Transcranial Magnetic Stimulation to Augment Behavior Therapy for Tics

Investigator Team Contact Information:

Investigator Name: Christine Conelea, PhD Investigator Departmental Affiliation: Department of Psychiatry & Behavioral Sciences Phone Number: (612) 626-6773 Email Address: cconelea@umn.edu	Staff Name: Kerry Houlihan Investigator Departmental Affiliation: Department of Psychiatry & Behavioral Sciences Phone Number: 612-625-8448 Email address: CANLab@umn.edu

This research is supported by funds from the National Institutes of Health.

What is research?

The goal of research is to learn new things in order to help people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Key Information About This Research Study

You have been invited to participate because you are between the ages of 12-21 years old and have chronic tics. This study is designed to learn if non-invasive brain stimulation can improve the outcomes of an existing therapy for tics.

If you choose to participate, your participation in this study may last up to 20 weeks. There will be approximately 3 weeks of assessments and treatment plus two follow up visits happening one month and three months later.

The study uses medical technology called Transcranial Magnetic Stimulation (TMS) for non-invasive brain stimulation. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

Detailed Information About This Research Study

"Tics" are movements or sounds that some people make repeatedly that are not done on purpose. Chronic Tics are the primary symptoms of Tourette syndrome and persistent motor/vocal tic disorders.

Currently, the standard treatment for tics is a therapy called Comprehensive Behavioral Intervention for Tics (CBIT). However, CBIT does not work for everyone. Some research shows that tics may be reduced after a TMS procedure that changes activity in a part of the brain that causes tics. This part of the brain is called the "supplementary motor area." We are doing this study to see if we can improve CBIT by pairing it with this type of TMS.

What is the purpose of this study?

This present research study is being done to examine whether combining the standard tic therapy, CBIT, with TMS to the supplementary motor area (SMA) improves tic suppression ability and enhances CBIT outcomes in young people.

The TMS is administered using an investigational device called the Magstim® Rapid^2. While this device has been approved by the FDA for the treatment of Major Depressive Disorder, its use in this study is investigational because it has not been approved by the FDA for the treatment of tics.

How many people will be studied?

60 people between the age of 12 and 21 years are expected to participate.

How long will the research last?

Your participation in this study may last up to 20 weeks, this includes screening, approximately 3 weeks of assessment and treatment, and two follow up visits happening one month and three months after the completion of the last study visit.

Study Procedures:

Below is a table summarizing the procedures that will be done at each visit.

VISIT	ACTIVITY

Pre-assessment Visit	At this visit, the study procedures will be explained to you extensively, you will sign informed consent forms, provide demographic information, complete a video recorded tic observation, undergo a brain scan (MRI), and complete other questionnaires assessing your symptoms. Those capable of pregnancy will complete a urine pregnancy test. We will confirm youreligibility for the rest of the study. Total participation time is up to 3.5 hours. You can choose to split this up into two visits and to do some parts remotely over video chat.
Visit 1-10 (CBIT+TMS)	You will be assigned randomly to one of three types of TMS. The TMS will be either active stimulation or "sham"/placebo. Neither you nor your therapist will know which experimental treatment you are getting. You will come into the Non-invasive Neurostimulation Lab (NNL) at the University of Minnesota for 10 sessions where you will undergo the brain stimulation you have been assigned combined with the CBIT treatment. On each treatment day, you will complete a tic observation, the TMS treatment, and CBIT session. The tic observation and CBIT sessions will be video recorded. Total participation time is 1.5 hours each day, 10 out of 13 weekdays.
Post-Treatment Assessment Visit	At this visit, you will complete a video recorded tic observation, undergo a brain scan (MRI), and complete other questionnaires assessing your symptoms. Total participation time is up to 3.5 hours. You can choose to split this up into two visits and to do some parts remotely over video chat.
Follow Up Visit 1 (After 1 month)	After your post-treatment visit, you will come in for two follow up visits after 1 and 3 months. During each visit, you will complete video recorded tic observation and other symptom measures. Total participation time is 1.5 hours per follow-up visit. You can choose to do this visit remotely over video chat.
Follow Up Visit 2 (After 3 months)	

How does TMS work?

