The University of New Mexico Health Sciences Center

Consent and Authorization to Participate in a Research Study

Key Information for Individualized Targeting and Neuromodulation of Late-Life Depression

You are being invited to take part in a research study about how to make transcranial magnetic stimulation (TMS), an FDA-approved treatment, more effective for patients with late-life depression.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

Approximately 10-15% of elderly persons will suffer from **late life depression (LLD)**, but the treatments for this condition can have significant side effects, such as memory loss. Newer therapies such as transcranial magnetic stimulation (TMS) don't seem to work as well in elderly people, and it is not understood why this is the case.

Our *long-term goal* is to develop safer, more effective treatments for LLD that improve functioning, and prolong quality of life. This purpose of this study is to **use brain scans (MRI) to help make TMS possibly more effective for elderly people**, by directing the TMS to a specific brain area in each person. A total of 16 persons will be recruited for this study.

In this study, each subject will answer questionnaires, answer test questions, and undergo magnetic resonance imaging (MRI). Each person will then receive TMS for 30 separate sessions. They will repeat the tests after 15 sessions and after 30 sessions. Participation in this research will last about 2 months.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might choose to volunteer for this study, because you are interested in getting TMS for your depression. You might also choose to volunteer for this study because you wish to contribute to the scientific knowledge about how TMS works. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might not choose to volunteer for this study, because you do not wish to receive TMS or you do not have depression. You also might not choose to volunteer because you do not want to answer cognitive questions, or undergo a brain scan. For a complete description of the risks, refer to the Detailed Consent/Appendix

Alternative treatments that might be advantageous to you could be antidepressant medications, psychotherapy, electroconvulsive therapy, or TMS outside of this study. For a complete description of alternate treatment/procedures, refer to the Detailed Consent/Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Dr. Davin Quinn of the University of New Mexico Health Sciences Center, Department of Psychiatry and Behavioral Sciences. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, his contact information is 505-272-9494 and dquinn@salud.unm.edu.

If you have any questions or concerns about your rights as a volunteer in this research, contact staff in the University of New Mexico Health Sciences (UNMHSC) Human Research Review Committee (HRRC) between the business hours of 8AM and 5PM, Mountain Standard Time (MST), Monday-Friday at 505-272-1129.

DETAILED CONSENT

Version #1

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

If you have any of the conditions below, you would not qualify for this study.

a) Current diagnosis of bipolar disorder, schizophrenia, schizoaffective disorder, or any other psychotic disorder
b) Any substance use disorder, with active use within the last 3 months
c) Legal or mental incompetency, or having a legally appointed representative
d) Unstable medical illness, or hospitalization within 3 weeks of study entry
e) Current diagnosis of a neurological disorder or neurocognitive disorder
f) Prior neurosurgical procedure
g) History of seizure
h) History of ECT treatment within the past three months
i) History of any previous TMS treatment
j) Any reason making it unsafe to obtain magnetic resonance imaging (MRI) safely
k) Pregnancy

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at the UNM Psychiatric Neuromodulation Lab, located on the 2nd floor of the Center for Psychiatry Research, Pete and Nancy Domenici Hall, on the UNM North Campus, 1101 Yale Boulevard NE, Albuquerque, NM, 87106. You will need to come for 3 testing visits, as well as 30 TMS session visits, during the study. Each of the testing visits will take about 2 hours. Each of the TMS visits will take about 60 minutes. The total amount of time you will be asked to volunteer for this study is 36 hours over the next 2 months.

WHAT WILL YOU BE ASKED TO DO?

In this study you will be asked to do the following:

Baseline Visit (Session 1): Give Demographic Data (15 minutes): As part of the first Visit, your basic demographic data may be noted down, including age, gender, economic status, education level, handedness, and your use of common stimulants such as caffeine.

Baseline Visit (Session 1): Complete Cognitive, Emotional, and Behavioral Assessments (45 minutes): You will be asked to fill out questionnaires about anxiety and depression symptoms, and how well you are functioning in your life. You will be asked to answer test questions using paper and pencil or a computer that will assess your memory, attention, and other brain functions.

