS) by the University. The level of reimbursement for this study is at a level that the potential exists for the federal tax reporting to the IRS for your participation in this study. To do this, Emory University Department of Finance needs to keep your Social Security Number on file. We are asking you to allow us to communicate your name, address, date of birth, research study name and Social Security Number to Greenphire and Emory University Department of Finance. If you want to receive e-mail or text alerts when payments are made to you, we will ask you to provide your e-mail or phone number as well. All of this information will be stored on computers owned by Greenphire. Greenphire will not have access to any other information collected during this study. Full instructions about using your card are included when we issue it. Please ask if you have any questions or concerns about the card scheme. You can decline payment if you are concerned about confidentiality.

Each of your visits will be prorated according to the table below. An additional $25 will be provided to cover travel expenses for participants that travel equal to or greater than 30 miles one way to Atlanta. Please let us know if you have any questions regarding the compensation schedule.

Table 2: Compensation Schedule

Visit	Total Amount	Amount put on Clincard immediately after visit	Amount put on Clincard at the end of study participation
Intake (phone or virtual)	**No payment**	**No payment**	
(Visit Total)	**n/a**		
Screen A			
Rapid CRP, Vitals and BMI, MRI Safety Questionnaire, Urine Toxicology, Screening Labs (including serum pregnancy test if applicable), EKG, SCID and Clinician Assessments (may be done virtually or as part of intake)	$50	$50	
(Visit Total)	**$50**	**$50**	
Screen B			
Physical Exam, CRP, Fasting Blood, Report Forms, Practice Computer and Paper Tasks	$50	$50	
Practice Computer Motivation Task In and Out of Scanner (depending on choices made in task)	$5-$10	$5-$10	
(Visit Total)	**$55-60**	**$55-60**	
Visit 1 (Baseline)			
Medical and Psychiatric Update, Urine Toxicology	$50	$50	

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and Pregnancy Screens, Self-report Surveys and Tasks, Research Bloods, and Dispense Medication			
Complete Scan (~1 hr)	$100		$100
Incomplete Scan	$25**	$25**	
Computer Motivation Task in Scanner (depending on choices made in task)	$0-$20	$0-$20	
Computer Motivation Task Out of Scanner (depending on choices made in task)	$5-$10	$5-$10	
(Visit Total)	**$25-$180**	**$25-$80**	**$0-$100**
Visit 2 (Week 1)			
Medical and Psychiatric Update, Urine Toxicology and Pregnancy Screens, Self-report Surveys and Tasks, Research Bloods, Medication Check and Continue Medication (as tolerated)	$50	$50	
Complete Scan	$100		$100
Incomplete Scan	$25**	$25**	
Computer Motivation Task in Scanner (depending on choices made in task)	$0-$20	$0-$20	
Computer Motivation Task Out of Scanner (depending on choices made in task)	$5-$10	$5-$10	
(Visit Total)	**$25-$180**	**$25-$80**	**$0-$100**
Visit 3 (Week 2)			
Medical and Psychiatric Update, Urine Toxicology and Pregnancy Screens (in-person only), Self-report Surveys, Medication Check and Continue Medication (as tolerated)	$50	$50	
(Visit Total)	**$50**	**$50**	
Week 4 (Week 3)			
Medical and Psychiatric Update, Urine Toxicology and Pregnancy Screens, Self-report Surveys and Tasks, Research Bloods, Medication Check and Continue Medication (as tolerated)	$50	$50	
Complete Scan (~45 min)	$100		$100
Incomplete Scan	$25**	$25**	
Computer Motivation Task in Scanner (depending on choices made in task)	$0-$20	$0-$20	
Computer Motivation Task Out of Scanner (depending	$5-$10	$5-$10	

