



INFORMED CONSENT DOCUMENT

Project Title: Slow Wave Induction by Propofol to Eliminate Depression (SWIPED) Trial: Phase I

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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.

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 Ben Palanca, MD, PhD, MSc, having to do with the effects of anesthesia on your sleep, thinking and mood. You should carefully consider the information in this consent document and discuss it with the research team. Be sure you 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. All of the information below will be explained and is listed in more detail in the consent document below. The research team must give you a copy of this signed consent document.

How will this study affect me?

- The purpose of this study is to investigate the effects of an anesthetic called propofol on sleep, thinking, and mood in people who have depression despite trying different types of medications.
- As a voluntary participant, you will be asked to record your sleep at home using provided equipment, undergo propofol sedation, and complete questionnaires about how you are thinking and feeling at various stages of the study.
- You will be in this study for up to 13 weeks beginning from time of enrollment.
 - Visit 1: Approximately 1-2 hours
 - Visit 2: 3-5 Hours
 - Visit 3: 3-5 Hours
 - Visit 4: Approximately 1-2 hour
 - Home-sleep study: 4-8 Hours per night
- You will need to come to Washington University School of Medicine/Barnes Jewish Hospital.

- There may be no direct benefit to you. However, other people might benefit from this study because we will understand more on the relationships between sleep and depression and potential impact of anesthetic agents.
- The main risks to you are drowsiness because of the anesthetic. Although less likely, you may also experience impaired breathing, low blood pressure, low heart rate, and burning/stinging at injection site. More detail about risks is provided below.
- You will be paid up to \$305 for participating in this study. You will not have costs for participating in any portion of the study. Should you withdraw, you will receive payment based on completed parts of the study.
- If you withdraw from the study, the research team may continue to use information already collected about you in this study.

The rest of this document provides more details about the study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you experience severe forms of depression that continue despite trying many types of medications. A contributor to depression may be a lack of slow wave sleep. Slow wave sleep is important as this is when our bodies regenerate and repair but is known to decrease with age. Brain waves known as electroencephalography (EEG) are used to detect slow wave sleep. A commonly used anesthetic, propofol may improve slow wave sleep.

The purpose of this research study is to investigate the effects of propofol on your slow wave sleep, as well as to assess the effects of propofol on your thinking and mood.

Propofol has been approved for sedation by the U.S. Food and Drug Administration. However, propofol has not been approved by the U.S. Food and Drug Administration for the treatment of depression and insomnia.

We will use the DREEM device to acquire data. This device has not been approved by the U.S. Food and Drug Administration for clinical purposes.

WHAT WILL HAPPEN DURING THIS STUDY?

Your participation in this study will take place over approximately 13 weeks. You will be asked to continue all current medications except that for the day that you will receive anesthesia, you may be asked to not take a medication for treating high blood pressure. You will complete two propofol sessions where the medication will be given through an IV while you are monitored closely by a doctor. Before each session, we will ask you to not eat or drink up to 8 hours before the anesthetic. Each session will take up to 3 hours. We will ask you to record your sleep at home each night using a wearable headband. You will be asked to wear the headband for six different nights after the second propofol session. You will be instructed to wear a wrist watch throughout the study period. You will be asked to complete a series of questionnaires measuring (1) suicidal ideation, (2) depression severity, (3) anhedonia, (4)

mood, (5) cognitive performance, and (6) alertness/activity level. You will also be asked to keep a diary on when you went to sleep and awoke.

Many procedures will be performed at Barnes-Jewish Hospital, within clinical areas typically used for sedation prior to surgical procedures.

Baseline/Consent Visit 1:

One of the doctors in this study will meet with you to make sure you meet the participation requirements for the study. During this interview, they will ask you questions about your health history and any medications or dietary supplements that you might take. They will also complete an exam on you as they would prior to a surgery requiring anesthesia. Some questions may be asked over the phone. You will be asked about your alcohol intake and to take a urine drug test. You can have your additional questions about the study answered at this time. Research staff will then teach you on use of the Dreem headband and wrist watch. The Dreem headband is a wireless wearable device that will record your sleep data. Directions for use, charging cord, alcohol pads for cleaning, and a box for sending your recorded data back to us will be supplied. We will ask that you record two nights of sleep prior to your first sedation visit. You will also be asked to complete survey questionnaires at this time.

- We will ask for return of the device to ensure that you qualify for continued study.
- If you remain eligible, you receive guidelines for fasting prior to your sedation visits.
- It is imperative that you follow these fasting guidelines to ensure your safety during sedation.
- We will ask you not take any high blood pressure medications ending in “pril” or “artan,” only on the days of sedation.
- We will ask you to abstain from illegal drugs.

If available, electronic medical records will be accessed for the past five years. These records will help confirm study eligibility, cardiovascular health, and depression history.

