VA INFORMED CONSENT PROCESS CHECKLIST

Complete this checklist for each consent obtained and file with the original informed consent document

RESEARCH STUDY IDENTIFICATION (Required information)
STUDY TITLE: _____ **PI: _____** **NAME OF STUDY TEAM MEMBER OBTAINING CONSENT:_____** **ROLE OF STUDY TEAM MEMBER OBTAINING CONSENT: _____**

RESEARCH SUBJECT IDENTIFICATION: (Required information)

Last Name	First Name	Mid. Init.	Last-4 SSN	Todays Date (mm/dd/yy)
			| | |	/ /

A.	**Date ALL required SIGNATURES (Subject, Witness (If required by IRB) and Person Obtaining Consent), their PRINTED NAMES and the DATES they signed the informed consent document (ICD) have been Checked and Verified Accurate and appear in the proper location**
B.	**DATE AND TIME (ICD) WAS REVIEWED AND DEEMED COMPLETE AND VALID** ****Must be prior to date/time of Subject's First Study Activity****
C.	**DATE AND TIME OF THE SUBJECT'S FIRST STUDY ACTIVITY OR INVOLVEMENT**
	Verify and Initial each requirement below.
1.	**Informed consent and HIPAA Authorization, if required by VA-IRB was obtained from this subject prior to study participation.**
2.	**A VA Scope of Practice Form has been signed by the PI and approved by the VA IRB which designates me as an authorized agent of the PI and qualified to obtain consent for this study.**
3.	**This prospective subject was given adequate time necessary to carefully and fully read the Informed consent document (ICD) and all questions were answered to his/her satisfaction.**
4.	**All aspects of this subject's study involvement, including the purpose of the study, known and potential risks, possible benefits and alternatives to study participation were explained and discussed prior to subject signing the ICD.**
5.	**If required, a scanned image of the Research Enrollment Note, Consent Form and/or HIPAA Authorization will be entered into the subject's electronic medical record (CPRS).**
6.	***Subject has been consented using the most recently approved, VA date-stamped version of the consent form (VA Form 10-1086) and HIPAA Authorization Form (VA Form 10-0493).***
7.	**A copy of the completed and signed, original informed consent document has been issued to this subject and the subject was instructed to retain that copy for reference and to ask any and all questions that might arise throughout their study involvement.**
8.	**The subject has been shown where in the ICD to locate study team phone number(s) and the phone number of the VAAAHS IRB Coordinator. The subject has been reminded to call with any questions or concerns. Cathy Kaczmarek @ 734.845.3439**
9.	**The subject has been informed that participation is entirely voluntary and that they may withdraw their participation at any time and for any reason.**
10.	**Original ICDs and all copies are printed and issued as single-sided documents and that the original signed ICD must be kept in the investigator's project files on VA property.**
11.	**Upon completion of the Informed Consent Process, this subject's name was added to the Master List of All Subjects. [Per revised VHA Handbook 1200.05 (11/12/14) a MLS is no longer required, but a list of all enrolled participants is considered good research practice.]**
12.	**I know I can contact the VAAAHS IRB Coordinator at 734.845.3439 or the Research Compliance Officer at 734.845.4013 if I have questions or concerns regarding the consent of this or any individual considering study participation.**

ORIGINAL FORM VERSION: 4/15/09. REVISIONS: 9/17/09, 10/30/09, 11/30/09, 12/07/11, 2/27/12, 10/7/13 2/19/14, 4/1/14, 6/18/14, 12/19/14, 4/27/15

Title of Study:	**Promoting Adaptive Neuroplasticity in Mild Cognitive Impairment**	
Principal Investigator:	**Benjamin M. Hampstead, Ph.D.**	**VAMC**: VA Ann Arbor Healthcare System

PURPOSE OF RESEARCH STUDY:

You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study**.** It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. You will not give up any legal rights by signing this form

DESCRIPTION:

The general purpose of this study is to examine the effects of two types of treatments for memory impairment in those with mild cognitive impairment (MCI). One form of treatment is cognitive rehabilitation, which involves teaching you new ways to learn and remember information. The second form of treatment uses a type of electrical brain stimulation called transcranial direct current stimulation (tDCS) to increase activity in certain brain areas that may be involved with memory. We will use brain imaging to see whether these treatments changed how you learn and remember information. We will also use cognitive tests and questionnaires to examine whether your memory (and related abilities) changed because of treatment.