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on choices made in task)			
(Visit Total)	**$25-$180**	**$25-$80**	**$0-$100**
Visit 5 (Week 4)			
Medical and Psychiatric Update, Urine Toxicology and Pregnancy Screens, Self-report Surveys and Tasks, Research Bloods, Medication Check and Continue Medication (as tolerated)	$50	$50	
Complete Scan (~45 min)	$100		$100
Incomplete Scan	$25**	$25**	
Computer Motivation Task in Scanner (depending on choices made in task)	$0-$20	$0-$20	
Computer Motivation Task Out of Scanner (depending on choices made in task)	$5-$10	$5-$10	
(Visit Total)	**$25-$180**	**$25-$80**	**$0-$100**
Visit 6 (Week 5)			
Medical and Psychiatric Update, Urine Toxicology and Pregnancy Screens (in-person only), Self-report Surveys and Tasks, Medication Check and Continue Medication (as tolerated)	$50	$50	
(Visit Total)	**$50**	**$50**	
Visit 7 (Week 6)			
Medical and Psychiatric Update, Urine Toxicology and Pregnancy Screens, Self-report Surveys and Tasks, Research Bloods, Medication Check	$50	$50	
Complete Scan (~45 min)	$100		$100
Incomplete Scan	$25**	$25**	
Computer Motivation Task in Scanner (depending on choices made in task)	$0-$20	$0-$20	
Computer Motivation Task Out of Scanner (depending on choices made in task)	$5-$10	$5-$10	
(Visit Total)	**$25-$180**	**$25-$80**	**$0-$100**
Completed Study Compensation	**$980-$1110**		

*= If you are unable to complete the scan, you will not be able to participate in the rest of the study

What are my other options?

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If you decide not to enter this study, there is care available to you outside of this research study. The study doctor and/or clinicians will discuss these options with you should you have questions. You do not have to be in this study to be treated for depression. If you do not have insurance, or your insurance does not cover mental health care, you may contact the 24-hour Georgia Crisis and Access Line at 1-800-715-4225 to speak with a mental health clinician about affordable mental health resources and/or guidance with assessing your care. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org if this study is not a good fit for you. Taking part in this study, however, may make you unable to participate in some other research studies, if they exclude people who have taken certain treatments. You should discuss this with the researchers if you have concerns.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Please note that study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), including your de-identified genetic information, may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data and specimens from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information. For example, your deidentified data from this study may be shared with national repositories such as the National Institute of Mental Health Data

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Archive (NDA) or the Gene Expression Omnibus (GEO). A data repository is a large database where information from many studies is stored and managed. These national databases allow researchers to collect and share deidentified information with each other. With an easier way to share, researchers hope to learn new and important things about diseases more quickly than before.

We will use your sample and data only for research. The samples and information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial cell line, a medical or genetic test, a drug, or other commercial product) that could be sold by a company. You will not receive money from the sale of any such product. You will not be able to request destruction of these samples in this study.

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Medical Record

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

We will take reasonable steps to keep copies of this form out of Emory Healthcare's medical records system. If we aren't successful in keeping these forms out, despite our efforts, we will take steps to remove them. If they cannot be removed, we will take steps to limit access to them.

Emory Healthcare may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results (Screening lab work results) will be put in your Emory Healthcare medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include: All study procedures other than screening laboratory assessments processed in EML.

Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

How is my Genetic Information Protected? What are the Risks?

The Genetic Information Nondiscrimination Act (GINA) is a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

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- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that GINA does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, and does not apply to employers with less than 15 employees.

In addition to GINA, the State of Georgia has laws that prohibit insurers from using genetic testing information for any non-treatment purpose. However, like GINA, this state law protection has exclusions: life insurance policies, disability income policies, accidental death or dismemberment policies, Medicare supplement policies, long-term care insurance policies, credit insurance policies, specified disease policies, hospital indemnity policies, blanket accident and sickness policies, franchise policies issued on an insurance policy written as a part of workers' compensation equivalent coverage, or other similar limited accident and sickness policies.

Privilege
In the State of Georgia, in some circumstances your genetic information has may have special legal protections called "privilege." This means that the information cannot be used as evidence in a court. By allowing us to use and disclose your genetic information for this research study along with other information about you that genetic information used in the research may no longer have that legal protection. Other protections described in this form will still apply. There are also other confidentiality protections for research data in general under Georgia state law.

In Case of Injury
If you get ill or injured from being in the study, Emory will help you to get medical treatment. Emory and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs. For Emory, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory employee. "Negligence" is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

If you believe you have become ill or injured from this research, you should contact Dr. Jennifer Felger at telephone number 404-727-3987. You should also let any health care provider who treats you know that you are in a research study.

