

INFORMED CONSENT DOCUMENT

Project Title: Cannabis, HIV and Mental Processing Systems (CHAMPS)

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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. By signing this form, you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

KEY INFORMATION

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

This is a research study conducted by Dr. Ances having to do with HIV infection and regular cannabis (marijuana) use. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. As a voluntary participant, you will be asked to spend approximately 6-7 hours at the research lab. You will need to come to Washington University in St. Louis. During that time, you will be asked to complete some memory testing and questionnaires, provide a urine sample, and have an MRI, and allow us to draw some blood. The main risks to you if you participate are potentially being stiff from lying still or uncomfortable inside the MRI scanner if you do not like to be in closed spaces; not liking the loud noise the MRI makes; and feeling pain and bleeding a little when we draw your blood. After these tests, we will ask you to return for a lumbar puncture. The lumbar puncture can cause pain from the needle stick to administer lidocaine; slight pressure and discomfort while the doctor locates the spinal fluid; and a possible headache from the procedure. Rare risks include: lowered blood pressure, infection, leaking of spinal fluid after the procedure, nerve injury, and bleeding at the needle insertion site. Additionally, an allergic reaction to the antiseptic (e.g. iodine) or the numbing medicine (lidocaine) used during the spinal tap could include itching, hives, swelling, shortness of breath, difficulty breathing, changes in blood pressure and heart rhythm, loss of consciousness or, in a rare case, death.

We don't expect this study to benefit you directly, but it will help us understand if cannabis use in people living with HIV (PLWH) leads to increases in inflammation that could adversely affect memory and brain integrity. By volunteering you may help someone else in the future. There is no cost to you and you will be paid up to \$275 for being a volunteer participant. All of this information will be explained and is listed in more detail in this consent document. The research team must give you a copy of this signed consent document.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are 18-70 years old and are HIV+ or HIV negative.

The purpose of this research study is to see if using cannabis/marijuana leads to increases in inflammation that could harm memory and brain integrity, especially in PLWH.

WHAT WILL HAPPEN DURING THIS STUDY?

In order to determine your eligibility to continue in the study, you will have a screening evaluation, which will include:

1. Urine pregnancy tests (done on the day of the scan, only for females with no documented history of sterilization, menopause, etc.)
2. A urine drug screening test for cocaine, amphetamines, methamphetamine, barbiturates, benzodiazepines, marijuana, opiates, PCP, methadone, and tricyclic antidepressants, such as amitriptyline or nortriptyline. A positive result will not necessarily exclude you from the study. If you are accepted into the study, your urine will be further analyzed and compared to other data that is being collected.
3. Oral HIV test (for healthy volunteers only). This test is done by rubbing a swab over your gum line once. If this test is positive, you will be referred for further clinical testing.
4. The Neuroimaging Screening Form, which asks questions about your feelings about being inside a closed space like the MRI scanner, questions about history of head injuries, and questions about any metal that subjects may have implanted in your body or any metal piercings that cannot be removed.
5. A Locator Form with your basic contact information, as well as additional names of people who might also be able to contact you should you be lost to follow up. When asking for your address and zip code on this form, we will use it not only to contact you, but also to determine the median income and other social determinants of health for the area in which you live.
6. Scanning Cover Sheet – You will be asked questions about your demographics and other basic information, such as age, race, gender, handedness, years of education, first language, height/weight, date of HIV diagnosis (and date started medications if applicable), as well as information about drug, alcohol, tobacco and caffeine use.
7. Beck Depression Inventory – A self-reported questionnaire to assess symptoms of depression.

8. You will also be asked to sign a Release of Information form so we can obtain your medical records, including but not limited to medical, hospitalization, HIV, STD, substance use/abuse/dependence and mental health records from your doctors, results from prior blood, diagnostic, imaging and laboratory tests and other information obtained from interviews or questionnaires related to your medical care. We may also review the records of any Washington University research study in which you participate. This will allow us to better determine your eligibility to continue on study, insure and improve your safety, and decrease your burden if the results of tests done in one research study could be used as data for another instead of asking you to unnecessarily repeat a procedure.

9. We will review your medical history and records related to any HIV/AIDS-related outpatient visits or any significant medical history, inpatient hospitalizations, blood/diagnostic/laboratory/imaging tests (such as CD4 count, viral load, lowest CD4 count, duration of infection, STD history, and any other HIV- or inflammatory-related labs deemed necessary, any abnormal/exclusionary imaging results, etc.), substance use/abuse/dependence, and mental health treatment. Additional information may also be obtained from clinical interviews or questionnaires found in your records related to your medical care. We may also review your research records from other Washington University studies (to see if previous results indicate any exclusionary criteria or provide any results that we could use as data for this study so as to not have you repeat procedures and decreasing your burden whenever possible). These records will only be accessed as long as necessary to acquire study data.