Baseline Visit (Session 1): Magnetic Resonance Imaging (60 minutes): You will be asked to lie down on a table and be placed into a long donut-shaped magnet. During the scan, you will be asked to rest quietly or to fixate on a dot on a screen in front of you. Images of your brain will be used to determine where the TMS should be given. Any female over 18 who thinks she may be pregnant will complete a urine pregnancy screen before the MRI scan. Results of pregnancy screens will be kept strictly confidential as per UNM policy. Urine samples will be disposed of immediately after testing. The MRI scan is being done to answer research questions, not to examine your brain for medical reasons. This MRI scan is not a substitute for one a doctor would order. The research scan may not show problems that may be picked up by a clinical MRI scan.

First 15 rTMS sessions (Sessions 2-16) (60 minutes each): After the Baseline Visit, you will be scheduled to receive 15 daily TMS sessions for depression at the Psychiatric Neuromodulation Laboratory (only on weekdays). TMS is delivered with the Magventure MagPro, an FDA-approved device for treatment of major depressive disorder. At each session, you will be seated in a comfortable padded chair with adjustable foot, arm, back, and head rests. At the first session, the correct dose for your brain will be calculated, by using small sensors attached to your right hand. Increasing magnetic pulses are delivered to the motor part of your brain until a small twitch occurs in your hand at least 50% of the time.
You will then be asked to wear small tracking markers on your forehead, and a camera will detect where your head is and follow it if you move. The TMS coil is then placed on the scalp location directly over the area of the brain determined by MRI for delivery of stimulation. A camera connected to the targeting computer will keep track of your head movements.
TMS is then delivered to your brain according to widely accepted clinical treatment parameters for major depressive disorder. Stimulation strength may be adjusted in the first week to help with comfort. Once each week you will answer a questionnaire about depressive symptoms.

Mid-Point Visit (Session 17): Following completion of sessions 2 through 16, on the next weekday, you will repeat all the assessments and MRI. Just like in the UNM TMS clinic, if there is not a 25% decrease in your depression scores compared to the Baseline Visit, you will be switched to opposite side TMS for the next 15 sessions. This is the same clinical protocol as is performed in the routine delivery of TMS at the UNM TMS Clinic.

Second 15 rTMS sessions (Sessions 18-32): After the Mid-Point Visit, you will be scheduled to receive the second set of 15 daily TMS sessions for depression at the Psychiatric Neuromodulation Laboratory (again only on weekdays).

End-Point Visit (Session 33): Following completion of the sessions 18-32, you will repeat all assessments and MRI one more time.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Participation in this study for subjects with late life depression may involve minor risks and discomforts associated with TMS sessions, possible breach of confidentiality risk, behavioral testing, or MRI.

TMS: Magnetic pulses delivered to the scalp may cause several common side effects, including muscle twitching during stimulation, (>90%), scalp "pricking" sensation during stimulation (>90%), mild headache afterward (30%), mild restlessness (10%), mild sleep changes (10%), mild fatigue (10%), or nerve pain

(<1%). Scalp sensation typically goes away as treatment sessions proceed, but the stimulation intensity can be adjusted during the first five treatments to allow for less discomfort. If there is nerve pain, the study staff will adjust the angle of the coil to avoid this. The clicking noise generated by the TMS coil at high intensities has the potential to cause high-frequency hearing loss over time without any ear protection, therefore you will wear foam ear plugs during treatments. There are no cognitive side effects associated with TMS for depression, and there are no known long-term effects of TMS. The most serious risk of TMS is a seizure, but it is extremely rare. The risk of seizure with TMS that is conducted within safe conventional parameters is extremely low (<0.01%). Only 12 cases in the world's TMS literature have been described, when either patients with known epilepsy were given TMS, or amounts of stimulation exceeding recommended doses were given. Both of these scenarios are specifically excluded by the protocol. In the unlikely event of a seizure, emergency medical services are immediately called to bring you to acute medical treatment.

