Washington University in St. Louis

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INFORMED CONSENT DOCUMENT

Project Title: Behavioral Activation and Medication Optimization for Perioperative Mental Health Feasibility Study

Principal Investigator: Michael Avidan, MBBCh

Research Team Contact: Theresa Cordner 314-273-7921

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 Dr. Michael Avidan and Dr. Eric Lenze about improving outcomes for older adult surgical patients. The study is testing feasibility of an intervention designed to improve mental, emotional, and cognitive health.

- The intervention includes post-surgical behavior therapy at no cost to you. Additionally, the study team will review your medications with you and discuss any recommendations that may improve mood, reduce stress, and reduce risks of post-operative delirium, falls, and re-hospitalizations.

- The main risk of being in this study is increased risk of depression or anxiety, and errors in medication recommendations or medication withdrawal symptoms.

- 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. Instead of being in this study, you could receive mental health care through a provider of your choosing and consult with your provider about your prescriptions.

- 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 complete surveys 4 times over approximately 3 months. You will be provided a specialized counselor known as a Perioperative Wellness Partner who will work with you in sessions conducted by phone or zoom. The sessions are patient-driven, scheduled at times and frequency that work for you. You will not be asked to make additional visits to campus for the study.

- You may or may not benefit from volunteering by participating in the behavioral therapy and medication optimization process with a Perioperative Wellness Partner. Additionally, by volunteering you may help someone else in the future, as the study data will contribute to future studies with aims of improvements in perioperative care.

- There is no cost to you for participating, and you will be paid up to a total of $125 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.

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

WHAT IS THE PURPOSE OF THIS STUDY?

We invite you to participate in this research study because you are age 60 or older, scheduled for a major orthopedic, oncologic, or cardiac procedure, and have some symptoms of depression or anxiety.

The purpose of this research study is to test the feasibility of a pre- and post-surgical intervention of personalized medication optimization and behavioral therapy to improve mental health for older surgical patients with symptoms of depression and/or anxiety.

WHAT WILL HAPPEN DURING THIS STUDY?

As part of the process to determine eligibility, if you agree to take part in the screening questions, a research team member will contact you to complete a brief survey about your feelings and current mood, then a short cognitive assessment where you will be asked a series of memory and brain health items. These questions will take approximately 15 minutes to complete.

If it is determined that you are eligible to participate, and you consent, then you will be asked to complete a set of baseline questionnaires. These include questions about your demographics and physical health, as well as about your quality of life, brain health, memory, and mental health. These will be delivered remotely via a web-based survey or by phone or postal mail. The baseline questionnaires will take approximately 20 minutes to complete. Following your baseline surveys, again approximately 1 month, 2 months, and 3 months, you will be asked to complete a shorter set of questionnaires, with the follow-up at months 1 and 3 taking approximately 20 minutes to complete, and at 2 months, approximately 5-10 minutes to complete. You are free to skip any questions that you would prefer not to answer.

After baseline and before your scheduled surgery, the study intervention will begin. The intervention includes meeting with a specially trained therapist on the study team, called a Perioperative Wellness Partner, and participating in a therapeutic technique called behavioral activation. The basic premise of behavioral activation is to help people with mental health problems to engage in activities that are reinforcing or meaningful and guided by their personal values. The goal of treatment is to gradually increase engagement in activities that have been shown to improve mood. Your Perioperative Wellness Partner will help you to adapt the intervention by choosing activities, per your preference. You should check with your physicians if there is any question about the safety of any physical activities that are included in your behavioral activation plan.

Behavioral activation will occur via telehealth or in person, and will begin pre-operatively, with sessions approximately weekly, per your preference. If your hospital stay is more than 1 week, the behavioral activation can continue weekly in this setting, if you like. Finally, after discharge, behavioral activation will continue, approximately weekly, out to 3 months after your surgery.

As part of this intervention bundle, your medications will be reviewed, and optimized by a psychiatrist and pharmacist on our team in consultation with your physician. Medication optimization sometimes includes adjusting the doses of anti-depressants and discontinuing medications that are harmful for brain health. Medication optimization consists of a simple set of principles: reconcile the patient's medications, identify the patient's likely need for, and interest in, a medication adjustment, make the adjustment, and assess the patient's response to that adjustment.