If, on the basis of these tests, you are eligible to continue in the study, you will be asked to complete the following study procedures. The Screening Evaluation and Baseline Assessments can be completed on the same or separate days.

BASELINE ASSESSMENTS:

1. Neuropsychological (Memory) Tests -- These are exercises that are related to memory, how fast you do things with your hands, and how you pay attention to tasks. There are a number of different tasks; some are timed and some are not. These will take approximately 2-2½ hours to complete.
2. Gait assessment -- We will have you walk a short distance to measure how fast you are able to walk, as well as to assess your balance.
3. Questionnaires regarding your mood, ability to care for yourself, as well as your drug and alcohol history. These will take approximately 1-1½ hours to complete, and you may skip any questions that make you feel uncomfortable.
4. Neuromedical and physical examination -- A doctor will examine the nerves in your face, as well as test your reaction to touch and will test the reflexes in your arms and legs. We will check your waist circumference, height, weight, take your vital signs (blood pressure, heart rate, respiration, etc.), and also perform a regular physical. This will take approximately 20 minutes.
5. Laboratory assessments: We will draw some of your blood to look at the amount of fat and sugar in your body, as well as markers of inflammation and insulin resistance. The blood draw will be equivalent to approximately 10 tablespoons, including blood samples taken to determine if you are a carrier of the *Apolipoprotein E (ApoE) ε4* allele. This is a genetic test to help further our understanding of HIV-

related dementia (memory loss and thinking problems) and other neurodegenerative disorders (neurodegeneration refers to the progressive loss of structure or function of nerve cells). Some versions of this allele may increase a person's risk of developing Alzheimer's disease in their lifetime. This *ApoE* test is for research purposes only and its result will not be reported to you or your physician. If we are having trouble locating a vein, a Butterfly Network hand-held portable ultrasound device may be used to do so. If, during your first visit, we are unable to acquire the full amount of blood necessary to perform these laboratory tests, you may be invited back to try again. You are under no pressure to agree to return, however, if you do, you will be paid again for letting us attempt another blood draw.

Genes are a unique combination of molecules (called DNA) that we inherit from our parents. There are millions of tiny differences in our genes. These differences may make us more or less likely to develop certain diseases or conditions or to have certain characteristics. Genetic research involves studying the differences in genes and DNA between individuals. This type of testing creates information that is as unique to you as your fingerprint.

6. Magnetic Resonance Imaging (MRI) -- The MRI scanner is a powerful magnet that uses simple radio waves to take pictures of your brain. You will be positioned on your back on the scanner bed and made to feel as comfortable as possible. The scanner bed will be moved inside a large tube so that your head and your chest are inside, but you will be able to see out into the room by your feet. During the scan, you will hear loud, rhythmic knocking sounds. Your ears will be covered to keep the noise at a minimum. There is a speaker and a microphone in the scanner so that you can talk to the MRI technician if there is something you need. Once the scan starts, you will need to lie still since moving around will interfere with taking pictures of your brain. You will be able to end the scan at any time if you feel uncomfortable. You may be asked to do a task while in the scanner. The scan will take approximately 60-90 minutes. Often, these research images are not officially read by a radiologist, and there is no report placed in the medical record. The MRI images you will have 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, however, if we happen to notice something unusual, we will let you know and with your permission, assist you in receiving clinical follow up and notifying your health care providers.

7. Lumbar Puncture -- Sometime within approximately 6 months after you complete the memory testing and MRI, you will be asked to return for a lumbar puncture (LP). We will ask you to fast (not have anything to eat or drink other than water) overnight (approximately 10-12 hours) before you come in for the LP. This procedure lasts approximately 45 minutes and involves putting a small needle in your lower back through the space between bones below where the spinal cord ends to collect some cerebral spinal fluid (CSF) (up to 25 cc's or 1-2 tablespoons). Spinal fluid is the fluid that moves around the brain and spinal cord. You will have your vitals (blood pressure & heart rate) taken before and after the procedure, and you will be given a numbing medication before the LP is done in order to reduce any pain or pressure you may feel during the procedure. At the physician's discretion, a Butterfly Network hand-held portable ultrasound device may be used to locate the LP interspace during this procedure. If we are unable to acquire the full amount of CSF necessary, you may be invited back to try again. You are under no pressure to agree to return, however, if you do, you will be paid a second time for letting us attempt another LP.

