Network-Targeted Neuromodulation for Nicotine Dependence in Schizophrenia

NCT06389266

1/30/2025

Study Title: Network-Targeted Brain Stimulation for Nicotine Dependence
Version Date: 08/27/2024
PI: Heather Burrell Ward, MD

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 invited to take part in a research study about the use of a technique of brain stimulation to reduce craving for individuals who use nicotine. We are enrolling individuals with and without psychosis, a disease that may affect the way you think. The method of brain stimulation is called transcranial magnetic stimulation (TMS).

The main purpose of this study is to learn how stimulating a network in your brain related to nicotine use influences those networks and craving for nicotine. We will stimulate your brain networks using TMS. Functional magnetic resonance imaging (fMRI) will be used to identify areas in your brain that we will stimulate and to examine the networks related to craving. In this study, we will test if TMS can be used to change brain networks in a way that also changes craving and nicotine use.

You will be asked to attend a total of 16 visits over about 4 weeks. Each visit will last between 1-2 hours with breaks. The study will involve interviews, questionnaires, computer tasks, an MRI, and TMS.

There are minor risks associated with this study. Answering some of the study questionnaires may cause stress or fatigue. The physical risks of the MRI are minimal, and a health questionnaire will be filled out before to determine if it is safe for you to complete the MRI. You may experience mild pain or headache during or after receiving TMS. This is generally transient and can be treated with over-the-counter pain medication. We will minimize any risk of hearing loss during TMS by having you wear earplugs for the entire procedure. We will also complete an evaluation of your medical history to ensure that it will be safe for you to receive TMS. There is no direct benefit to you from being in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

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

You are being asked to take part in this research study because you are a patient at the Vanderbilt University Medical Center or have previously stated a willingness to be contacted about research at Vanderbilt University Medical Center.

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.

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

Clinical Assessments: You may be uncomfortable answering questions about your history of mental health symptoms. This includes questions about psychotic experiences, anxiety, depression, childhood trauma, and social functioning. Because these questions are very personal, this information could be damaging to you if it was released. However, ID codes will be used in place of your name to safeguard your identity and keep all responses confidential (more information is presented about this in the section labelled Privacy).

Cognitive and Neuropsychological Tests: You may experience some mental fatigue and/or anxiety while you are taking the pen and paper neuropsychological and/or computerized cognitive tests. You may ask to take a break during testing if you are feeling tired or uncomfortable.

MRI of the Brain: MRI scanners of the type used in this study have never been shown to have any negative health effects for healthy persons. However, because of the strong magnetic field inside the scanner, persons who have magnetic life-support devices (e.g. pacemakers and aneurysm clips), metal body parts or other metallic implants (e.g. cochlear implants, IUDs) cannot be included in this study. Individuals who have welded metal must also be excluded because they may have metal specks embedded in their eyes that could be dangerous in the scanner, unless they get an X-Ray of their eyes. If you have metal pins or screws in bones in your arm, hands, hip, leg or foot, you may be able to participate, but you should mention this to the researchers, as they will need details to verify that you can participate.

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You will be required to lie as still as possible in the scanner for a relatively long period of time. Cushions and padding will be used to reduce discomfort. The scanner is very noisy at times. Earplugs or headphones will be used to muffle the noise. You will be asked to lie in a small, enclosed space for 60-90 minutes during the scan. This can make some people anxious. However, you will be able to talk to the researchers with an intercom during the entire session. You may stop the scan at any time. You will be paid for your time, even if you stop the scan early.

The images obtained during this study are not collected to look for a problem in your brain. However, if your scan shows something unusual, we will have a neuroradiologist (a doctor who is an expert in detecting problems on brain scans) look at your scan at no charge to you. If the neuroradiologist thinks that there is anything in the scan that warrants further attention, we will share the results with you. If there is a problem, and you request it , we will provide your doctor with the images. However, because the scans are being conducted solely for research, there will not be a formal report, and your doctor may want to order more detailed scans that would not be covered by the present study. Learning that there is something unusual on your MRI could cause you some distress.