Sedation Visits 2/3:

If you are eligible to receive the study treatment, a team member will meet you at Washington University Medical Center and accompany you to the Department of Anesthesiology. We will review the screening information that you provided and ensure that your current health status has not changed. You will undergo a brief physical exam and confirm that you have adhered to the fasting guidelines. You will then be escorted to the post-anesthesia care unit (PACU) or the Clinical Translational Research Unit (CTRU). Once in the PACU or the Clinical Translational Research Unit (CTRU), an IV will be placed for the infusion of propofol. If you decide to participate in an optional blood draw procedure, a study physician or nurse will draw up to two samples of blood before and after the infusion, approximately 20 mls of blood or 4 teaspoons will be drawn. You will also be placed on a monitor that will allow the study team to track your heart rhythm, heart rate, breathing rate, and oxygen level. EEG scalp electrodes attached in a net will be placed on your head to monitor your brain activity.

Propofol will be given through the IV via a pump. Your infusion, lasting up to 3 hours, will be targeted for EEG slow waves that resemble slow wave sleep. During your sedation, vital signs and EEG

waveforms will be monitored by a board-certified anesthesiologist as if you were undergoing a surgical procedure. You will be monitored until the sedative effects of the propofol have worn off and your vital signs are stable. Propofol is approved by the U.S. Food and Drug Administration for the use of sedation. Propofol is known to suppress breathing when given in large doses. You will be receiving low to moderate doses that induce EEG slow waves without additional respiratory support. The exact dose depends on the individual. You will be monitored constantly during the infusion by a board-certified anesthesiologist and emergency equipment is readily available in the event it is needed.

You must have a designated driver available to accompany you after the anesthetic. You will not be able to drive or use heavy equipment until the next day.

We will also ask that you record your sleep (post-sedation sleep) with the DREEM on the same night that you receive treatment. Once all recordings are complete the DREEM can be mailed back to the study team or dropped off at the Washington University Medical Center. Additionally, you will be asked to continue wearing the actigraphy wristband up to the final post-sedation sleep recording (3 weeks total of semi-continuous wear). You will be called at home and asked questions about how you think and feel.

Follow-up Visit 4:

We will ask you to return for a follow up visit to return the wrist watch and DREEM. We will ask you to complete questionnaires as you have previously done. We will again record your EEG with a net. We will ask you to give a blood sample if you have previously done so.

Follow-up Visit 5:

Approximately 10 weeks after the second infusion, you will be asked questions about your mood and thinking. This may be done in person or by telephone.

If available, electronic medical records for the subsequent year after infusion will be accessed to evaluate potential effects on sleep, depression, and cognitive function. No study procedures or results will be added into the medical record.

Optional Sub-Study

You will be asked to provide blood samples for a smaller study aimed at identifying small molecule related to circadian rhythm. This includes examining the amount of small molecules in your blood including inherited factors called genes. Genes are 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 have certain characteristics.

A study physician or research nurse will draw up to two samples on visit 2, 3 and 4 (a total of up to 6 sample collection events may occur. Overall, not more than 50 mls of blood or 5-10 teaspoons will be drawn).

This molecular testing will be performed for research purposes only. The results of this testing will not be placed in your medical record, nor will they be shared with your or any of your physicians.

<u> </u> Yes	<u> </u> No
Initials	Initials

If we have issues contacting you by phone or text, we may send up to three reminders via email and/or letter over a one-month period.

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

We would like to use the data (brain signals, sleep records and blood samples) 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 sedation, 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 data you give up any property rights you may have in the data.

Sharing of your brain signals, sleep records, and blood samples for future research is mandatory.

We may share your de-identified data and/or samples 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 will 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 data will be stored without your name or any other kind of link that would enable us to identify which data are yours. Therefore, it will be available for use in future research studies indefinitely and cannot be removed.

How will we use and share your samples and data for other research?

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many NIH studies are stored and managed. Sharing your deidentified study data helps researchers learn new and important things about brain science more quickly than before.

Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. The study researchers will have to collect your personal information from you in order to make that code number. The code number cannot be used to identify you. The study researchers will never send your personal information to NDA.

It is possible that you will participate in more than one study that sends data to NDA. NDA can connect your data from different studies by matching the code number on your deidentified data from each study. This data matching helps researchers who use NDA data to count you only one time. It also helps researchers who use NDA to better understand your health and behavior without knowing who you are.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA. Other researchers across the world can then request your deidentified study data for different research projects. Every researcher (and the institution to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about brain science and how to help others who have problems with brain science. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to NDA. You can still participate in this research study even if you decide that you do not want your data to be added to NDA. If you know now that you do not want your data in NDA, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, it is available on-line at <http://nda.nih.gov>.

We may also share study data that has no identifiable information through the National Sleep Research Resource, a research data repository. The research data will allow investigators to further study sleep and related health measures, behavior, and physiology.

You will not be asked to provide additional informed consent for these uses.