General procedures:

1. You will take part in nine (9) sessions in which you complete cognitive testing, tDCS, and/or magnetic resonance imaging (MRI). The first 8 sessions will be performed within 2-3 weeks of each other, the last session will occur 3 months after the 8th session. This last session measures the long-term effects of treatment. If needed, transportation (e.g. University registered vehicle, cab) may also be provided to transport you to and from research related activities only.
2. The first cognitive testing session will last approximately between 85-120 minutes. For the MRI sessions, you may undergo MRI scanning where we will ask you to look at and remember information like faces and names and the location of objects within rooms. The MRI session will last approximately 60-70 minutes. You will have the option of utilizing a mock scanner located in 1433 East Hall (530 Church Street, Ann Arbor, MI 48109) at the University of Michigan prior to the actual fMRI session. The mock scanner will allow you to get familiar with the scanner environment and procedures. There are no magnetic fields involved with the mock scanner and no data will be collected from the mock scanner.

RESEARCH SUBJECT IDENTIFICATION: (Required information)

			| | |	/ /
Last Name	**First Name**	**Mid. Init.**	**Last-4 SSN**	**Todays Date (mm/dd/yy)**

The mock scanner will require up to 1 additional (~20 minute) session, although we will typically attempt to add this onto the first cognitive testing session. There will be 3 MRI sessions (before treatment, after treatment, a 3 month follow-up).

a. We will also test your memory for the information seen in the scanner. This will occur during and/or after the MRI is performed. Individuals who do not undergo MRI will perform these activities in a quiet office. This will take about 45 minutes.

3. You will engage in structured cognitive activities with a research staff member on each of 5 days between the MRI sessions. These activities include things like memory quizzes where you recall recent and past events or where you learn different ways to structure information you are trying to remember. We will also collect digital audio recordings of conversations that occur during these sessions. In addition, you will also receive either real or fake tDCS for 20 minutes as you receive the cognitive rehabilitation. These sessions will last about 60-75 minutes (depending on how long it takes to place the tDCS electrodes).

ENROLLMENT CRITERIA:

- We will enroll 225 patients who have been diagnosed with mild cognitive impairment (MCI).
- Exclusion criteria include: a history of
  - other neurologic conditions that may be responsible for the cognitive problems (e.g., stroke, epilepsy).
  - mental illness (e.g., severe refractory depression, bipolar disorder, schizophrenia
  - sensory (especially visual) impairments that limit the ability to take part in the study
  - learning or attentional disorder
  - history of (or current) alcohol or drug abuse/dependence

- You will also complete an MRI safety questionnaire to make sure you can take part in this study.
- Some participants may receive just the stimulation and behavioral portions of the study if they cannot undergo MRI scanning.

Each session will consist of one or more of the following activities:

1. Cognitive Testing: You will be asked to complete some “paper and pencil” activities, some of which are done by speaking to one another while others are done on paper. We also use a number of computerized tests, some of which include eye tracking that allows us to know where you are looking on the computer screen. This lets us make sure that you were paying attention to the test and better understand how you were performing the test. All of these tests are necessary to make sure that you are eligible for this study. Some of the tests will be repeated after treatment to measure any changes that may occur.

2. Transcranial direct current stimulation (tDCS): Steps involved in tDCS include:
   Step 1. You will receive tDCS at the University of Michigan. You will sit in a comfortable chair as we measure different points on your head. This lets us determine where to place the electrodes.