TMS: The risks associated with TMS can be categorized as "More Common" and "Rare."

More Common:

Pain: As many as 20-40% of people having TMS experiences headaches – that is 4 in 10 participants. You may have pain – such as a headache, pain in your face or neck pain during or after TMS.

Rare:

Hearing Problems: The TMS procedure includes a loud clicking noise throughout. It is possible that you could experience a temporary change in your hearing. There is one report of someone whose hearing protection fell out who experienced permanent hearing loss from TMS. You will wear earplugs during the TMS to reduce the noise to prevent the risk of hearing problems. We will ask you to let us know immediately if your ear plug loosen, becomes detached or falls out. You will be promptly referred for hearing tests if you experience hearing loss, ringing in the ear, or ear fullness following completion of the TMS.

Seizures: TMS may very rarely cause a seizure. This is rare and occurs in less than 1 in 10,000 participants. A seizure may be thought of as a convulsion where a person's body shakes. Many seizures are not like this. Some have very mild symptoms. If you have a seizure, you will receive immediate medical care. You may be transferred to the emergency room. Experiencing a seizure

caused by TMS does not mean that you will have another seizure. Participants who had seizures from TMS have not had any continued seizure related health problems.

Syncope (Fainting): It is possible that you could faint during TMS. This does not happen often, but can happen if you are anxious, nervous, or have not eaten. You could immediately tell the study staff if you feel dizzy, lightheaded or that you might pass out. If you have any of the above symptoms, the TMS will be stopped immediately. You will be monitored until you are feeling better.

Concentration: TMS could cause changes in your attention and concentration. It could be related to some of the study procedures like wearing a tight cap or headband and positioning. This could also be related to other side effects like headache or sleepiness. These changes would be very mild. If this occurs you will experience these changes for less than 1 hour. These changes happen very rarely.

Mood: If you have depression or mood disorder, you may experience an episode of mania (an abnormally high mood that can be dangerous) when treated with TMS, although the risk is low. There have been rare reports of psychiatric problems such as psychotic symptoms (personality changes, acting irrationally and losing sense of reality), anxiety, agitation, suicidal thoughts (thoughts of killing or harming yourself) and insomnia (trouble sleeping). These problems have not been found to be more common in people with psychosis. In every case, these side effects from TMS did not last long, resolved after TMS was stopped or when medication was given. In a rare circumstance in which you experience suicidal thoughts, Dr. Ward or a covering physician will be contacted to provide care and, if necessary, arrange transportation to an emergency room for further care.

Dental Pain: The possibility of dental pain during TMS has been reported. If this happens to you, alert the study investigator. The TMS will be immediately stopped. This may mean that you have a cavity and that you need dental care. This dental pain should not lead to any lasting problems or complications.

Hallucinations: The possibility that hallucinations may increase in frequency as a result of TMS has been reported. If this happens to you, alert the study investigator. The TMS will be immediately stopped. You will be monitored until you are feeling better.

Although TMS has been used worldwide since 1984, there may be complications that are not yet known.

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Pregnancy: Because of the effects of TMS on the developing fetus are not known, you may not participate in this study if you are pregnant. You will be required to take a pregnancy test to verify that you are not pregnant before TMS will be given.

For the duration of the study, if you are engaged in sexual activity that could cause you or your partner(s) to become pregnant, you and your partner(s) must agree to use a highly effective method of birth control or abstain from sexual activity that could cause you or your partner(s) to become pregnant.