Audio Recording/Video Recording/Photographs

One aspect of this study involves making mandatory video recordings of you during the sedation sessions. These video recordings will allow the research team to precisely determine the times at which you become sedated and wake up during the study. Only members of the research team will have access to these videos; the video data will not be shared. The videos will be stored on a physical hard drive and kept in a secured location accessible only via key by research personal. The videos will not be destroyed. By signing this form, you agree to be video recorded. While all video recordings are stored in a confidential manner, please be aware that the recording will likely contain information that would identify you.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 15 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

Your direct involvement in study procedures will last for approximately 13 weeks from the time of enrollment to completion of follow up testing. We may review the last five years of documentation available in your electronic medical record to confirm eligibility and the subsequent year of records to evaluate long-term outcomes.

- Consent visit: Approximately 1-2 hours.
- Infusion visits (2): These may last 3-5 hours each.
- Follow-up visits (2): Approximately 1-2 hour.
- At home sleep recordings: Up to 9 overnight sleep recordings 4-8 hours each taking place up to 13 weeks following the consent visit.

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.

Some risks described in this consent document, if severe, may cause death.

Propofol

Likely: Drowsiness

Less likely: Burning or stinging at injection site, difficulties in breathing, low blood pressure, and low heart rate. Vitals signs are continuously monitored. Staff are present to assist your breathing, should you need it. Medications are ready to be administered to reverse them, as is standard during sedation and procedures in the hospital.

Rare: Allergic reaction, abnormal heart rhythms/blood flow, or rash. You will be attended by a board-certified anesthesiologist during sedation, with all standard sedation and airway management equipment available should any adverse events occur.

The investigation does not involve a route of administration, dose, patient population, or other factors that significantly increase the risk (or decrease the acceptability of the risk) associated with the use of propofol.

IV

Less likely: Tenderness or bruising at or near the insertion site, redness or itching from Tegaderm (clear bandage that hold IV in place), dizziness or fainting.

Rare: Infection

Blood Draw

Less likely: Feeling faint – as with any medical procedure, some people feel faint. This is a normal response and is not a physical effect of the needle. Discomfort from the phlebotomy needle during procedure. Bruising at the phlebotomy site may occur due to leakage of a small amount of blood from the vein into the surrounding tissue. This will get better on its own.

Rare: Infection

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.

EEG

Less likely: Small skin abrasions at site of electrode. Care will be taken to minimize pressure at the electrode sites.

Rare: Skin tear or inflammatory reaction to electrode gel.

Questionnaires

Less likely: Some of the questions may make me uncomfortable but these are questions that are asked of everyone. You may discuss this with the research staff and choose not to answer.

Actigraphy

Less likely: Irritation of skin from strap of actigraphy.

Very rare: Some individuals with very sensitive skin may have irritation of their skin from actigraphy straps.

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 because we will understand more on the relationships between sleep and depression and potential impact of anesthetic agents.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not 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 continue with your care as prescribed by your doctor.

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 up to \$305 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 4-6 weeks for the check to arrive after study completion. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

Compensation is broken down as follows:

- **\$30 for each baseline home sleep study (2 maximum)**
- **\$15 for each sedation session (2 maximum)**
- **\$25 for each post sedation home sleep study (7 maximum)**
- **\$40 for follow up study questionnaires**
- **\$305 possible for completion of all study procedures**

The total you will receive will be based on the parts of the study that you complete.

We will provide you with parking validation or public transportation tickets for parking. Please discuss any transportation concerns with a research team member. Remuneration for drivers (\$20) will be employed, if needed.

WHO IS FUNDING THIS STUDY?

National Institute of Mental Health (NIMH) is funding this research study. This means that Washington University is receiving payments from NIMH 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 NIMH 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 Dr. Ben Palanca at 314-273-9076, Study Coordinator Matthew Robeck at 314-362-2415, 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 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
- The National Institute of Mental Health
- 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 assign you a study ID number and that ID will be used to manage all your study related information. Additionally, the key to the ID code linking code numbers to names will be kept in a password-protected file, behind university's firewall, and only the research team will have access to it. We will destroy the link between your ID and your identifiers at the end of the study. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

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 authorities information shared with us or activities we observe concerning abuse, neglect or harm to others or yourself.

We will be in touch with your care providers about your involvement in the study.

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 hrpo.wustl.edu 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 or text?

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

- Informed Consent Document
- Study-related surveys
- Reminders for appointments and study-related tasks

Only the research team will have access to your email and/or text communications. We will only communicate by email to send you the information listed above. If you have any questions 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 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 email communications 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 in the Participant section of the Human Research Protection Office website at hrpo.wustl.edu.

If you decide to leave the study early, we will ask you to provide information on why you stopped before completion. We may also need your assistance in returning the DREEM and other devices if they are still in your possession. We may also need to follow up to ask questions regarding your satisfaction.

If you decide to leave the study, it will not affect your care at Barnes-Jewish Hospital or Washington University School of Medicine.

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 do not fulfill criteria for continuing, because in our judgment it would not be safe for you to continue, because your condition has become worse, because funding for the research study has ended, or because the study team has decided to stop the research.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Ben Palanca, 314-273-9076. If you experience a research-related injury, please contact: Dr. Ben Palanca, 314-273-9076.

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, 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: 05/19/26.

(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)