I agree to the lumbar puncture as described above.

____ Yes ____ No
Initials Initials

Will you save my research information and biospecimens to use in future research studies?

We would like to use the blood, urine, cerebral spinal fluid (CSF), neuroimaging and neuropsychological data and questionnaires we are obtaining in this study for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding cannabis use disorders, HIV, 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. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your blood, urine, cerebral spinal fluid (CSF), neuroimaging and neuropsychological data and questionnaires you give up any property rights you may have in the blood, urine, cerebral spinal fluid (CSF), neuroimaging and neuropsychological data and questionnaires.

Some of this future research may involve genetic testing. Genetics is a discipline of biology that studies how living things receive common traits from previous generations.

We will share your blood, urine, cerebral spinal fluid (CSF), neuroimaging and neuropsychological data and questionnaires with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

Your blood, urine, cerebral spinal fluid (CSF), neuroimaging and neuropsychological data and questionnaires] 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.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 320 people will take part in this study 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 approximately 6-7 hours total, split over 2-3 days, including screening, neuroimaging/memory testing, and lumbar puncture. Depending on scheduling availability and your preference, we will do our best to condense or expand the screening, MRI and neuropsych into as many or few days as is comfortable for you. The LP, however, must always be done on a separate day from the rest of the procedures, approximately 1 week to 6 months later.

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.

RISK OF THE SCREENING, NEUROPSYCHOLOGICAL (MEMORY) TESTS, & QUESTIONNAIRES

Likely: None

Less Likely:

- You may feel embarrassed or uncomfortable answering some of the questions.
- You may experience fatigue or embarrassment from the exercises of memory, movement, and attention.

You may discuss any question that concerns you with the coordinator, and you may choose not to answer any question that makes you feel uncomfortable.

Rare: None

RISKS of 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:

- a loud hammering noise which has caused hearing loss in a small number of patients.
 - To minimize this risk you will be given earplugs.
- 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.

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

Devices

If you have a device such as a pacemaker, bone hardware, 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.

Rare:

- Occasionally, some people may experience a short period of dizziness or feel faint after being in

the scanner.

There is a rare possibility that a serious abnormality may be discovered by the technician during the MRI picture of your brain. A radiologist will review MRI scans for clinical findings. If there is an incidental observation on the MRI which may be clinically significant, the Principal Investigator (PI) will be contacted. If indicated, with your permission, the PI or his/her designee will contact your doctor with this information. If you request it, a copy of your brain MRI scan can be shared with your doctors. In this event, you will be referred to your primary care physician and/or the WUSM Neurology Clinic for clinical follow up and treatment as appropriate. While we will never put your consent form or study data in your medical records, once we notify your physician and make relevant brain MRI's and test results available to him/her for clinical follow up, that information may become part of your health care records.

RISKS ASSOCIATED WITH BLOOD DRAW

Likely: Pain, stinging, bruising and bleeding at the site of needle insertion.

Less Likely: None

Rare: Infection at the site or blood clot. Additionally, an allergic reaction to the ultrasound gel, if the Butterfly device is used during the blood draw, could include itching, hives, swelling, shortness of breath, difficulty breathing, changes in blood pressure and heart rhythm, loss of consciousness or, in a rare case, death.

RISKS ASSOCIATED WITH THE LUMBAR PUNCTURE

Likely: Pain at the site of needle insertion.

Less Likely: Headache.

Rare: Lowered blood pressure, infection, leaking of spinal fluid after the procedure, nerve injury, and bleeding at the needle insertion site. Additionally, an allergic reaction to the ultrasound gel, antiseptic (e.g. iodine) or the numbing medicine (lidocaine) used during the spinal tap could include itching, hives, swelling, shortness of breath, difficulty breathing, changes in blood pressure and heart rhythm, loss of consciousness or, in a rare case, death

Women Capable of Becoming Pregnant

If you are a woman 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.

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).

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.

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.

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.

If people not involved in the study learn that you participated, you might have problems getting life and health insurance. This may also cause problems getting a job, finding a place to live, or place you at risk of criminal or civil charges.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit directly from being in this study.

