A Pilot Mechanistic Study of Psilocybin-Assisted Therapy as a Treatment for Depression

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INFORMED CONSENT DOCUMENT

Project Title: A Pilot Mechanistic Study of Psilocybin-Assisted Therapy as A Treatment For Depression

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This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have a diagnosis of Depression.

The purpose of this research study is to understand the acute (short term: up to 1-week post-dose) and persistent (long term: 4-6 weeks post-dose) effects of psilocybin on the brain. We will measure changes in the brain using **p**recision **f**unctional brain **m**apping (PFM) via **f**unctional **m**agnetic **r**esonance **i**maging (fMRI) and the **s**enolysis-**a**ssociated **s**ecretory **p**henotype (SASP) profile, a set of blood biomarkers linked with biological aging and depression.

Psilocybin belongs to a class of drugs called psychedelics. It is known to cause hallucinations. Psilocybin is produced in nature by some species of mushrooms. When psilocybin breaks down in the body, it produces a substance called psilocin, that works in the brain and throughout the body and may affect mood and mental health. While psilocybin is a naturally occurring substance, for the purposes of this study, the psilocybin has been produced synthetically, meaning that it is man-made.

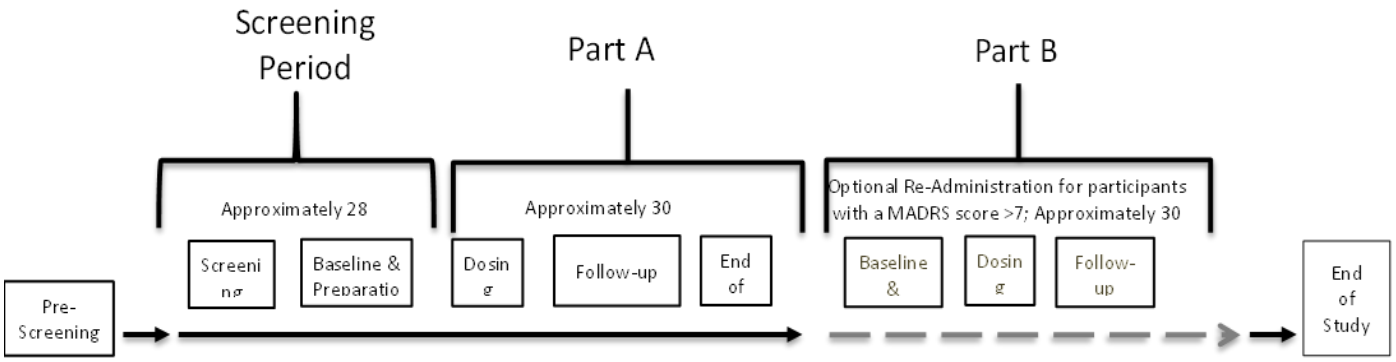
Psilocybin is considered investigational, which means that it has not been approved by the U.S. Food and Drug Administration.

WHAT WILL HAPPEN DURING THIS STUDY?

Participation in this study requires completion of interviews/questionnaires, health/medical screenings, blood draws, MRI scans, dose of Psilocybin, and preparation and integration visits.

The approximate total trial duration for each participant (from signed consent) will range from 12-16 weeks, allowing adequate time and flexibility with participant, scanner, and MRI technician schedules. and include a *repeat dosing period* for participants who meet inclusion criteria.

All eligible participants who meet pre-defined depression severity criteria (MADRS score > 7) on the Day 30 visit will be eligible to receive re-administration with a second dose of psilocybin 25mg, following the same timeline described above.



What is the Screening Period?
During the Screening Period, you will be asked to undergo medical tests and complete interviews and questionnaires to ensure it is safe for you to take part in the study. This screening period may be split into multiple visits including a Baseline visit before you receive the study drug.

