Neural Basis of Human Working Memory

NCT ID: NCT07617506

8/13/2026

VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Neural Basis of Human Working Memory
Version Date:	6/18/2026
PI:	Dr. Christos Constantinidis, PhD

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

You are being asked to take part in this research study because you are undergoing stereo EEG (small wires with contacts that record activity on the surface of and deep inside the brain to study seizure activity – SEEG or depth electrode) monitoring at Vanderbilt. The goal of this study is to learn more about the brain activity underlying working memory, as well as other cognitive and psychiatric functions. Participating in the study can involve a number of activities depending on your interest, including filling out 6 questionnaires, resting quietly while we record your brain activity, and participating in a neurocognitive task while we record your brain activity and/or deliver electrical stimulation through the electrodes to temporarily alter brain activity. Participating in this study can also involve the implantation and use of electrodes capable of recording brain activity from the greater clinical level (macro) and single cell level (micro). In order to record brain activity and/or deliver stimulation, we may connect your electrodes to a research device called the Ripple Neuromed Summit system. It takes approximately 45 minutes to complete all 6 questionnaires, approximately 20 minutes to complete the brain recordings while you are resting quietly, and approximately 20-30 minutes for each session of the neurocognitive task you choose to complete. Different portions of the study activities can be performed on different days. You do not have to have a psychiatric disorder to participate in this study.

You will not directly benefit from participation in the study; however, we hope that the information that we gain from this study will help us to develop new treatments for patients with cognitive and psychiatric disorders. There is a risk of distress from filling out the psychiatric and cognitive questionnaires or participating in the neurocognitive tasks, although they are not designed to create stress or distress. Although we will make every effort to protect the confidentiality of your information, there is also a risk to privacy from participating in the study. There is a risk of experiencing a temporary

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side effect from the electrical stimulation delivered during the experiment. There is a risk of having a seizure with electrical stimulation. There is a risk of infection with any surgical procedure. The implantation of macro-micro research/clinical electrodes will not increase any risk otherwise present from regular clinical care.

You may stop participation in the study at any time. Your decision whether to participate in this study will not impact the care you receive at Vanderbilt.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

We are interested in learning more about the brain activity underlying working memory, a cognitive function that involves manipulating information for very shorts periods of time (seconds). We are also interested in learning about brain activity underlying other cognitive functions, as well as psychiatric functions. We hope that this information will help us to develop new therapies to treat cognitive and psychiatric disorders in the future.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:

- There is a risk of stress or distress from completing the cognitive and psychiatric questionnaires and/or participating in the neurocognitive tasks. This is not the intent of this study; however, some subjects may find it upsetting to think about cognitive or psychiatric symptoms or frustrating to complete a cognitive task.
- There is a risk of loss of privacy should the confidentiality of your study data be compromised. We will make every effort to protect the confidentiality of your data.
- There is a risk of experiencing a temporary side effect from the electrical stimulation delivered during the experiment. This could cause a symptom such as an involuntary movement, abnormal sensation, difficulty talking, or other neurologic symptom. If you experience such a

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symptom, we will immediately stop stimulation and the symptom will go away. We will test the stimulation settings prior to using them during the task so that we can determine whether they cause you any side effects.

- There is a risk of inducing a seizure with electrical stimulation delivered during the experiment. To minimize this risk a neurosurgeon or neurologist will be present during stimulation to monitor your EEG and symptoms.
- There is inherent risk of infection associated with any surgical procedure. The implantation of macro-micro research/clinical electrodes will not increase any risk otherwise present from regular clinical care.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study:
You will not directly benefit from this study. However, we hope that the work completed in this study will help us to understand the brain signaling underlying working memory and other cognitive functions, as well as psychiatric functions. Understanding the brain signaling of these processes will hopefully help us to further understand the dysfunctional brain signaling underlying cognitive impairment and psychiatric disorders. Ultimately, we hope that this will help us to develop improved treatments for cognitive impairment and psychiatric disorders in the future.

Procedures to be followed:
You may choose how many of the study activities to participate in depending on your time availability and interest.

There are 6 cognitive and psychiatric questionnaires which take approximately 45 minutes in total to complete. The Montreal Cognitive Assessment (MOCA) measures cognition and involves tasks such as remembering a set of words. The Center for Epidemiologic Studies Depression Scale – Revised (CESD-R) measures symptoms of depression and asks questions about things such as your mood and sleep. The Barratt Impulsiveness Scale (BIS11) is used to measure impulsivity and asks questions about things such as how you plan ahead. The State Trait Anxiety Inventory (STAI) measures anxiety and asks questions such as whether your feel nervous. The Yale-Brown Obsessive Compulsive Scale (YBOCS) measures symptoms of obsessive compulsive disorder and asks questions about obsessive thoughts and compulsive behaviors. The Behavioral Inhibition System/Behavioral Activation System (BIS/BAS) scale measures how you are motivated by rewards and punishments and asks questions such as what motivates you to take actions. If you participate in the resting brain recordings, we will ask you to rest quietly for approximately 20 minutes. During this time, we will record brain activity from your SEEG electrodes. Depending on the tasks performed, we will collect these recordings with either the clinical system or with our research recording system, the Ripple Neuromed Summit System. The Ripple

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Neuromed Summit System has been designed for research but is not approved by the FDA and is, therefore, considered investigational.

If you participate in a neurocognitive task while we record brain signals, we will ask you to view stimuli on a screen and press a button to indicate your response. During this time, we will record brain activity from your SEEG electrodes with our research recording system.