   Step 2. We will place the electrodes on the points we measured in Step 1. We will use a head strap, cap, or netting to hold the electrodes in place. These straps or caps will be tight but not painful. This is necessary to keep the electrodes in contact with your scalp, which is how the electricity is

delivered. Please tell us if the strap or cap hurts and we will adjust it.

Step 3. A small amount of saline solution (salt water) or gel will be placed between the electrode and your scalp. It may be necessary to move your hair to make sure the electrode is accurately placed. This helps the electric current flow more efficiently. We may wet the electrodes from time to time during the session. This may cause some saline to drip down your head. We will provide a towel. **Do not use any hair gels or other products on days you will be receiving tDCS since this can prevent stimulation from having an effect.** It may be necessary for you to wash your hair at a sink within our office in order to remove any hair products. We will provide all shampoo and towels.

Step 4. Once the electrodes have been placed, we will slowly increase the electric current. Many people report having a tickling or slight burning sensation that usually goes away after a short period of time. Other people feel these sensations throughout the entire session. Other people never feel anything. All of these sensations are normal.

Step 5. Once started, stimulation sessions will last 20 minutes using a current of up to 2mA (2 miliamps). There may also be a "sham" (fake) stimulation condition that does not provide enough electrical current to affect the brain. This sham condition lets us measure the effects of "real" stimulation.

Step 6. Once stimulation has started, you will begin the structured cognitive activities. During this time, a research team member will guide you through a series of questions and activities. We will record your responses so that we can later measure how effective these activities were.

Step 6. After stimulation is finished, we will ask you to complete a questionnaire about your experience with tDCS so that we can monitor safety issues.

- Please tell us if the stimulation becomes painful. You are free to stop at any time.

3. Functional Magnetic Resonance Imaging (fMRI): You will lie on a bed that is moved into the scanner. Pictures of your brain will be taken to show its structure as well as its function during the memory tasks. There are no injections required. These pictures will allow investigators to study changes occurring in brain blood flow during the tasks and compare it with how you performed on the memory tasks. We will also collect some scans that look at the structure of your brain. You will be interacting with the investigator(s), trained research assistant(s), and MRI technician(s) during these sessions. You will receive one or more MRI scans during this study.

RISKS:

Cognitive testing - These procedures are entirely non-invasive and painless. It is possible that you will become frustrated during these tasks or while completing questions about your mood or past emotional events. If this occurs, you may request a break from the procedure(s). If you become so upset that you cannot continue, you may ask to be withdrawn.

Magnetic Resonance Imaging (MRI): MRI is a very common test used by physicians. Its only known risk is that it can cause a metal implant or foreign body in the eye, brain or other organ (including pacemakers, aneurysm clips, shrapnel, metal fragments, orthopedic pins, screws, or plates, IUDs, or piercings that you cannot remove) to move, which could cause serious harm and even be fatal. It is very important to know if you have any metal in your body. If there is, you will not be allowed to undergo the MRI scan. If this precaution is taken, MRI scanning is safe. A small percentage of people are unable to tolerate MRI scanning because they are claustrophobic (they become uncomfortable in the enclosed space of the

scanner). If you have a history of this, you will not participate in this study. If you become uncomfortable while in the scanner, you will be removed at once. We may review your medical history with a family member or close friend to make sure you can undergo MRI.

The Food and Drug Administration (FDA) approved the scanner used in this study for diagnostic purposes. There is no evidence that it is harmful.

The following are potential risks for MRI:
[1] There is a minor risk of discomfort or anxiety from being in the confined space of the MRI scanner. We will provide pads and blankets to make you as comfortable as possible. You will be able to talk to us during the study if needed, and you will be able let us know right away if you want to stop the study and get out of the scanner.

[2] The MRI scanner makes loud, vibrating noises. You will wear foam earplugs to reduce the loud noises made by the scanner and prevent any hearing damage.