MRI: Radio and magnetic waves during MRI scans are not associated with any known adverse effects. MRI is non-invasive and considered minimal risk by the FDA and OHRP. However, the scanner is a large magnet, so it could move objects containing ferrous metal in the room during the scan. You will be screened using the MRI safety screening form prior to be being scanned. Participants with any MRI scanning contraindications will be excluded from study participation. Some people may be bothered by feelings of claustrophobia (<10%). The MRI also makes loud 'drum' beating noises during the study. Headphones are provided for protection. Rarely, large or recent tattoos can heat up during an MRI scan and cause skin irritation like a sunburn (<1%). No long-term harmful effects from MRI are known. However, since the effect of MRI on early development of the fetus is unknown, participants who are pregnant will not be allowed to go in the MRI. Females 18 years of age or older who suspect they may be pregnant will be asked to take a urine pregnancy test before being allowed to participate in the study. The pregnancy test results will only be shared with you.

Due to the very high sensitivity of MRI in detecting abnormalities, there is a risk of false-positive findings, identifying something on imaging studies that may or may not be important. This may result in anxiety and additional testing, possibly including a recommendation for clinical scans at your cost. The radiology report or other study data will not be put into your medical record unless you provide it to your physician. If the radiology report becomes part of your personal medical record, it may or may not have an effect on getting health insurance or life insurance in the future.

Cognitive and Behavioral Assessments. The symptom questionnaires and cognitive tests involved in the study have no foreseeable risk, besides possible fatigue or boredom. These are typically very mild risks. If you get tired during testing they are given a rest break or are rescheduled. There is also mild psychological stress inherent in discussing emotions and experiences related to depression.

One potential risk is breach of confidentiality related to collection of sensitive information. Confidentiality issues are significant since this study collects sensitive data, in particular with respect to mental health and substance use. Because personal information is gathered, there exists the risk of possible invasion of privacy. However, hard copy data is stored in locked cabinets in locked rooms within a locked, security-patrolled building; and there has never been a breach of confidentiality in our lab. Therefore we believe that the likelihood of invasion of privacy is minimal.

Special Precautions: You will be asked about any changes to medications or use of recreational substances or changes in eating/drinking habits at each assessment point. At study enrollment you will be asked to keep your medication use constant between the assessments, unless changes are medically recommended during that time, and that you should alert study personnel to any changes in your medications during the study period. You will be asked not to smoke cigarettes or drink coffee 1 hour prior to arrival for MRI/testing, and that you should bring any and all assistive devices or wearable prosthetics with them to study appointments, including hearing aids, glasses, contact lenses. You will be advised to notify study

personnel of any new medical issues or other medical symptoms.

Depending on public health guidelines, there may be a small increased risk of exposure to infection by participating in a research study. You may be required to wear a mask during your study visits and to observe hand hygiene and social distancing measures in order to participate in the study.

In the event that you cannot tolerate stimulation on one side prior to completing at least 15 sessions (due to side effects or worsening depression), you will be switched to opposite side stimulation prior to the Mid-Point Visit. If you are unable to tolerate both left and right stimulation due to side effects or worsening depression, you will be withdrawn from the study, and referred to psychiatric care through the UNM Mental Health Center, or a community mental health clinic of your choice. The study staff have brochures outlining mental health resources in the Albuquerque metropolitan area that they can provide to you. Additionally, Drs. Abbott and Quinn will make necessary referrals for you.

If at any you indicate suicidal ideation during a study session or on a study questionnaire, Drs. Quinn or Abbott will be immediately notified, and you will be evaluated by one of them for need for urgent or emergent psychiatric care. If determined to need urgent/emergent attention, you will be escorted to the UNM Psychiatric Emergency Service by the study staff, which is a 5 minute walk from the study area.

No special care or special equipment is needed to be enrolled in the study.

There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from participating in this study. However, similar to TMS done in a clinic, some people have experienced improvement in their depression symptoms when receiving TMS. If you take part in this study, the information learned may help others with your condition.

WHAT WILL IT COST YOU TO PARTICIPATE?

You may have to pay for the cost of getting to the study site and a parking fee.