Costs
There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study
You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan. The researchers may end your participation in the study if you are not compliant with following guidelines for taking study medications or for not following any other study guidelines. For example, failure to take at least 85% of your study

medication over more than one week (unless discussed with or authorized by the study investigative team) may result in the end of your participation.

30 Day Off-Study Policy

There may be situations based on your schedule or ours that require more than 30 days to occur between study visits. If this is the case, for the purposes of your care and safety, a research assistant will inform you of the delay and temporarily remove you from the study. In the meantime, you should feel free to start or resume any form of treatment. When you return for your next study visit, you will be reevaluated for study eligibility and re-consented by a study clinician or coordinator. Based on your status, we will continue the study where you left off and will use as much previously collected data as possible. However, you may be asked to repeat some bloodwork or assessments to evaluate any changes in your status.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the main study and for any optional studies in which you may choose to participate.

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study

Use and Disclosure of Your Information That is Required by Law:

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI.

Authorization to Use PHI is Required to Participate:

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related medication. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:

The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.

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- Emory may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- National Institute of Mental Health (NIMH) is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: Behavioral.immunology@emory.edu

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly, and the data is correct. If you revoke your authorization you will not be able to stay in the main study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The Sponsor, and people and companies working with the Sponsor on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing

records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

If you decide to sign consent for enrollment into this study, there are a couple of items that you may opt to check on the signature pages. You do not have to check these items in order to be in the study. They are optional. The first item is whether or not you are willing to receiving appointment reminders and scheduling information via text message. If you are not willing to receiving appointment reminders and scheduling information via text message you may still participate in the study. The second item is agreeing to allow the results of your screening assessments and any data collected from you during the study to be shared with other research studies of your choosing. If you decide not to check this item you may still participate in the study. The third item is whether or not you would like to be contacted about future studies. If you no do not wanted to be contacted about future studies you may still participate in the study.

Contact Information

Contact the study coordinator, Daniel Hong at [redacted]

- if you have any questions about this study or your part in it, or
- if you have questions, concerns, or complaints about the research

Contact Andrew Miller, MD by calling [redacted] and asking the operator to page ID [redacted]

- if you feel you have had a research-related injury or a bad reaction to the study drug
- if your condition significantly worsens

Contact the Emory Institutional Review Board at [redacted]

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

You are also free to agree or disagree to the option below:

In the box below, please put your initials under "Yes" if you agree to the statement, or "No" if you do not agree and then sign on the appropriate line below:

TO BE FILLED OUT BY SUBJECT ONLY – CONSENT TO BE CONTACTED VIA TEXT MESSAGE

If you are interested, we may send appointment reminders and scheduling information via text message to your mobile phone. All standard data rates would apply.

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Please indicate below (with your initials) if you are interested in being contacted via text message.

_____ I am interested in receiving appointment reminders and scheduling information via text message.

_____ I am **NOT** interested in receiving appointment reminders and scheduling information via text

Yes	No	
☐	☐	I DO agree, if I consent to participate in any additional studies, that the results of my screening tests (laboratory, medical, and psychiatric) and any data collected during my study visits for this project may be shared with the study team of the project for which I gave consent. I also authorize the use of my PHI for this purpose.
☐	☐	May we contact you in the future regarding participation in future research studies? You may then decide if you are willing to participate.

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____

Signature of Person Conducting Informed Consent **Date** **Time**

Please download a pdf copy of the consent document for your review/record

[Attachment: "IRB00000361_DTA_IC_V8_4.19.22_CLEAN.pdf"]

◯ I have read the consent form and I wish to participate in the study
◯ I have read the consent form and I DO NOT wish to participate in the study

I DO agree, if I consent to participate in any additional studies, that the results of my screening tests (laboratory, medical, and psychiatric) and any data collected during my study visits for this project may be shared with the study team of the project for which I gave consent. I also authorize the use of my PHI for this purpose.	◯ Yes ◯ No
May we contact you in the future regarding participation in future research studies? You may then decide if you are willing to participate.	◯ Yes ◯ No

Please type your name, sign and date below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. You will be provided a signed copy of this consent.

First Name

_____

Last Name

_____

Please sign with your mouse or stylus

_____

Date of signature

_____