[3] Some studies, like this one, have the potential to cause "peripheral nerve stimulation" (PNS). PNS is a light touching sensation on the skin surface, lasting only for a few seconds. It may cause mild discomfort, but is not harmful to you. The MRI machine is operated within FDA guidelines so the potential for inducing PNS is low.

[4] Sometimes, subjects report a temporary, slight dizziness, light-headedness or nausea during or immediately after the scanning session. If you feel dizzy or light-headed, we will have you get up slowly from the scanner.

[5] Because the strong electromagnetic fields can move metal objects and cause heating, there is a risk that loose objects (jewelry, keys) outside your body could be accelerated by the magnetic field and strike you, causing you injury. We require you to remove all jewelry for this reason. There is also a risk that the magnetic fields could disturb a metal fragment in your body, interfere with an implanted device, such as a pacemaker or neurostimulator, or cause metal (including foil-backed medication patches) on or in your body to heat up, causing you harm. We keep the environment around the MRI scanner completely free of loose metal objects that could be moved by the magnetic field, and we will make sure that you have no metal on your body that could be affected by the MRI scanner. We will also ask you questions and have you complete an MRI screening form to make sure that you have no metal inside your body that would cause you harm during the MRI scan.

[6] There is the potential that a magnetic resonance image may reveal an abnormality that is already in your body, such as a cyst or tumor. Many such abnormalities are not clinically significant, but you may need or want to investigate them further. Such a finding might require additional studies, and maybe even treatment, which would not be paid for by the investigators, the sponsor, or the University of Michigan.

[7] If you believe there is any possibility of having metal in your body, an X-Ray can be performed to verify this. There will be no charge to you for this procedure.

[8] Due to the investigational nature of this study, there may be risks, discomforts or side effects that are not yet known.

[9] A copy of your MRI scan may be sent to collaborators in order to develop models that show how much electrical current actually reached your brain. Scans will include only your study identification number. They will not include any personal identifiers. Scans will be transferred using a secure process that complies with VA regulations. Our collaborators will only use these scans while they are developing the electrical current models. They will not keep any data.

[10] A copy of your MRI scan may be uploaded to NeuroQuant in order to help us to better understand the relationship between neural integrity and cognitive functioning. Scans will be transferred using a secure process that complies with VA regulations. NeuroQuant will only use these scans while they are generating comprehensive volumetric reports. They will not keep any data.

Transcranial direct current stimulation (tDCS):

tDCS is an investigational device. It has been used in thousands of individuals and laboratories all over the world. The available evidence suggests that it is safe. However, it is investigational in nature, which means that we are doing these studies to learn more about tDCS.

The most common side effects associated with tDCS based on the available scientific data are:

Sensations under the electrode: These sensations usually stop shortly after tDCS begins but can sometimes continue throughout and for a brief period after tDCS.

- Mild tingling
- Light itching
- Slight burning sensation
- Discomfort

Effects reported that occur ONLY during tDCS:

- Visual sensation during switching on and off the stimulation

Other effects that can occur both during and after tDCS include:

- Fatigue
- Skin redness
- Headache
- Changes in concentration, memory, or other cognitive abilities. This is partially what we will be testing.

Additionally the following rare side effects have been described in previous studies that used tDCS:

- Nausea
- Nervousness
- It is also possible that the electric current can cause a burn on your skin. This is unlikely because we are using a smaller dose than what is known to cause burns and because we use saline or gel to reduce electrical resistance that leads to burns.
- A shock-like sensation at the initiation of tDCS was reported in one participant.
- Changes in the activity of the prefrontal region (front of your head) have the potential to induce sudden changes in your mood. Hypomania has been reported in a few patients receiving tDCS for bipolar disorder and depression but never in normal controls. Subjects with a history of bipolar

disorder will be excluded from the study.

At this time, tDCS has never been reported to cause a seizure in any patient population. Seizures are, however, theoretically possible and a seizure plan is in place for such an unlikely event.