What are Preparation Sessions?
If you are able, eligible, and agree to take part in the study, you will attend at least 2 Preparation Sessions to meet members of the study staff, called Facilitators. Up to 2 Facilitators will talk about what you can expect to happen during dosing sessions, so you feel comfortable with your safety and ethical boundaries. The Facilitators will be in the same room as you throughout any of the dosing sessions. At least 1 of the Facilitators will be a licensed healthcare provider. The Preparation Sessions should be done in-person, will last about 6 to 8 hours in total and may be spread over several days. If needed, some of the preparation sessions may be done by phone. You will be asked questions, and some of them are the same as questions you were asked during the Screening Period. Additionally, during these Preparation Sessions, the Facilitators will ask you questions about your life history, current situation, important relationships and events in your life, and other questions to get to know you so they can understand how to best support you during your dosing sessions with the study drug. The Facilitators will also work with you to help you set intentions for your participation in this study.

What is Dosing Day?
After you have completed the Preparation Sessions, you will be scheduled to receive a dose of psilocybin 25-mg capsule that you swallow with water. You will be required to fast (not eat anything but you can drink water) for 3 hours before taking study drug. The dosing session will last about 8-10 hours in total, and you will remain in the study clinic for your safety until you have been discharged by the study staff – this is called a "release check" and will happen at least 7 hours after taking the study drug. You may not drive home after taking the study drug and must identify a support person, such as a family member or trusted friend, who will accompany you home from the study clinic.

What to Expect on Dosing Day
To ensure your safety and comfort, please review the following schedule and requirements for your dosing session:

1. Preparation and Arrival
- **Fasting:** You must fast (no food, water only) for **3 hours** before taking the study drug.
- **Initial Check-in:** Upon arrival, the study team will conduct brief assessments to ensure you are

ready for the session. This includes checking your vitals and discussing your well-being since your last visit.
- **Meeting Your Facilitators:** You will then meet with your facilitators to ensure you are comfortable and prepared.

2. Support and Therapeutic Touch
Your facilitators will remain with you throughout the entire day.
- **Therapeutic Touch:** During your preparation session, you and your facilitators will talk about if and how physical touch might be used during your experience. You'll set clear boundaries, so everyone understands what feels comfortable for you. Together, you'll also decide on a simple way to comfort you if needed—such as a gentle touch on your hand for reassurance.
- **Safety Exception:** If you are uncomfortable with therapeutic touch, facilitators will only touch you if it is necessary to prevent physical injury (e.g., to prevent a fall).

3. Dosing Experience
- **Administration:** When you are ready, you will take one **25 mg capsule** of psilocybin with a glass of water.
- **MRI Session:** Shortly after dosing, the team will escort you to the MRI scanner. You will be asked to lie still while the psilocybin takes effect. The study team and facilitators will be with you and available to talk at any time.
- **The Dosing Room:** After the MRI, you will return to a prepared dosing room. You will be invited to lie down with eyeshades and headphones playing a music playlist (you may remove these if they become uncomfortable).

4. Safety and Care
- **Monitoring:** Your facilitators will support you through any emotional or physical sensations. We will monitor your blood pressure and heart rate throughout the day, and a study doctor is available for any medical needs.
- **Meals:** Lunch, snacks, and drinks will be provided after the dosing process begins.

5. Discharge and Going Home
- **Duration:** The session lasts approximately **8 hours**.
- **Release Check:** You must remain at the study site until discharged by staff. This "release check" occurs at least **7 hours** after dosing to ensure you are stable. If you have lingering effects, you may be asked to stay longer for your safety.
- **Transportation:** You may not drive yourself home. You must have a designated support person *(a friend or family m*ember) to accompany you home from the site.

What are Integration Sessions?
After dosing, you will take part in ~3 Integration Sessions where you talk about your dosing experience and receive support. Each Integration Session will last about 80 mins for a total of ~4 hours and will be done in person. Integration Sessions are to support you in turning the insights and experiences you had in the dosing session into long-lasting lifestyle and behavioral changes.

Each study visit may include some or all the following tests/procedures:
Qualifying Questions: The study staff will ask questions to see if you qualify to be in this study, based on specific study requirements. Study staff may contact your usual doctor to confirm that you have depression and discuss any concerns about your ability to be in this study.

Demographic Questions: The study staff will record demographic information such as your age, sex/gender, race/ethnicity, etc. as response to study drug may vary between different groups.

Medical and Psychiatric History Review: You will be asked about any significant illnesses and conditions you have experienced in the past and any illnesses and conditions you currently have. Also, a member of the research team will ask questions about your immediate family members' current and past medical conditions.