TMS uses a strong hand-held magnet, like the strong magnet used for MRI scans. The TMS magnets we use are called “magnetic coils.” The TMS coils are about the size of a human hand and are shaped like a “figure of 8.” We place the coil gently over the scalp of the person being studied and trigger it to give an impulse. The impulse causes the brain cells underneath to activate and send a message through the brain, just as brain cells activate when a person decides to move part of his or her body. The result depends on where the magnet is placed. If the magnet is placed over the “thumb control area” of the brain, then the magnetic pulse will activate the brain and cause the thumb to twitch. By using TMS, we can influence how the brain cells talk to each other.

During TMS, you will sit on a reclining chair with wires attached with tape to the skin over muscles in the hand. The TMS coil is held with a coil stand, and a series of pulses will be administered over the scalp. An example of what the TMS procedure looks like can be found in the Appendix of this form.

The duration of a TMS session will depend on which group you are placed in and will range from 5 minutes to 33 minutes.

The specific type of TMS you will get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what type of TMS you get. You have a two in three chance of being assigned to one of the “active” types of TMS versus the sham/placebo type ofTMS.

CBIT sessions will follow TMS sessions and will take approximately 60 minutes.

Is there any way that being in this study could be bad for me?

To emphasize, participation in this study is entirely voluntary. We will also work hard to create a pleasant, positive atmosphere, including breaks as necessary to minimize boredom, frustration, and fatigue.

Nevertheless, there are some risks associated with the various procedures in this study. Those risks are rare but will be shared with you to help you make an informed decision about participating in the study.

1. **Clinical Assessment.** Some of the questions that will be asked in the interviews or study questionnaires may make you feel uncomfortable. You will not be required to answer any question that makes you feel uncomfortable. Some questions are asked to make sure the study is safe for you, so not answering certain questions may impact your ability to participate. The research team will let you know if this is the case for a question you prefer to not answer.

2. **MRI**. MRI machines use a strong magnet and radiofrequency magnetic fields to take images of your body. The scanning process is similar to an x-ray or CT scan, but MRI does not use ionizing radiation (high-energy radiation that can potentially cause damage to DNA) like x-rays or CT scans. The risks associated with MRI scans are:

Projectiles: Metallic objects (such as watches, cell phones, and hair pins) can be pulled towards the magnet becoming a projectile. You will be asked to remove metallic objects before entering the scanner area. If you have iron or steel on or in your body (except teeth fillings), please let us know, as there is a risk that the metal may move or come loose. If you have certain iron or steel implants in your body that cannot be removed, the scan may not be able to be performed.

Claustrophobia: Some people feel uncomfortable while in the magnet because they do not like to be in closed places (claustrophobia). This can often be reduced significantly by speaking with the scan operator when possible during the scanning and by gradually introducing you into the magnet.

Hearing Damage: The scanner makes knocking and beeping sounds during the scan, these sounds can be loud enough to cause hearing damage if you do not wear hearing protection. We will provide you with hearing protection to reduce the noise to a more comfortable and safe level.

Nerve Stimulation: Some people experience localized tingling, twitching, or muscle contractions during MRI scans. This is expected, but if you become uncomfortable you should notify the operator of the scanner.

Disruption of Devices: Some devices can be damaged by magnetic fields and should not be brought into the scanner room. This includes some implanted devices such as pacemakers, cochlear implants, insulin pumps, nerve stimulators, etc. If you have any implanted devices, please notify the study team.

Heating of Devices: The magnet in the MRI scanner can heat conductive materials such as metal implants (screws, plates, rods, wires, artificial joints, etc.), certain tattoo inks, certain clothing fabrics, jewelry, medication patches, wigs, etc. You will be asked to remove these items if possible. If they cannot be removed, you will be asked to provide more information to allow the study team to determine if a scan can be performed safely.

A thorough pre-scan questionnaire will allow us to minimize the risk of device disruption and heating. During the scan, you will be in constant contact with the scan operator. You will have a squeeze ball in the scanner you can use to alert the scanner operator If you notice anything unusual, become claustrophobic, think that the hearing

protection is not adequate, or if you experience nerve stimulation that is uncomfortable.

In addition, there is a risk of unknown effects related to participation in MRI research. Long-term effects of exposure to high magnetic fields are unknown. Most people experience no short-term ill effects from the strong magnetic field, but some people report dizziness, mild nausea, headache, a metallic taste in their mouth, or sensations of flashing lights. These symptoms, if present, subside shortly after entering or leaving the magnet. If any sensations experienced during participation cause discomfort or pain, notify the researcher right away and your participation will stop and you will be taken out of the magnetic field.