Importantly, the majority of the above side effects have been also reported in association with sham (fake) tDCS, even with similar rates. The table below comes from a recent review of tDCS safety and shows the percentage of studies reporting these common sensations These data suggest that other factors may cause these sensations, such as your expectations or the pressure of head straps or caps.

Sensation	Real tDCS	Fake tDCS
Itching	39.3%	32.9%
Tingling	22.2%	18.3%
Headache	14.8%	16.2%
Burning	8.7%	10%
Discomfort	10.4%	13.4%

Due to the investigational nature of this study, there may be risks, discomforts or side effects that are not yet known.

The researchers will try to minimize these risks by:
1. Ensuring patients are fully informed of the risks during the current session.
2. Adhering to best-practice standards for cognitive/emotional testing, fMRI, and tDCS.

Although unlikely, it is possible that confidentiality will be breached.

BENEFITS:

The goal of the study is to investigate methods for improving learning and memory in those who are experiencing memory problems. Therefore, you may experience some improvement in your memory by taking part. The results of the study may provide information that could eventually help others.

ALTERNATE COURSES OF ACTION:

There are no alternate forms of treatment other than your ongoing clinical and medical care under your primary healthcare provider. Your participation is voluntary and you have the right to refuse to be in this study. You can stop at any time after giving your consent. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled. The study investigator and/or sponsor may stop you from taking part in this study at any time if they decide it is in your best interest or if you do not follow study instructions. We will give you a copy of this consent form to keep.

STATEMENT OF RESEARCH RESULTS:

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the recruiting

status and methods that will be used in this study.

We will keep information about you strictly confidential. The study staff will keep your study files locked in a file cabinet in a private office. People other than those doing this research study may have access to your medical and study records including:

- Food and Drug Administration (FDA)
- The Office for Human Research Protections
- The Government Accountability Office (GAO)
- The Office of Research Oversight (ORO)
- The Inspector General
- The VA Research Compliance Officer
- VA research staff within the VA Hospital or at the University of Michigan (when data is stored at UM)
- Data Safety Monitoring Board (if applicable)
- Any appropriate state or federal government agencies that make rules and policy about how research is done that are not listed above

We will keep your records private to the extent required by law. However, we may be required to release your record if we receive a subpoena or a court order. We will use a study number rather than your name on study records when we can. Your name and other facts that might point to you will not appear when we present this study or publish its results.

If you take part in the MRI portions of the study, there are two potential risks to confidentiality. First, the date that the scans were performed may be embedded in the scans. This date is considered a type of identifiable information. However, only your participant number (e.g., MM001) will be used to identify your brain scans and the appointment is scheduled under the study leader (Dr. Hampstead). These steps make it very unlikely that anyone could identify you. Second, it is theoretically possible that some type of biometric data (e.g., the shape of your head or brain) could somehow be used to identify you. This is also very unlikely to result in your identification.

To better protect the private nature of your research information, the results from the behavioral, MRI, and tDCS will not be included in your medical record. These research results will be kept only in a research record. However, we may share the results of these tests with your primary doctors (e.g. neurologists) if it is deemed necessary to improve your medical care. A copy of your signed Informed Consent form and signed HIPAA Patient Authorization form will be included in your medical record.

All research records and/or identifiers will be maintained in accordance with the VA record retention schedule.

We may learn new things during the study that you may need to know. We can also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information.

SPECIAL CIRCUMSTANCES:
Eligibility for medical care at a VA Medical Center is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study.

You (and/or your insurance company) will not be charged for any study-related tests and/or procedures.

COMPENSATION:

You will be compensated for your participation in the study at the rate of $25 for each of the 9 sessions. The maximum for completing the entire study is $225. As noted above, you will complete 8 sessions ($200) within 2-3 weeks and the remaining session ($25) 3 months later. If you do not finish the study, you will be paid for the visits you have completed. Our research team will track your time in the study and we will use our records to determine payment amounts.