The methods of highly effective birth control for this study are below:

1. Contraceptive implant, such as Nexplanon or Implanon
2. Levonorgestrel or copper intrauterine device (IUD), such as Mirena, Skyla, ParaGard or Liletta
3. Permanent female sterilization, such as tubal ligation or Essure with confirmed tubal occlusion
4. Male partner(s) has had a vasectomy more than three months before study enrollment
5. Oral contraceptives pill, patch or ring
6. Injectable contraception, such as Depo Provera
7. Consistent use of a barrier method, such as diaphragm with spermicide or condoms

If you believe you have become pregnant while participating in this study, you must inform your study doctor immediately. In this case, the study doctor may order a pregnancy test, and you will be withdrawn from the study if you are pregnant.

Electromyography (EMG): The sticky pads used for EMG may cause skin irritation or redness. Taking the sticky pads off causes discomfort similar to when taking off a band-aid.

Breach of Confidentiality: All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. If at any point during the study sessions you express an intent to harm yourself or others or a researcher becomes concerned for your safety, the researcher will contact the primary investigator or another licensed mental health professional on the research team, who will speak with you about these concerns and discuss a safety plan with you. If safety cannot be guaranteed and/or planned for, and the mental health professional believes you may be a threat to yourself or others, then your confidentiality may be breached. In this situation, you may be taken to the Psychiatric Assessment Services (PAS) for a more thorough safety evaluation. If the study session is being completed over Zoom, the clinician would call 911 to your address. Breach of confidentiality due to materials collected during the study will be discussed more in the "Confidentiality" section.

Risks that are not known:

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All of the procedures outlined have been previously completed in past research studies, with the risks and discomforts described above. There may be unforeseeable risks associated with being in the study. The study team will work to minimize or lessen those risks and will closely monitor risks throughout the study. While TMS is an FDA-approved treatment for other psychiatric conditions, its use in this study is investigational, meaning non-FDA approved. There may be unknown or unforeseeable risks associated with participation.

Good effects that might result from this study:

The benefits to science and humankind that might result from this study: This study may result in a greater understanding of how brain networks contribute to craving and nicotine use and if TMS can be used to change these networks and reduce nicotine use. There is no expected immediate benefit to you from participating in the study.

Procedures to be followed:

You will be asked to attend a total of 16 visits over about 4 weeks. There is a screening visit to determine if you are eligible and would like to participate in the study, a total of 4 MRIs, and 10 sessions of TMS. The details of each study visit are described below:

1. **Screening Visit & Informed Consent:** At this visit, you will be asked to read and understand this Informed Consent document. Please let us know if you have any questions about what you read in this document. We will answer any questions you have. We will also point out some important information to you. You may take as long as you need to read this consent document. Once you have read and understood this document, you will be asked to sign and date the last page. We will ask you questions about this study to make sure you understand all the most important parts. We will give you a copy of this Informed Consent to take home with you. You may call us if you think of any questions, even if you have already completed the study. After you have decided you would like to participate, we will ask you questions, ask you to fill out questionnaires, complete neuropsychology testing that will measure your thinking, and ask you to provide a saliva sample for nicotine testing, and a urine sample for drug, pregnancy, and nicotine testing. We will also ask you to do a breath test to measure how much you smoke.

2. **TMS Visits:** You will attend a total of 10 TMS visits spread over 2 separate weeks (5 consecutive days each week. For one week, you will receive TMS targeted to one particular brain network, the default mode network, and for the other week you will receive TMS targeted to a particular brain region, the left dorsolateral prefrontal cortex, which is the same brain region used for TMS

treatment for depression. The order of the type of TMS you receive will be randomly determined (like the flip of a coin).

- For each TMS session, you will be seated in a chair. You will have Electromyography (EMG) electrodes – small metal plates – placed on your hands to monitor muscle movements. These electrodes will not hurt at all. The research team will place a coil that is about the size of a telephone receiver against your head. The coil is made up of wires that are covered in plastic. A researcher will hold the coil firmly, but comfortably, against your scalp. The coil produces a magnetic field about the size of the tip of your finger on the targeted part of your head that will briefly affect your brain. You will hear a clicking noise when the magnetic stimulation or pulse is delivered, and you might feel a twitch of your scalp muscle. This may feel like a tap or a pinch on your scalp. When the magnetic pulse is delivered, your fingers may twitch. The TMS coil will be placed on your scalp for the stimulation. If the stimulation is too unpleasant for you, we will turn down the strength of the TMS or stop the experiment. Because the click made by the TMS machine can be loud, you will be asked to wear earplugs during the TMS session.