If you participate in a neurocognitive task while we stimulate your brain, we will first test stimulation settings to make sure that you do not have side effects with stimulation and that you are not able to perceive the stimulation. We will then ask you to complete a neurocognitive task involving viewing stimuli on a screen and pressing a button to indicate your response while we deliver electrical stimulation from our research system, the Ripple Neuromed Summit System, through your SEEG electrodes. The Ripple Neuromed Summit System will be used to generate the electrical stimulus that is delivered through your implanted electrodes during stimulation. Electrical stimulation through SEEG electrodes using a clinical stimulation system is routinely used in the epilepsy monitoring unit to help localize seizures and important brain functions and may be recommended for this purpose by your neurologist whether or not you participate in the study, but you may choose whether to also receive electrical stimulation while you participate in a neurocognitive task as part of this study. We expect to enroll a total of 100 patients in this study.

If you consent to macro-micro clinical/research electrode implantation, some of your clinical testing electrodes will be replaced by research/clinical electrodes. Clinical electrodes are used to collect recordings of local neural activity in targeted areas of interest in your brain. Research/clinical electrodes (or macro-micro electrodes) are capable of recording from single neuron cells in your brain (at the micro-level), in addition to routine clinical recording from areas of interest (macro-level). These clinical/research electrodes will only be implanted in areas previously planned for SEEG monitoring by your provider. No additional electrodes will be implanted due to research participation. Implanted macro-micro electrodes would replace otherwise used macro-electrodes, and as such, no additional risk will be added to clinical care.

Payments for your time spent taking part in this study or expenses:
You will receive $100 on completion of the study. We may ask you for your social security number and address before you are compensated for taking part in this study.

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You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Christos Constantinidis at **615-322-4229** or the research coordinator, Lucas Chang, at 615-421-3046. If you cannot reach the research staff, please page the study doctor at **615-835-4837**.
For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

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Reasons why the study doctor may take you out of this study:
The study doctor may take you out of this study if they determine that participation in the study is very distressing to you or if you experience significant side effects of stimulation.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way. If you decide to stop your participation in the study, we will immediately stop all study activities.

Clinical Trials Registry: A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Confidentiality:
All study data will be stored on a secure Vanderbilt server and an encrypted hard drive. Study information will be labeled with your study code and will not be directly linked to identifying information, although we will store a separate key linking your study code to identifying information on the encrypted study laptop to allow data collection. Only study staff within Vanderbilt University and Vanderbilt University Medical Center will be able to access study data.

After completion of the study, we will store data in a repository on a secure Vanderbilt server. This will allow the study data to be used in future research projects to continue to further our understanding of brain signaling. Only study staff approved by the Institutional Review Board will have access to this repository.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study, future research, or insurance purposes. Disclosures that you make yourself are also not protected.

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Privacy:
Any data and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your data. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:
You will not receive individual results regarding your participation in this study. However, if you are interested in receiving group level findings and any publications related to the study, we are more than happy to share them with you. Should you wish to receive information related to the findings of the study, please contact Dr. Constantinidis at Christos.Constantinidis.1@vanderbilt.edu or Lucas Chang at **lucas.m.chang@vu**mc.org.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers, insurance providers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

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How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

Please check Yes or No to the question below:

I consent to the implantation of macro-micro electrodes for research study purposes.

☐ **Yes** ☐ **No**

I have read this consent form, and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date _____ Signature of patient/volunteer _____

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Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

Time: _____

Consent for Data Storage and Future Research

You are being asked to give neural recordings, questionnaire responses, and participate in a neurocognitive task during brain stimulation for research. What we learn about you from this data will not be put in your health record. Your test results will not be shared with you or your doctor. No one else (like a relative, boss, or insurance company) will be given your test results.

You may have macro-micro clinical/research electrodes implanted as part of your SEEG surgery. You may answer 5 cognitive and psychiatric questionnaires. In total these will take approximately 40 minutes to complete. You may have neural signals from your SEEG electrodes recorded by a research recording system, the Ripple Neuromed Summit. If you perform these during rest it will take approximately 20 minutes, if this is done during a neurocognitive task it will take approximately 20-30 minutes per task you complete. You may participate in a neurocognitive task while neural stimulation is delivered through your SEEG electrodes using the research Ripple Neuromed Summit system and your task performance monitored. It takes approximately 20-30 minutes to perform each neurocognitive task.

Risks of the study include distress from filling out the psychiatric and cognitive questionnaires or participating in the neurocognitive tasks, although they are not designed to create stress or distress. Although we will make every effort to protect the confidentiality of your information, there is also a risk to privacy from participating in the study. There is a risk of experiencing a temporary side effect from the

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electrical stimulation delivered during the experiment. There is a risk of having a seizure with electrical stimulation. There is a risk of infection due to the invasive nature of the surgical procedure.

One risk of giving data and information for this research may be the release of your name that could link you to the stored data and/or the results of the tests run on your data.

To prevent this, this data will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only Dr. Christos Constantinidis and his study staff will have access to your name.

Your data will be kept for an unknown length of time (maybe years) for future research. The data will be destroyed when it is no longer needed.

Your data may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

Your data and information about you may be made available to others to use for research. To protect your privacy, we will not release your name.

You will not receive any benefit as a result of the tests done on your data and information. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Giving data for research is your free choice and you may be in the study even if you do not want your information and data used or stored for future research.

Date _____ Signature of patient/volunteer _____

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