Pre-dosing Checks: The Study Doctor will check to ensure it is safe for you to be given 25 mg psilocybin.

Medication and Treatment Review: You will be asked about any medications or treatments you have taken in the past and any you are taking now, including prescription medications, over-the-counter medications, vitamins, herbal supplements, and natural remedies. Throughout the study you will be asked to report any changes in your medications or treatments.

Assessment of Side Effects: You will be asked how you are feeling and to report any side effects or symptoms you may experience while in the study. The study staff will monitor any changes in your health throughout the study.

Physical Exam: You will have an overall examination of your body (general appearance, skin, neck, thyroid, eyes, ears, nose, throat, heart, lungs, abdomen, lymph nodes, abdomen, extremities [legs, feet, arms, and hands], and nervous system) at screening and re-administration. At other timepoints, you will have a brief physical exam based on any new symptoms you may have.

Vital Signs: Your vital signs will be measured. This includes your heart rate (the number of heart beats per minute), blood pressure (how much pressure it takes to move your blood through your body), breathing rate, and body temperature.

Height and Weight: Your height and weight will be measured.

Electrocardiogram: This is a test that measures the electrical activity of your heart. You will be asked to lie down, and small sticky pads will be placed on your arms, legs, and across your chest.

Blood and Urine Sampling for Safety Testing: Blood and urine samples will be collected to ensure you are eligible to take part in the study, test for any infections or diseases, and monitor your general health throughout the study

Urine Drug Screen: Urine samples will be collected to see if you have taken any drugs or medicines that would stop you being able to take part in the study.

Pregnancy Test: If you are able to become pregnant, a blood or urine pregnancy test will be done. This may need to be confirmed with a blood test or from your medical history.

Study Interviews and Questionnaires: You will be asked to complete interviews and questionnaires about your depression, the impact of depression on your life, your quality of life, how much you expect to improve following study drug dosing, your dosing experience, and any suicidal thoughts and behavior. Some of these interviews and questionnaires you will complete yourself, some will be done at the clinic site with a member of study staff asking questions, and some will be done by telephone with questions asked by a trained person.

MRI Scans
An MRI scanner is a large machine that contains a hollow tube and takes pictures of the inside of your body by sending out a magnetic field and radio waves. You will be asked to lie on your back on a special table that slides into the tube. The sides of the tube will be somewhat close to your body, and the scanner makes a loud hammering noise while you are inside.

Because the MRI scanner contains a very strong magnet, you may not be able to have the MRI if you have certain kinds of metal in your body (for example, from medical devices or a metal plate). A member of the study team will ask you questions about this before you have the MRI.

The MRI images for this study are for specific research purposes and are not being used to evaluate your health or find medical abnormalities. These images will not be reviewed by a radiology physician to diagnose existing abnormalities.

During the procedure, you will be able to talk with the MRI staff through a speaker system. If you do not wish to continue, you can ask that the scan be stopped immediately.

Study Drug Dosing: You will swallow the study drug with some water. There will be at least 2 members of study staff present when you take the study drug. You should fast (not eat or drink anything except water) for at least 3 hours before taking the study drug.

Release Checks: The Study Doctor will check if it is safe for you to leave the study clinic.

Facilitator Assessments: Facilitators will complete various assessments and questionnaires regarding your preparation and integration sessions and your dosing day experiences.

How Much Blood Will be Collected?
Over the course of the study, you will be asked to provide blood samples at 6 timepoints: Baseline, preparation, dosing day, day 8, day 15, and day 30. Approximately 70mL of blood will be collected. Blood samples will be used to test SASP and other as-yet undetermined blood-based markers.

All of your samples will be labelled with a special unique code. Only the Study Doctor and the study staff will be able to link your samples to you. All the information they get from your samples will be kept confidential as stated in the privacy and confidentiality section of this document.

You can ask the Study Doctor or study staff about any of the tests required for this study. It is possible that, after the end of the study, the Study Doctor may ask you to come back for more safety tests.

Will you save my research information and/or biospecimens to use in future research studies?
The data/biospecimens we are obtaining in this study may be made available for studies going on right now as well as studies that are conducted in the future. These studies may be done by researchers at Washington University, other research centers and institutions, or private companies involved in research.