In select situations, we may provide you with transportation (e.g. cab service) to and from locations for research related activities (i.e., University of Michigan Commonwealth building, fMRI scanner). We may also arrange a hotel room during your time in the study. In this case, you may receive compensation for meals and other incidental expenses (M&IE) at the standard per diem rate for Ann Arbor, MI (up to $59 per day) for the days you are completing research related activities. We will not pay for any additional incidental expenses that you may incur, such as phone calls and movie rentals. If you choose to end your participation before the scheduled time, we will do our best to arrange earlier transportation. However, we cannot guarantee that alternative accommodations can be made outside of the originally scheduled transportation.

We will directly arrange and pay for hotel and/or transportation. You will receive your compensation (per diem and participation payment) as a whole in one check mailed to you after your participation is finished.

Should you quit the study before it is finished, you would be compensated only for those days that you actually participated. The study team will track and determine the amount of compensation.

If you are on Active Duty, you may only receive payments if you are off duty or on official leave.

Title of Study:	**Promoting Adaptive Neuroplasticity in Mild Cognitive Impairment**	
Principal Investigator:	**Benjamin M. Hampstead, Ph.D.**	**VAMC**: VA Ann Arbor Healthcare System

RESEARCH SUBJECT'S RIGHTS:

Dr. Hampstead or a member of his staff has explained this research study and answered all questions. The risks or discomforts and possible benefits of the study have been described. Other choices of available treatment have been explained. Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply for VA care and services that are not part of this study.

Participation in this study is entirely voluntary. You may refuse to participate. Refusal to participate will involve no penalty or loss of rights to which individuals are entitled. Participants may withdraw from this study at any time without penalty or loss of VA or other benefits. The VA will provide necessary medical treatment should you be injured by participation in this study. You will be treated for the injury at no cost to you, but no provisions have been made for additional compensation. No reimbursement, compensation or free medical care is offered by the University of Michigan. You may be among the veterans required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

In case there are medical problems, an injury, or if you have questions, concerns or complaints about the research study, you can contact member(s) of the research study team: Dr. Hampstead can be called at 734-763-9259 during the day and the emergency room can be contacted at after hours. The sponsor of this research study is Veterans Affairs.

You may contact the VA Human Studies coordinator at 734-845-3440 to ask questions about your rights as a research subject and to verify this study is reviewed and approved by the VA. You may also call when research study staff are not available or to discuss your questions or concerns with someone other than study staff. You may learn more about research at the VA Ann Arbor Healthcare System at www.annarbor.research.va.gov

I have been informed about my rights as a research subject, and I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

x_____	x_____	x_____
Signature of Subject	(Print Name)	**Todays Date (mm/dd/yy)**
x_____	x_____	x_____
Signature of person obtaining consent (Study personnel must be approved by VA IRB)	(Print Name)	**Todays Date (mm/dd/yy)**

IF MORE THAN ONE PAGE IS USED, EACH PAGE (VAF 10-1086) MUST BE CONSECUTIVELY NUMBERED.

Department of Veterans Affairs	**Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research**

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

VA Facility (Name and Address):

VA Ann Arbor Healthcare System
2215 Fuller Road, Ann Arbor, MI 48105

VA Principal Investigator (PI):	**PI Contact Information:**
Benjamin Hampstead, PhD	(734) 763-9259

Study Title:

Promoting Adaptive Neuroplasticity in Mild Cognitive Impairment

Purpose of Study:

The general purpose of this study is to examine the benefits of two types of treatments for memory impairment in those with mild cognitive impairment (MCI). One form of treatment is cognitive rehabilitation, which involves teaching you new ways to learn and remember information. The second form of treatment uses a type of electrical brain stimulation called transcranial direct current stimulation (tDCS) to increase activity in certain brain areas that may be involved with memory. We will use brain imaging to see whether these treatments changed how you learn and remember information. We will also use cognitive tests and questionnaires to examine whether your memory (and related abilities) improved because of treatment.

USE OF YOUR INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (IIHI):

Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and/or the VA research team members to access and use your past or present health information in addition to new health information they may collect for the study named above. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care.