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave information, or what the information is. Only the PIs and research technicians on the study will have access to *your personal identifying information (PII) or personal health information (PHI),* both electronically and physically. All of the information we collect about you will be coded with a unique research subject identifier (URSI) or other subject code and will be kept on password protected computers, and stored

securely in restricted and protected databases according to information security policies. The demographic and symptom data will be stored in the PI's locked office, and on the secure HSC network. A key linking PII and the URSI will be stored separately from the data, in the PI's locked office*, and only Dr. Quinn or the study coordinator will have access to that key*. The data *collected may* include information that may be considered sensitive or require additional protections such as HIV status, mental health information, and substance abuse information. At the end of the study, the record linking your name and other identifying information to your URSI (which the study data is labeled with) will be made unavailable to the research team; however, it will be kept indefinitely (forever) at the MRN in a confidential manner so that you may continue to have access to your MRI information.

You should know there are some circumstances in which we may have to show your information to other people because of safety concerns. For example, the law may require us to share your information with the following agencies and for the following reasons:

- The law requires us to share your information with authorities if you report information about a child or elder being abused
- If you pose a danger to yourself or someone else.
- A court or agencies, if you have a reportable disease or condition.
- Authorities, if you report information about a child being abused, if you pose a danger to yourself or someone else.

A Certificate of Confidentiality from the National Institutes of Health will be obtained to cover this research once funding is secured. The researchers with this Certificate of Confidentiality may not disclose or use the information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by the Certificate of Confidentiality cannot be disclosed to anyone who is not connected to the research. Except if, there is a federal, state, or local law that requires disclosure, (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate of Confidentiality cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by University of New Mexico which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. The study intervention will no longer be provided to you and may not be available for purchase. This may occur for a number of reasons.

The investigators will refer you to appropriate clinical services if you require them at time of withdrawal.

You may be removed from the study if:

- You are not able to follow the directions.
- You develop a condition that prevents you from participating in the study or meets exclusion criteria.
- They find that your participation in the study is more risk than benefit to you.
- The agency paying for the study chooses to stop the study early for a number of scientific reasons.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEACH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may not take part in this study if you are currently involved in another research study in which you receive a treatment. It is important to let the investigator and your doctor know if you are in another research study. You should discuss this with the investigator and your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should contact the study coordinator, CJ Ojeda, at 505-272-6972 or Dr. Quinn at 505-695-8565.

- You may also call the UNM Psychiatric Emergency Service at 505-272-2920 and discuss the matter with the psychiatrist on-call.

Either Dr. Quinn or the psychiatrist on-call will determine what type of treatment, if any, is best for you at that time.

It is important for you to understand that the University of New Mexico does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of New Mexico will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be up to you or your insurance company to pay for.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will receive $50 for each testing and MRI study Visit you complete, up to $150 dollars over three Visits, which equates to approximately $25 per hour. Compensation will be provided in the form of a merchandise card, as per HSC policy.

You will not receive compensation for the TMS sessions.

If you earn $600 or more by participating in research, it is potentially reportable for tax purposes.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESARCH TESTS?

Study results including behavioral assessments of depressive symptoms and cognitive test results may be shared with you at the conclusion of the study. Structural MRI will be read by a board-certified neuroradiologist and the results mailed directly to you. Functional MRI results, as they are experimental and not interpretable in a clinical context, will not be shared.

Incidental findings may be detected during MRI imaging. Once the the scan is read, you will receive an e-mail letting you know you can download your MRI report from the Participant Portal Homepage. If we find an abnormality that requires follow-up, we may also mail a copy or contact you and your doctor (with your permission) by phone to help answer questions and get the right follow-up care for you.

University of New Mexico is providing financial support for this study, in the form of a grant to the PI Dr. Quinn to carry out the research.

A description of this clinical trial will be available on 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 website at any time.

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 16 people to do so.

FUTURE USE OF YOUR PROTECTED HEALTH INFORMATION.

Identifiable information such as your name, medical record number or date of birth may be removed from the information collected in this study. After removal, the information may be used for future research or shared with other researchers without your additional informed consent.

HIPAA AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION (PHI).

As part of this study, we will be collecting health information about you and sharing it with others. This information is "protected" because it is identifiable or "linked" to you.