We may also share your research data with large data repositories (a repository is a database of information) for use by others, such as the research community, institutions, private companies and other researchers. If your individual research data is placed in one of these repositories, your name and other identifying information will be removed. All reasonable precautions will be taken to protect your privacy and confidentiality. Necessary approvals will be obtained to use the data. Certain summary information may be available to the general public.

We may share your MRI scans. While these images will not include what we call traditional identifiers (name, address, date of birth) someone could use the images to identify you.

These future studies may provide additional information that will be helpful in understanding depression or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. Should this occur, there are no plans to provide financial compensation to you. It is unlikely that what we learn from these studies will have a direct benefit to you. By allowing us to use your data you give up any property rights you may have in the data. We will protect the confidentiality of your information to the extent possible.

This future research may include genetic research. Genes are a unique combination of molecules (called DNA) that we inherit from our parents. There are millions of tiny differences in our genes that determine things like our height or the color of our eyes. Some of these differences may make some people more or less likely to develop certain diseases or conditions or to have certain characteristics. The future genetic research may include looking at the difference in genes between different groups of people. It may also include whole genome sequencing, which involves studying your entire DNA sequence. This type of testing creates information that is as unique to you as your fingerprint.

Your data/biospecimens will be stored without your name or any other kind of link that would enable us to identify which sample(s) or data are yours. Therefore, it will be available indefinitely for use in future research studies without your additional consent and cannot be removed.

Audio Recording / Video Recording
One aspect of this study involves making audio recordings / video recordings of you. We will record the facilitators during preparation and integration sessions for training purposes and to monitor fidelity to the therapeutic protocol.

While all recordings are stored in a confidential manner, please be aware that it may be possible to identify you or your voice.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 50 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for 12 to 32 weeks. The initial study time commitment may range from 12 – 16 weeks to allow enough time and flexibility to schedule research activities. If chosen, willing, and able for re-administration of psilocybin, the time commitment may be an additional 12 – 16 weeks.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Possible Side Effects of Psilocybin

Psilocybin is still being studied, so it may have side effects that are not known at this time. As with any investigational drug, there is a risk that unexpected adverse reactions may occur. Almost all drugs, both old and new, can cause severe reactions. In previous research studies of psilocybin in people, participants received psilocybin at doses of up to 50 mg. Psilocybin was generally well-tolerated (people were able to handle the side effects). Some of the experiences that people report after taking psychedelic substances like psilocybin may be challenging. Possible adverse reactions you may experience when receiving psilocybin may include:

Likely / Common

- Disorientation
- Lethargy (extreme tiredness)
- Euphoria (a feeling of intense happiness)
- Emotionality (feeling very emotional)
- Religiosity (religious feelings)
- Visual hallucination or illusions could be severe or distressing.
- Anxiety
- Pupil dilation
- Increased heart rate
- Changes in blood pressure
- Tremor
- Dysmetria (Lack of coordination)
- Nausea

Less Likely / Less Common

- Moderate to Severe Anxiety
- Headache

Rare

- Severe anxiety or paranoia
  - Fear/panic
  - Distressing effects including frightening hallucinations or illusions, feeling over-aware of your body, and troubling thoughts or feelings

Suicide Risks

Suicide is a risk in depression. You must tell your study doctor right away if you have any thoughts about hurting yourself.

If you are having suicidal thoughts or feel in crisis, call the study doctor at the telephone number listed on the first page of this form. You can also call or text the National Suicide & Crisis Lifeline at 9-8-8 or 1-800-273-TALK (8255). The Lifeline numbers are answered 24 hours a day every day of the year by a skilled, trained counselor. You can also present to a healthcare provider, your local emergency room, or call 9-1-1 to be connected to local emergency services.

Allergic Reactions

As with taking any drug, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of an allergic reaction are: shortness of breath, itchy rash (hives) or swelling, flushing (feeling warm), low blood pressure, and slow heart rate. Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms.

Blood Sampling

To take blood from you, a needle will be inserted into your vein. The risks of taking blood include fainting and pain, bruising, swelling, or rarely, infection where the needle was inserted.