Signing this authorization is completely voluntary. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you sign this authorization.

Your individually identifiable health information used for this VA study includes the information marked below:

☒ Information from your VA Health Records such as diagnoses, progress notes, medications, lab or radiology findings

☒ Specific information concerning:

☒ alcohol abuse ☒ drug abuse ☒ sickle cell anemia ☐ HIV

☒ Demographic Information such as name, age, race

☐ Billing or Financial Records

☒ Photographs, Digital Images, Video, or Audio Recordings

☐ Questionnaire, Survey, and/or Subject Diary

☐ Other as described:

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

USE OF YOUR DATA OR SPECIMENS FOR OTHER RESEARCH: (Instruction: When banking or further analysis is an **optional** research activity, complete page 5 and leave this section blank. If banking is a required research activity to store "Data" and/or "Specimen" for future use or if "Not Applicable" is selected, remove page 5 in its entirety.)

☒ Not Applicable - No Data or Specimen Banking for Other Research

An important part of this research is to save your

☐ Data

☐ Specimen

in a secure repository/bank for other research studies in the future. If you do not agree to allow this use of your data and/or specimen for future studies approved by the required committees, such as the Institutional Review Board, you will not be able to participate in this study.

DISCLOSURE: The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you.

Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.

☐ Non-VA Institutional Review Board (IRB) at _____
who will monitor the study

☐ Study Sponsor/Funding Source: _____
VA or non-VA person or entity who takes responsibility for; initiates, or funds this study

☒ Academic Affiliate (institution/name/employee/department): University of Michigan (when data is stored at UM)
A relationship with VA in the performance of this study

☒ Compliance and Safety Monitors: The Inspector General, The VA Research Compliance Officer/Research Staff
Advises the Sponsor or PI regarding the continuing safety of this study

☒ Other Federal agencies required to monitor or oversee research (such as FDA, OHRP, GAO):
US Food and Drug Administration (FDA) , The Office for Human Research Protections (OHRP),
The Government Accountability Office (GAO), The Office of Research Oversight (ORO)

☐ A Non-Profit Corporation (name and specific purpose):

☒ Other (e.g. name of contractor and specific purpose):
Soterix Medical and City University of New York (CUNY), NeuroQuant; data analysis.

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial)**:**	**Subject SSN** (last 4 only)**:**	**Date of Birth:**

Note: *Offices within VA/VHA that are responsible for oversight of VA research such as the Office of Research Oversight (ORO), the Office of Research and Development (ORD), the VA Office of Inspector General, the VA Office of General Counsel, the VA IRB and Research and Development Committee may also have access to your information in the performance of their VA/VHA job duties.*

Access to your Individually Identifiable Health Information created or obtained in the course of this research: While this study is being conducted, you

☐ will have access to your research related health records

☒ will not have access to your research related health records

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

REVOCATION: If you sign this authorization you may change your mind and revoke or take back your permission at any time. You must do this in writing and must send your written request to the Principal Investigator for this study at the following address:

2101 Commonwealth Blvd, Suite C Ann Arbor, MI 48105

If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your written revocation is effective as soon as it is received by the study's Principal Investigator.

EXPIRATION: Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will:

☒ Expire at the end of this research study

☐ Data use and collection will expire at the end of this research study. Any study information that has been placed into a repository to be used for future research will not expire.

☐ Expire on the following date or event:

☐ Not expire

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial)**:**	**Subject SSN** (last 4 only)**:**	**Date of Birth:**

TO BE FILLED OUT BY THE SUBJECT

Research Subject Signature. This permission (authorization) has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint.

I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this form. I will be given a signed copy of this form for my records.

Signature of Research Subject _____ Date _____

Signature of Legal Representative (if applicable) _____ Date _____

To Sign for Research Subject (Attach authority to sign: Health Care Power of Attorney, Legal Guardian appointment, or Next of Kin if authorized by State Law)

Name of Legal Representative (please print) _____