  At each TMS session, we will ask you to complete some questionnaires, perform tests of your thinking and do either a breath test or a urine test to measure any nicotine use.

3. **MRI Visits:** There are 4 MRI visits in this study, 1 MRI visit will occur the week before and the week after each TMS week. An MRI is a machine that allows us to take pictures of a person's brain. It measures the shape and size of different brain regions and the connections between brain regions. It also allows us to see how hard different brain regions are working when you are resting or when you are doing a mental task. The MRI session will be carried out in one of the MRI scanners in the Vanderbilt University Institute of Imaging Sciences. The session will take approximately 60-90 minutes. You will begin by completing an MRI Screening form. You will be asked to remove all metal and magnetic objects from your body. Scanners are known to erase credit card strips, so you must leave your wallet in the control room. After you have reviewed the screening form with the staff member running the scanner, you will be given a chance to tour the scanner. You will begin the scan session by lying on your back on top of the scanner's gurney (movable table). Your head will be positioned within a device known as a head coil, which resembles a hockey helmet. To limit movement of your head during the scanning, inflatable pillows or foam will be placed around your head and inflated, and a light strap may be placed across your forehead. You will be asked to put in earplugs or to wear headphones to reduce the noise of the scanner. You may be asked to wear goggles to help you see the tasks during the scan. The gurney will then be moved so that your head and part of your body are in the scanner. You will be asked to lie very still in the MRI scanner.

For part of the time, you will be asked to lie quietly while resting so that we can measure the structure and level of connections between different regions of the brain.

You will also be asked to complete cognitive tasks while in the scanner. In each task you will be asked to make button presses to indicate your responses. These tasks are listed below:

- Cue-Induced Craving Task: We will show you pictures of smoking cigarettes or vaping nicotine. We will then ask you to rate how much you are currently craving a cigarette or vape. This task takes approximately 20 minutes to complete.

- Gradual Continuous Performance Task: You will see pictures of continuously changing city and mountain landscapes. You will be asked to respond (i.e. press the button) when you see pictures of cities but not when you see mountains. This task takes 10 minutes to complete.

During the MRI visits, we will also ask you to complete questionnaires, measure your nicotine use, and ask you to perform some cognitive tasks (which test your thinking) outside of the scanner.

4. Virtual Follow-Up Visit: One week after the last MRI visit, we will ask you to attend a brief virtual visit where we will ask you about your nicotine use, psychiatric symptoms, and any potential side effects. This visit may also occur by telephone and will take about 30 minutes.

Payments for your time spent taking part in this study or expenses:
You will be paid for each study visit that you complete, as shown in the table below, for a total of up to $525. Transportation costs may be reimbursed, or transportation may be arranged

Table 2. Study Visit Compensation

	Screening	MRI #1	TMS #1-5	MRI #2	MRI #3	TMS #6-10	MRI #4	Follow-Up
Visit Duration	2h	2h	1h/visit	2h	2h	1h/visit	2h	30min
Compensation		$50	$25/visit	$75	$50	$25/visit	$100	

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.