Electrocardiogram (ECG)

The sticky pads placed on your skin for the ECG may sometimes cause some skin irritation, such as redness or itching.

Interviews/Questionnaires

You may find some of the questions on the interviews/questionnaires uncomfortable to answer. If you are uncomfortable, you can discuss the importance of the question with the study team. You have the right to not answer any question you do not want to.

Risks to an Unborn Baby

Females Who Can Become Pregnant

If you are capable of becoming pregnant, we will ask you to have a pregnancy test before beginning this study. You must use effective birth control methods and try not to become pregnant while participating in this study. If you become pregnant, there may be unknown risks to your unborn child, or risks to your unborn child that we did not anticipate. There may be long-term effects of the treatment being studied that could increase the risk of harm to an unborn child. You must tell the doctor if your birth control method fails while you are on the study. If you believe or know you have become pregnant while participating in this research study, please contact the research team member identified at the top of this document as soon as possible. Please discuss with the research team how long you need to wait before

becoming pregnant after completing the treatment or procedures on this study.
You may not take part in this study if you are breastfeeding, pregnant, think that you may be pregnant, or are trying to get pregnant. If you are pregnant or breastfeeding, there may be risks to you and your baby that are not known at this time. Taking the study drug may harm an unborn baby (no data are yet available regarding the effects of the study drug on an unborn baby). Females who can get pregnant will be tested to ensure that they are not pregnant during the study.

To take part in this research study you must either be: post-menopausal, surgically sterile, or willing to use a highly effective method of contraception for the duration of the study, starting at Screening and for at least 1 week after the last dose of study drug. Acceptable contraceptive methods include:

- Combined (estrogen and progestogen containing) hormonal contraception (e.g., oral pills)
- Progestogen-only hormonal contraception (e.g., implant or injection)
- Intrauterine device (contraceptive device fitted inside the womb)
- Intrauterine hormone-releasing system (hormone-releasing contraceptive device fitted inside the womb)
- Bilateral tubal occlusion (surgical procedure in females that blocks the tubes carrying eggs)
- Vasectomized partner (surgical procedure in males that blocks the tubes carrying sperm)
- Sexual abstinence (refraining from heterosexual vaginal intercourse)

You must also abstain from egg donation. You cannot start the process of egg donation at least 1 month before receiving the intervention drug until at least 1 week after your final study visit.

It is important for you to tell the Study Doctor immediately if you get pregnant or think that you might be pregnant while you are in the research study. If you get pregnant before the double-blind study drug dosing, you will be asked to stop taking part in the study, and you will not receive the study drug. If you become pregnant during the study, you will not be able to receive any additional open label 25 mg psilocybin re-administrations. The Study Doctor may ask for your permission to collect information regarding the pregnancy and its outcome.

Males
It is important that you not impregnate anyone or donate sperm during your participation in this study. There may be unknown risks to the unborn child or risks we did not anticipate. If pregnancy is a possibility, you must agree to use birth control if you want to take part in this study. If you believe or know that you have impregnated anyone or donated sperm during your participation in this study, please contact the research team member identified at the top of the document as soon as possible.

Psilocybin may harm an unborn baby. To take part in this research study you must either be: surgically sterile, willing to abstain from vaginal intercourse, or you must inform your female partner that you are taking part in this study and you must both agree to use a highly effective method of contraception. If engaging in vaginal intercourse with a female of childbearing potential, you must use a condom with spermicide during the study and also for at least 90 days after your last dose of study drug, or 1 week after your final study visit, whichever is later. Your partner must use a contraceptive method as listed above.

You must also abstain from sperm donation for the duration of the study and at least 90 days after your last dose of study drug.

If you think that your partner has become pregnant, you, in agreement with your partner, must tell the Study Doctor immediately. The Study Doctor may ask permission from your partner to collect information regarding the pregnancy and its outcome.

Magnetic Resonance Imaging (MRI)

Common risks:

- discomfort inside the MRI scanner if you do not like to be in closed spaces ("claustrophobia")
- muscle stiffness from lying still
- feeling warm
- feeling a twitching sensation briefly during the scan.

Rare risks:

- temporary sensation of flashing lights while in the MRI scanner
- burns that could be serious
    - To minimize this risk we will have you change out of your clothing and into clothing that we provide.