After your surgery, a member of the study team will visit you briefly in the hospital to ask a few questions about your thinking and memory, to ask if you experience any changes in your mental status like confusion. This visit will only take about 5 minutes, and if you stay in the hospital more than 12 hours, we will visit 2 times per day for up to 3 days. If you leave the hospital in less than 3 days, we can call and ask the questions on the telephone (for up to 3 days after surgery). If you have a care partner at home, and if you give your consent, we would also like to ask your care partner if they notice any changes in your thinking. This can be asked by survey which could be sent to them by mail or email if they prefer, and we would like to follow up with them once per week for 1 month after your surgery.

We may access your medical record throughout your participation as well as up to an additional 1 year to verify your completed surveys and to follow-up when you have had any medical complications following your surgery. Your medical record contains private, protected health information, which is information that can personally identify you. Specifically, we will access/use information such as your name, date of birth, and diagnosis. The research team only collects existing medical information and will not create or add any information to your medical record.

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

We would like to use the data 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 persistent pain, 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.

We may share your data 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 data 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 for use in future research studies indefinitely and cannot be removed.

Please place your initials in the blank next to Yes or No for the questions below:

My data may be stored and used for future research as described above?

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

Unless you agree to future use as described above, your private information including data collected as part of this study will not be used or distributed for future research studies, even if identifiers are removed.

Audio /Video Recording

One aspect of this study involves making audio recordings of your intervention sessions. These recordings will routinely be made during visits (by phone, in-person, or by Zoom if you prefer) with your Perioperative Wellness Partner so that they can later be reviewed by members of the study team. If you prefer to meet for your sessions by Zoom, then the recordings could also include video, if you agree to that. If you agree, we would also like to audio record the brief interview after the last study visit. The purpose of the recordings is for tracking quality and consistency of the study intervention, as well as making adaptations to the intervention. The recordings will be destroyed at the conclusion of the study.

Do you agree to Audio/Video recording of study visits and interview?

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

HOW MANY PEOPLE WILL PARTICIPATE?

Up to 70 people will take part in this study conducted by investigators at Washington University.

Up to 45 patients will participate; additionally, up to 25 patients' caregivers, will be invited to participate in a phone interview about the patients' study participation.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately 4 months from today. The research team may review medical records during this period, and after your active participation has ended, up to 1 year.

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.

Unlikely but potential risks include increased risk of depression or anxiety, and errors in medication recommendations or medication withdrawal symptoms. The risk of medication withdrawal (i.e., from benzodiazepines) is mitigated by slowly tapering the dosages of these medications rather than stopping these medications abruptly. Patients who are identified as being acutely suicidal will be excluded from the study.

It is possible that answering the test questions may make you uncomfortable. You are free to refuse to answer any of the questions that we will ask you.

A 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. Although the study is designed to improve symptoms of depression and anxiety and other outcomes of care, there is no guarantee that the study participants will receive any clinical benefits by participating in the study.

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 receive mental health care through a provider of your choosing and consult with your provider about your prescriptions.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional 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. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

You will receive payment in the form of a reloadable debit card. The data collection visits at Baseline,

1, 2, 3 months, and post-End of Study data surveys and semi-structured interview, will be compensated at $25 per visit, up to $125 after completion of your participation.

WHO IS FUNDING THIS STUDY?

The National Institute of Mental Health (NIMH) is funding this research study. This means that the 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 Katie Holzer, 314-273-8841 or Theresa Cordner at 314-273-7921 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
- National Institute of Mental Health (NIMH)
- 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 be available to your health care providers who are not part of the research team.
- 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.

To help protect your confidentiality, we will code your completed surveys and computerized tests with a unique ID. All electronic data will be hosted on a password-protected, firewall-secured server that is only accessible to the research team through password-protected departmental computers.
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. Sharing this information will allow 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.

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

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?

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

- to send you the secure survey links so you can complete the consent form and/or surveys online
- to send you reminders to complete computerized surveys

Only the research team will have access to your email 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.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- 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 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.

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

_____ **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 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: Katie Holzer, 314-273-8841 or Theresa Cordner, 314-273-7921. If you experience a research-related injury, please contact: Katie Holzer, 314-273-8841.

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: 10/24/24.

_____ _____
(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)