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Table 1. Study Visit Table

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21	Day 28^
Consent	X															
Demographics	X															
Medical History	X															
MRI Safety	X															
TMS Safety	X															
SCID	X															
Urine Drug Screen	X	X						X	X						X	
Pregnancy Test*	X															
Saliva NMR	X															
Nicotine Testing	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Nicotine Use	X															
PSECDI		X						X	X						X	
Recent Substance Use	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
TLFB	X	X						X	X						X	X
MAIA		X														
DERS-18		X														
BPRS		X						X	X						X	X
FTND		X						X	X						X	
Tiffany QSU		X						X	X						X	
MCQ-SF		X						X	X						X	
WSWS		X						X	X						X	
STAI		X						X	X						X	
FSBT		X						X	X						X	
ACPT		X						X	X						X	
Animal Fluency		X						X	X						X	
Trails		X						X	X						X	
Digit Symbol Coding		X						X	X						X	
Readiness to Quit Ladder		X						X	X						X	
MRI		X						X	X						X	
TMS			X	X	X	X	X			X	X	X	X	X		

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Craving VAS		X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Anxiety VAS		X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Adverse Effects			X	X	X	X	X			X	X	X	X	X		X
Time	2h	3h	1h	1h	1h	1h	1h	3h	3h	1h	1h	1h	1h	1h	3h	0.5h
Compensation		$50	$25	$25	$25	$25	$25	$75	$50	$25	$25	$25	$25	$25	$100	

*If able to become pregnant; ^Day 28 visit will occur virtually or by telephone; ACPT: Auditory Continuous Performance Task; BPRS: Brief Psychiatric Rating Scale; CO: carbon monoxide; DERS-18: Difficulties in Emotion Regulation-18; FTND: Fagerstrom Test for Nicotine Dependence; MAIA: Multidimensional Assessment of Interoceptive Awareness; MCQ-SF: Marijuana Craving Questionnaire Short Form; MRI: Magnetic Resonance Imaging; NMR: Nicotine Metabolite Ratio; PSECDI: Penn State Electronic Cigarette Dependence Index; SCID: Structured Clinical Interview for DSM-5; STAI: State-Trait Anxiety Inventory; Tiffany QSU: Tiffany Questionnaire of Smoking Urges; TLFB: timeline followback; TMS: transcranial magnetic stimulation; WSWS: Wisconsin Smoking Withdrawal Scale; VAS: Visual Analog Scale

Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator with Sponsor input that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury. There are no plans for Vanderbilt or the Sponsor to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt or the Sponsor 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. Heather Ward** at **(615) 936-3555**.

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.

Reasons why the study doctor may take you out of this study:
Dr. Ward may remove you from the study at any time if it is in your best interest or the best interest of the study. For example, if you are experiencing psychiatric symptoms to the point that it is interfering

with your ability to complete the study, she may decide that it is better for you to stop the testing. Withdrawal by Dr. Ward will not affect any future clinical care at Vanderbilt University Medical Center.

MRI scanner time is expensive and we have to pay for MRI scanner time if we have a late cancellation. We request that you inform us at least 24 hours in advance if there is even a chance that you might have to cancel the MRI appointment. If you do cancel after the deadline, you will not be penalized, but the study team may decide not to reschedule your MRI session.

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. You will be paid for all study visits that you completed.

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 efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Documents containing identifiable subject information, like this consent form, will be stored in locked filing cabinets located in the Departments of Psychiatry and Radiology at Vanderbilt. Electronic files containing identifiable information will be stored on password protected systems at Vanderbilt. If the study is conducted over video-conferencing, links to the video-call will be sent only to the research participant and approved staff. Video-calls will take place in private locations where the risk of

someone hearing or seeing the research visit is minimized. Subjects will be assigned a numeric code that will be used to label all research data, including brain imaging scans. Only Dr. Ward and approved research staff will have access to this data. The PRL task is run through a secured, HIPPA-compliant server hosted by Yale University. Only de-identified data will be stored on this server.

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.

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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 or future research. Disclosures that you make yourself are also not protected.

Privacy:
Any samples 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 samples. 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:
Your individual study results will not be shared with you. The final results of the study will potentially be published in the scientific literature.

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 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.

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. Dr. Ward's mailing address is 1601 23rd Ave. S., Office 3040, Nashville TN, 37212. 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.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

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

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

Time: _____