Devices

If you have a device such as a pacemaker, bone hardware, cardiac stent, or device placed in your uterus there may be additional risks. We will review what device you have and inform you of these risks. In general, these risks could be:

- heating or movement of the device
- device malfunction
- damage to the tissue that surrounds the device.

Risks of Genetic Research

There may be information obtained from the genetic testing that indicates that you, or potentially a family member (since we inherit genes from our parents, and pass genes on to our children) are at risk for a particular disease or condition. For example, genetic sequencing may indicate that an individual is more prone to develop certain types of cancer or other types of diseases, (e.g. Alzheimer's or other inherited diseases).

While the data developed for this study is being stored without traditional identifiers (stored only with coded ID numbers, no names), there may be ways of linking the genetic materials back to you. Because your DNA is unique to you, it is possible that someone could look at the information in the DNA database and compare it to information in another database, and use that to identify you. This is difficult to do and is very unlikely to happen.

If made available to persons or agencies outside of our research group, information about genetic test results could affect your employment or insurance. For instance, employers, insurers, or others may use this information when making decisions about you or your family members regarding employment, insurance, or other benefits.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans and employers with greater than 15 employees to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance or long term-care insurance.

Breach of Confidentiality
One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study as we understand how psilocybin effects the brain.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could explore treatments for depression including drug-based therapies and psychotherapy (talking with a mental health professional).

Electroconvulsive therapy (electrical shocks given to the brain) and transcranial magnetic stimulation (applying magnetic fields to promote brain activity) are available for people who do not respond to drug-based therapies.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will be asked to provide your social security number (SSN) for payment by check or gift card. You may need to provide your address if a check is mailed to you. Please allow 6-8 weeks to receive payment by check. Payments are estimated at $100 for each in-person visit and $250 for dosing day.

WHO IS FUNDING THIS STUDY?

The University and the research team are not receiving payment from other agencies, organizations, or companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at 314-747-1862 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those listed below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will have all data collected as part of the study coded with a unique study identification number. A master list linking the identification number and your name will be kept separately from where data are stored. Your identifiable information will not be shared with anyone outside of the research team. All written data will be kept behind multiple locked doors and cabinets, and all digital data will be secured behind multiple passwords on a secure server.

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.

We will disclose to the proper authority's information shared with us or activities we observe concerning abuse, neglect or harm to others or yourself.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?".

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter found in the Participant section of the Human Research Protection Office website at hrpo.wustl.edu.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

Can we contact you by email and/or text?

Electronic mail (email) and text messaging are very common and convenient forms of communication. We would like to contact you by email and/or text for the purposes listed below. Some of these messages may contain protected health information (PHI) that identifies you.

- General study communication

It is important for you to understand that there is a potential risk that email and/or texts containing your protected health information may be intercepted by someone else. Before we can send your information by email and/or text, we are required to make you aware of these risks and to obtain your authorization.

- There is always a risk that the message could be intercepted or sent to the wrong email address and/or phone number.
- If you share a home computer or cell phone with other family members, be aware that your family members might have access to the email and/or text message.
- If you elect to communicate from a workplace computer, email account, or workplace phone, your employer and people that work for your employer might have access to the email and text message.

Only the research team will have access to your email and/or text communications. We will only communicate in this method to send you the information listed above. We will limit information sent to you to the minimum necessary for your participation in this study. If you have any questions, wish us to stop sending these messages or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

Do you agree to allow us to send your health information by unsecured email?

_____ Yes _____ No
Initials Initials

Do you agree to allow us to send your health information by unsecured text?

_____Yes _____No
Initials Initials

IS BEING IN THIS STUDY VOLUNTARY?
Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?
You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found in the Participant section of the Human Research Protection Office website at hrpo.wustl.edu.

Will I receive new information about the study while participating?
If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?
Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because it is determined to be unsafe for you to continue participation.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Anna Kinghorn at (314) 362-8761. If you experience a research-related injury, please contact our 24/7 hotline at 800-909-4903 (Toll Free) and tell the operator that you are a research participant in Dr. Ginger Nicol's research study.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 04/21/27.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)