Will I receive any imaging results after an MRI?
The pictures created during this study are for research purposes only and are not intended to provide health care to you. The investigator in charge of this study has decided that results from your scan will not be shared with you or your physician. The study doctors will contact you or your physician if the images show something unusual. Any medical costs related to imaging follow up with you or your doctor will be your responsibility and/or the responsibility of your healthcare provider.

3. **Transcranial Magnetic Stimulation (TMS).** There are limited risks associated with the use of TMS. The potential risks and discomforts associated with TMS are mild and temporary. Potential mild and temporary side effects from this procedure include: headache (12% of young people experience this), scalp discomfort (2.5%), twitching (1.2%), mood changes (1.2%), fatigue (0.9%), tinnitus (0.6%), and nausea.

Seizures: Other researchers have reported seizures in patients after TMS. However, this is extremely rare. The risk of a TMS-related seizure is estimated to be less than 0.1%. Also, a seizure has never happened in kids or adults with tics who have participated in various TMS studies. We will ask you questions and look at your medical records before deciding if you can do TMS. We will ask you how you are feeling during and after TMS. If you have a seizure, we will call 911. In the rare case that you experience a seizure caused by TMS, this does not mean that you will have another seizure. Seizures have occurred in different TMS contexts and those participants who had seizures from TMS have not had any continued seizure related health problems.

4. **Tic Suppression Task:** There is minimal risk associated with this task. You may experience temporary increases in tics, anxiety, or physical tension. There is no evidence that this poses a risk to you. We have found that any increase in tic rate, anxiety, and tension will lower rapidly (within minutes).

5. **Loss of Confidentiality Risk:** Personal information collected during study procedures could result in social or psychological risk if released inappropriately to unauthorized individuals. However, this is an extremely unlikely event considering all the protective measures and precautions taken by the University and the research team.

6. **Delay of Non-experimental Treatment Risk:** All participants will receive CBIT, a well-established treatment that is considered by the American Academy of Neurology to be the first-line intervention for tics. Because we exclude those with planned medication changes, participation in this study could cause a delay in receiving medications or updating medications used for treating tics.

7. **Unknown Risks.** In accordance with this study, and all research studies, there may be unknown or unforeseen risks associated with participation.

What do I need to know about reproductive health and/or sexual activity if I am in this study?

The risks of exposure to high magnetic fields are unknown for fetuses. Therefore, if you are capable of becoming pregnant and you have any reason to believe that you might be pregnant, you should not participate in this study. Those who could potentially be pregnant will be tested for pregnancy and, if positive, will not be allowed to participate. If testing is refused, participation will not be allowed.

Research Related Injury

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study doctor know right away.

Notification of Significant New Findings.

You will be told of any important new information that is learned during the course of this research study that might affect your condition or your willingness to continue participation in this study.

Will being in this study benefit me in any way?

If you are eligible for the study, you will receive CBIT, which is considered a first-line treatment for tics by the American Academy of Neurology. Prior research shows that 50-60% of people who receive CBIT experience an improvement in tic symptoms. Therefore, there is a chance you will benefit from the CBIT, but we cannot guarantee that this will happen. The TMS procedure is experimental, so we cannot guarantee that the TMS itself will benefit

you. If you do not experience improvement in tic symptoms at the end of the study, we will provide you with treatment and referral information.

Alternatives to Study Participation

Your participation in this study is voluntary. If you do not wish to participate, you can withdraw your consent at any time.

Will it cost me anything to participate in this research study?

- There will be no cost to you for any of the study activities or procedures.
- You or your insurance company will have to pay for all costs for medical care related to participation in this study, including copayments and deductibles. You will have to pay for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may have to pay, you should contact your insurance company. If you do not have health insurance, you will have to pay all costs for your medical care just as you would if you did not take part in this study.
- If you need treatment for side effects while you are on the study, you or your insurance will need to pay for this treatment.

Compensation

You will be compensated for your participation in this study as per the table below:

ACTIVITY	PAYMENT AMOUNT
Pre-treatment Assessment	$30
MRI (per scan, for a total of 2 scans)	$50
Treatment (per session)	$10 per day for 10 days (total: up to $100)
Post-treatment Assessment	$30
1 Month Follow Up	$40
3 Month Follow Up	$50
Total	up to $350

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 6 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name, address, and date of birth. They will use this information only as part of the payment process. Greenphire will only need your social security number if the payment exceeds $599. Greenphire will not receive any information about your health status or the study in which you are participating.