Protected Health Information (PHI)

By signing this Consent Document, as described in this consent form, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information includes results of physical and mental status exams, medical, surgical, and behavioral health histories, medication lists, and results of radiological and blood tests.

In addition to researchers and staff at UNMHS and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include health oversight activities and public health measures, safety, monitors, other sites in the study, companies that sponsor this study, government agencies such as Food and Drug Administration (FDA).

Right to Withdraw Your Authorization

Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. This is because the information used and created during the study may be analyzed for many years and it is not possible to know when this will be complete. Your health information will be used or disclosed as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send letter notifying them of your withdrawal to:

Dr. Davin Quinn
2600 Marble Avenue NE
Albuquerque New Mexico 87106

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before the date that your withdrawal is received.

If you become pregnant anytime during the study, you must inform the study doctor.

The researchers agree to only share your health information with the people listed in this document. Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form it will not affect your:

- Current or future healthcare at the University of New Mexico;
- Current or future payments to the University of New Mexico;
- Ability to enroll in any health plans; or
- Eligibility for benefits.

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to Dr. Davin Quinn to inform him of your decision.
- Researchers may use and release your health information already collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of New Mexico Health Sciences

Privacy Officer between the business hours of 8am and 5pm Mountain Pacific Time, Monday-Friday at (505) 272-1493.

The University of New Mexico Health Sciences Center

Consent and Authorization to Participate in a Research Study

APPENDICES

Appendix 1: Risks

Appendix 2: Alternative Treatments/Options

Appendix 3: Study Visits/Procedures

Appendix 4: Subject Information to be stored for future research (registry, database, contact list).

Appendix 5: Subject bio specimens to be stored for future research

Appendix 1: Risks

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Possible Risk/Side Effect	How often has it occurred?	How serious is it?	Can it be corrected?
Muscle twitching	It occurs very commonly	Not serious at all	No, but it occurs only during stimulation
Scalp sensation	It occurs very commonly	Not serious at all	No, but energy can be lowered in the first week until you get used to it
Headaches	It happens occasionally	It will not impact your overall health	Yes, you can use over the counter headache medicine
Sleep changes	It happens occasionally	It will not impact your overall health	Yes, you can use your usual means of sleeping better
Energy changes	It happens occasionally	It will not impact your overall health	No

Restlessness	It happens occasionally	It can be difficult to tolerate sometimes	Yes, if it is intolerable we can switch the side of stimulation
Hearing loss	Extremely rare	Serious	Yes, we will give you ear plugs
Seizure	Extremely rare	Serious	Yes, you will receive emergency medical evaluation
Claustrophobia (MRI)	It happens occasionally	It can be difficult to tolerate sometimes	No

Appendix 2: Alternative Treatments/Options

IF YOU DON'T' WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

Alternative treatments/options for treatment of major depression include:

1) Trying antidepressant medications
2) Trying psychotherapy
3) Trying electroconvulsive therapy
4) Trying TMS outside of this study

Appendix 3: Study Visits/Procedures

WHAT WILL YOU BE ASKED TO DO?

		STUDY PERIOD				
TIMEPOINT		Baseline Visit (Session #1)	First 15 TMS Treatments (Sessions #2-16)	Mid-Point Visit (Session #17)	Second 15 TMS Treatments Sessions (#18-32)	End-Point Visit (Session #33)
Eligibility screen		•				

Informed consent	•				
TMS		•		•	
MRI	•		•		•
Assessments					
Demographic Surveys	•				
Depression Surveys	•	•	•	•	•
Behavioral Surveys	•		•	•	•
Cognitive Tests	•		•		•

INFORMED CONSENT SIGNATURE PAGE

You are participating in this research study. This consent includes the following:

- Key Information Page
- Detailed Consent
- Appendices 1, 2, and 3

You will receive a copy of this consent form after it has been signed.

_____ _____

Signature of research subject **Date**

_____

Printed name of research subject

_____ _____

Printed name of [authorized] person obtaining informed consent/HIPAA Authorization

Date

_____

Signature of [authorized] person obtaining informed consent/HIPAA Authorization

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