However, we hope that, in the future, other people might benefit from this study by understanding if cannabis use in people living with HIV (PLWH) leads to increases in inflammation that could harm memory and brain integrity.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

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

You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. It may take approximately 2-4 weeks for you to receive your check. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

You can earn up to \$275 if you complete all portions of the study:

- MRI \$ 75
- Neuropsychological testing \$ 60
- Questionnaires \$ 15
- Blood draw \$ 25
- Lumbar puncture \$100

WHO IS FUNDING THIS STUDY?

The National Institutes of Health (NIH) is funding this research study. This means that Washington University is receiving payments from NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIH for conducting this 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 314-747-8423 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 and NIH. 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 indicated 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.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- NIH
- NIH may also inspect any part of your medical record for the purposes of auditing the conduct of the study.
- Your primary care physician if a medical condition that needs urgent attention is discovered. Any abnormal laboratory results shared with your provider may become part of your medical record and will need to be repeated for diagnostic purposes.
- Hospital or University representatives to complete Hospital or University responsibilities.
- A radiologist will review MRI scans for clinical findings if we discover an incidental observation on the MRI which may be clinically significant, and the Principal Investigator (PI) will be contacted. If indicated, with your permission, the PI or his/her designee will contact your doctor with this information. If you request it, a copy of your brain MRI scan can be shared with your doctors. This scan may then become part of your healthcare records.
- 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.

- 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 other entities with whom PHI may be shared
- 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 keep all information in a locked area. The information you give us will be given a code number. A master list linking the code number and your identity will be kept, but only the Principal Investigator and people helping him will be able to see the list. All staff involved with this project have been thoroughly trained in the protection of research participants. We will always try to protect your information, but there is a chance somebody might see it.

We will protect your genetic information by using a code which cannot be traced back to you. This code will be assigned once we've collected all of the information we need for our study from your medical record. This may take up to one month. We will not sequence your DNA until your identifiers have been stripped.

Your MRI will be labeled with a code number. It will be stored at Washington University using the code number, along with the date of the scan. Using the code number, it will be linked to the other information about you that is collected in this study.

Our database will contain details from your medical record (name, date of birth, address, social security number, medical record numbers) and associated with a participant code number. Dates of procedures will also be recorded in the database. Only qualified study staff within the Washington University School of Medicine who agree to keep your data secure, however, will have access to identifiers when needed. This database will be updated on a periodic basis from your medical records in the following years in order to update your information on medications, surgeries, cognitive testing, disease activity, and disease history. We will store your medical information indefinitely. In the event that the medical record does not contain this information, you may be contacted by study staff to obtain that information directly from you.

Research Electronic Data Capture (REDCap) is a secure, password-protected, web-based electronic data capture application that is on the Washington University Secure Network. REDCap is HIPAA compliant and in compliance with university policies. Electronic Records will be created, maintained and stored in Redcap where possible. Paper records that are required for the study will be kept behind double lock and key.

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

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify

you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others;
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

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

<https://hrpo.wustl.edu/participants/withdrawing-from-a-study/> or you may request that the investigator send you a copy of the letter.

○ **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?

We would like to contact you by email and/or text for the purposes listed below. Some of these messages may contain health information that identifies you.

- appointment scheduling/reminders containing PHI
- links to complete study assessments on REDCap
- links to complete study assessments on Redcap
- copies of current/updated consent forms and other information for this study
- consent forms and information for other studies you have requested.

Only the research team will have access to your email and text communications. We will only communicate in this method to send you the information listed above. 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.

You should be aware that there are risks associated with sending your health information via email and/or text:

- Text messaging is not a secure communication method.
- There is always a risk that the message could be intercepted or sent to the wrong email address and/or phone number. To avoid this, we will send a test message to ensure we have the correct email address and/or telephone number.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer or cell phone with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any messages sent or received on any electronic devices used for work or through a work server.
- If you lose your phone, others may be able to access the messages that we send.

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

_____ **Yes** _____ **No**
Initials **Initials**

Do you agree to allow us to send your health information via 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 at <https://hrpo.wustl.edu/participants/withdrawing-from-a-study/> under Withdrawing from a Research Study.

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:

- you have certain medical conditions like seizures or become pregnant
- in our judgment it would not be safe for you to continue
- the funding for the research study has ended.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Regina Thompson at 314-747-8421. If you experience a research-related injury, please contact: Elizabeth Westerhaus at 314-747-1125. If you participate in the LP portion of the study, you will be provided with a 24-hour number for the study staff on call should you experience any side effects.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office 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, <http://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: 08/26/26.

(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)