Additionally, you will have the option to receive updates related to appointment reminders and payment reminders and updates via text message and email message (Standard text messaging rates will apply). You will have the opportunity to opt-in to receive these messages, you are not required to provide your cell phone or email address to be enrolled in the study or use a ClinCard. If you choose to receive messages and decide at a later date that you want to stop these messages, you will have the ability to opt-out. If you choose to receive any communications via texts or emails, you will be asked to sign a separate form.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision. If you decide to leave the research study, contact the research team so that we can make sure that you are stopping treatment safely.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this

study will not negatively affect your right to seek any present or future medical care, your academic standing as a student, or your present or future employment.

If you stop being in the research, information about you that has already been collected will not be removed from the study database. The investigator will ask you if you wish to provide further data collection from routine medical care after you withdraw from the study.

Can I be removed from the research?

It is possible that we will have to ask you to leave the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

What happens to the information collected for the research?

If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. Your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form, which may include creating audio and video recordings of you. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

Data from this study will be submitted to the National Institute of Mental Health Database (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many National Institute of Mental Health (NIMH) studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about mental health and substance use more quickly than before.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA. Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about mental health and substance use and how to help others who have problems with mental health and

substance use. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to the NDA. You can still participate in this research study even if you decide that you do not want your data to be added to the NDA. If you decide any time after today that you do not want your data to be added to the NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of the NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, this is available on-line at http://nda.nih.gov.

Who will access and use my health information?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on the research with us:
    - University of California, San Diego
- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB, which is the committee that provides ethical and regulatory oversight of research at the University), systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (such as the Quality Assurance Program of the Human Research Protection Program or HRPP) ,and individuals involved in processing any compensation you may receive for your participation.
- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration or FDA, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries).
- Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.

What health information will be made available?

Health information about you that might be used and shared for the research includes the following:

- Information collected as part of this research study, including research procedures,

research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?

Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

✓ My drug & alcohol abuse, diagnosis & treatment records _____ (initial)

☐ My HIV/AIDS testing records_____(initial)

☐ My genetic testing records_____(initial)

✓ My mental health diagnosis/treatment records _____ (initial)

☐ My sickle cell anemia records_____(initial)

Reporting Requirement

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition

that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

What will be done with my data when this study is over?

We will use and may share data for future research. They may be shared with researchers/institutions outside of University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your data.

Do I have to sign this Consent Form and give my permission to make my information, including my health information, available for use and sharing?

No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing this Consent Form.

Whom do I contact if I have questions, concerns or feedback about my experience?

If you have questions about research appointments, the study, research results, or other concerns, contact the researchers. You may ask any questions you have now, or if you have questions later, you are encouraged to contact the study staff or doctors.

Does my permission for making my health information available for use and sharing ever expire?

No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?

Yes. You may cancel your permission at any time by writing to the researcher at the address on the first page of this Consent Form. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the research team if canceling will affect any research related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form.

What happens to my health information after it is shared with others?

When we share your information with others as described in this Consent Form, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?

It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

Certificate of Confidentiality

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

A description of this clinical trial will be available at **http://www.ClinicalTrials.gov**, as required by U.S. Law. This Web site will not include your name or any other direct identifiers such as your contact information. The Web site may include a summary of the results of this research. You can search this Web site at any time.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP.

Use of Identifiable Health Information

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission, as described in this form. The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes, I agree	No, I disagree	
		The investigator may contact me in the future to see whether I am interested in participating in other research studies. If yes, provide the following contact information: **Email Address:** **Phone Number:**
		I would like to receive reminders using Greenphire.
		Do you give the study team permission to inform your primary care doctor that you are taking part in this study and communicate with them about your health information? If yes, please provide your primary care doctor or clinic information: **Primary Doctor/Clinic name:** **Phone Number:** **Location:**

		I give the study team permission to keep my tic observation video to use for future research.
		I give the study team permission to submit my deidentified data from this study to the National Institute of Mental Health Database (NDA) at the National Institutes of Health (NIH).

Statement of Consent

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent