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Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Northwestern University
Department of Preventive Medicine

Consent Form and HIPAA Authorization for Research

TITLE OF RESEARCH STUDY: Behavioral Activation and Varenicline for Smoking Cessation in Depressed Smokers

INVESTIGATOR: Brian Hitsman, PhD

SUPPORTED BY: National Cancer Institute

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are a smoker, have expressed an interest in quitting, have experienced symptoms of major depressive disorder, and meet the initial eligibility requirements of the 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.

Why is this research being done?

The main purpose of this research study is to compare traditional behavioral smoking cessation therapy with a different type of behavioral treatment, behavioral activation for smoking cessation. The study will also compare the use of varenicline, also known as Chantix® (study drug), with both forms of behavioral therapy. Half of the participants who enroll in the study will receive active Chantix® medication and the other half will receive a placebo, or inactive "sugar" pill. The study will compare smoking and quitting behavior between all possible combinations of the two behavioral therapies and two medication groups. There are four different treatment group possibilities to which you could be

randomized. We will compare the rate of quitting smoking across all four groups at the end of treatment (study week 14), and 14 weeks after the end of treatment (study week 27).

How long will the research last and what will I need to do?
We expect that you will be in this research study for about 28 weeks.

You will be asked to proceed through today's intake session. The intake session is necessary to make sure it is safe for you to participate. If at the end of today's visit you are eligible to participate, you will be asked to complete up to 12 additional sessions over a 7-month period. While enrolled in this research study, you will also be asked not to use any smoking cessation treatment (including medication or behavioral therapy) other than that which is provided to you within the context of this clinical study. If you have used smoking cessation aids including bupropion (Zyban®) or the nicotine patch, you are asked not to use these during the study. You will be asked not to use other treatments for nicotine dependence, including nicotine patch, nicotine gum, nicotine spray, nicotine lozenge, and nicotine inhaler. We also ask that you not use the e-cigarette while enrolled in this research study.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?
The risks from the study procedures include the following:

Nicotine Withdrawal Syndrome: Most individuals who quit smoking experience symptoms of nicotine withdrawal. These symptoms can occur almost immediately and last for about 10-14 days.

Varenicline (Chantix®): Like any medication, there is the possibility of experiencing drug side effects when taking Chantix. The most common side effects of Chantix® include nausea, sleep disturbance, constipation, flatulence (gas), or vomiting. Rare but serious mood-related effects have been reported in some patients taking Chantix®. These include, but are not limited to, suicidal thoughts or actions, new or worsening of mental health problems, and changes in emotional functioning or behavior. These events have occurred rarely in patients with and without pre-existing psychiatric disease. Other rare but serious potential side effects include allergic and skin reactions, such as swelling of the throat and tongue, increased risk of certain cardiovascular problems, particularly in patients with underlying cardiovascular disease, and seizures in those with and without a history of seizures.

Assessments/Questionnaires and Smoking Cessation Therapy: Some people can experience anxiety and other types of general distress when they complete questionnaires and take part in smoking cessation therapy. This is generally related to your feelings about quitting as well as learning about some of the health risks associated with smoking. These reactions are usually very mild and typically diminish with time. The staff administering these questionnaires are trained to help you should you experience any concerns.

Blood Drawing: Blood drawing may result in bruising and/or slight bleeding at the needle site. Occasionally, blood drawing may result in a feeling of faintness. These side effects are rare, so the chances of these discomforts are minimal. Sample collection will be conducted by study personnel trained in phlebotomy to reduce the risks of discomforts.

Data and Results: Because we want to protect your confidentiality, we will identify your results with an identification number only (not your name). Only authorized study personnel will be able to link your identification number with your name.

Threats to Privacy/Confidentiality: Every attempt will be made by the investigators to maintain the strict confidentiality of all information collected in this study. We will store your information in a secure room with limited access. We will control access to the computer files that hold this information and all computers will be password protected. When the results of the study are published, no names or identifying information will be used.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me any way?

We cannot promise any benefits to you or others from taking part in this research. However, potential benefits include the opportunity to safely and effectively stop smoking with the support of professionals that are sensitive to your difficulties. Additionally, taking part in this study may help scientists better understand and handle the treatment of smoking cessation in people who also struggle with major depression.

What to do if you have suicidal thoughts or consider harming yourself.

Thoughts of suicide are a common symptom of major depressive disorder and indicate that what you are experiencing is more serious than just a "bad mood." As part of our safety monitoring procedures, you will be assessed for suicidal thoughts, urges and intent to harm yourself during your intake session as well as at every session using the Columbia Suicide Severity Rating Scale. Study staff will ask you a number of detailed questions as part of this assessment.

It is very important that you discuss suicidal thoughts with us, as they are important for us to know about. In addition to discussing them with our research staff, it is important that you also contact either your mental healthcare provider or primary care physician as soon as possible. Study staff will inform you at each step of the way if you require additional assistance or treatment.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled. Instead of being in this research study, your choices may include other quit smoking studies at our center or other treatment studies located in the Chicagoland area that we can provide you information on.

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

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (877)236-7487.

Dr. Brian Hitsman is the person in charge of this research study. You can call his office phone (312-503-2074) Monday through Friday between 9am and 5pm. If you are unable to reach him at his office, or if you have a question or encounter problems during evenings or weekends, you can call his cell phone (312-504-5834).

You can also call the study's research coordinator, Celine Reyes (312 503-3098), with questions about this research study during normal business hours (Monday through Friday between 9am and 5pm).

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu 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.

How many people will be studied?

We expect about 288 people here will be in this research study out of 576 people in the entire study nationally.

What happens if I say "Yes, I want to be in this research"?

Study visits are described in more detail below.

Intake visit. This visit will last between two and two and a half hours and take place at our Preventive Medicine research clinic located at 680 N. Lake Shore Dr., Suite 1410, Chicago IL 60611. During this session, you will be asked to:

- Complete the study informed consent and HIPAA form with a research staff member. You will have the opportunity to have your questions answered before signing the study consent and HIPAA form. If you chose not to sign this form, no procedures will be performed.
- Provide a 30ml (2 tablespoons) urine sample that will be used to assess pregnancy (females only). A positive test will result in exclusion from the study. Results of this test is for study purposes only and the results will not be shared with anyone but you.
- Complete a breath carbon monoxide (CO) assessment to measure your smoke exposure. Carbon monoxide is a poisonous gas that comprises less than 1% of the air we breathe and is

also produced through smoking a cigarette. Your CO levels provide an indication of how much cigarette smoke to which you have been exposed.

- Provide one 5 ml (1 teaspoon) saliva sample to assess your rate of nicotine metabolism, or how quickly or slowly nicotine leaves your body.
- Provide a 12.5 ml blood sample (about 2.5 teaspoons) to measure your cholesterol and glucose levels.
- Complete a psychiatric interview, during which we will ask you about any current and past depression symptoms as well as other emotional and behavioral symptoms.
- Complete a routine medical history. You will have your blood pressure, vital signs, height, and weight measured. You will also be asked about your medical history and about any medications, including antidepressants, that you are currently taking or have discontinued within the last two months. Your smoking rate will also be assessed.
- Paper and pencil assessments of your demographics, alcohol and smoking history, caffeine use, smoking and health behaviors, and mood.

If you are eligible at the end of this visit, you will receive one of four treatments. This study is a randomized clinical study, which means that you will be assigned at random to receive one of these plans. Which treatment you receive will be based on chance, almost like flipping a coin. Neither you nor the researcher chooses your assigned treatment group. You will have an equal chance of receiving one of the following four treatment plans:

1. Behavioral smoking cessation therapy plus 12 weeks of active medication
2. Behavioral activation for smoking cessation therapy plus 12 weeks of active medication
3. Behavioral smoking cessation therapy plus 12 weeks of placebo medication
4. Behavioral activation for smoking cessation + 12 weeks of placebo medication

Each of these treatments, even those involving placebo medication, is consistent with U.S. clinical treatment guidelines for tobacco use and dependence. Each participant will receive eight therapy sessions during the 12 weeks of treatment.

The study drug is approved by the U.S. Food and Drug Administration (FDA) for smoking cessation. The placebo pills look and taste just like the active medication but will contain no active ingredients. Researchers use a placebo to see if the study drug is safe and effective compared to not taking any medication. Neither you nor the research team will know which treatment group to which you have been assigned. You will begin your medication treatment plan at your second therapy visit.

Week 1 Clinic Visit: Pre-Quit 1. This in-person assessment at our clinic (680 N. Lake Shore Dr., Suite 1410, Chicago IL 60611) will last about 2 hours and 15 minutes. During Pre-Quit 1, you will:

- Complete a carbon monoxide, blood pressure, and heart rate reading.
- Complete a brief psychiatric interview, recent medical history review and assessments of medication use, height and weight, baseline side effects and smoking rate.
- Complete paper and pencil assessments of your mood and smoking behavior.
- Complete four brief computer-based tasks:

1. A memory task during which you will see pictures of foods, animals, or both on the computer screen and then disappear. You will be asked to order them from smallest to biggest. This task takes about 6 minutes to complete.
2. An attention task for which you will press the arrow key pointing the same direction as the arrow image in the middle of the screen. This task takes about 5 minutes.
3. A task that measures your response to reward. You will look at a number of cartoon faces and will be asked to judge the length of their noses or mouths. You can win a small amount of money for each correct response you provide (up to $4.20 in total given in cash immediately after task completion). This task takes about 15 minutes to complete.
4. A choice task that examines the relationship between cigarette cravings and mood, during which you will press a left or right arrow key to view 24 images of either chocolate or smoking after reading negative and positive emotional words. This task takes about 10 minutes to complete.

- Receive your first two blister packs of study medication (for study weeks 2-3) which will include pills and instructions on how the medication should be taken.
- Receive a medical card that includes emergency contact numbers and other important information about this research study.
- Meet with a smoking cessation therapist to set your Target Quit Date (TQD) and confirm the time of your TQD clinic visit.
- Take part in your first 45-minute smoking cessation therapy session to help prepare you for your upcoming quit attempt.

All participants will take part in either traditional behavioral smoking cessation therapy or behavioral activation therapy for smoking cessation. In total, you will receive eight therapy sessions. All sessions will last 45 minutes. Sessions may be audio-recorded to ensure that the therapy is consistent for all participants within each of the two therapy groups. Each digital audio file will be password protected on a study computer that is also password protected. Only research study personnel will have access to the passwords. Audio files will be destroyed at the end of the study.

Week 2 Phone Session: Pre-Quit 2. Pre-Quit 2 is a therapy-only session completed over the telephone that will last 45 minutes. It is designed to build on what you discussed during your first Pre-Quit visit about preparing for your target quit date. Your cessation therapist will review the medication and instructions on how the medication should be taken. Your therapist will also complete a brief mood check-in to make sure that you have not experienced any mood or depression medication changes since your last visit.

You will begin taking the medication in pill form on the day of your scheduled Pre-Quit 2 session. If you are unable to complete the session by telephone on your scheduled day, you should still begin taking your medication. If you are unable to take your medication as scheduled, please inform the study staff as we will have to make adjustments to your study schedule based on your medication start date.

You will continue taking the study drug until Week 13. Half of the participants will receive 12 weeks of active study medication. The other half of the participants will receive 12 weeks of placebo. The

dosing schedule used in this research study is consistent with FDA guidelines: Day 1-3 (0.5mg once daily); Day 4-7 (0.5mg twice daily); and Day 8-84 (1.0mg twice daily). Extensive information about this medication will be provided and you will be contacted by phone two days after you begin taking your medication to discuss how it is going for you.

The medication will be packaged in weekly blister packs. Each blister pack will be labeled with clear instructions and dosage, and you will be given written instructions regarding when to take your medication and what to do if you miss a dose. You will be given supplies of blister packs at Weeks 1, 3 and 7. You will be asked to return your used blister packs at each subsequent in-person visit.

Week 3 Clinic Visit: Target Quit Date. On your target quit date (one week following your medication start date), you will complete a 2 hour "quit-day" session in our clinic to review your quit attempt. This will include a 45 minute session with your therapist to review your quitting plan and discuss reasons why people often relapse back into smoking. You will also complete paper and pencil assessments of your mood and smoking behavior, a brief psychiatric interview, a recent medical history review and assessments of height and weight, medication use, side effects, and smoking rate. Additionally, you will complete carbon monoxide, blood pressure, and heart rate readings at this time. At this visit you will receive your second supply of study medication for Weeks 4-7.

Mid-Treatment Assessments

Following your target quit date session, you will complete five booster therapy sessions by phone at Weeks 4, 6, 8, 10, and 12. These sessions will focus on reinforcing your success and reviewing your quit plan, or on reestablishing another quit date and restarting the smoking cessation process. Prior to each therapy session you will complete a brief psychiatric interview and assessments of your mood, medication use, outside treatments, smoking rate and side effects. At Week 12, we will also assess aspects of your smoking behavior. These sessions will last about 75 minutes, including a 45-minute booster therapy session.

For Week 7, you will be asked to return to our clinic for an in-person visit to do some mid-treatment assessments. During this visit you will complete paper and pencil assessments of your mood and smoking behavior, a brief psychiatric interview, a recent medical history review and assessments of height and weight, medication use, smoking rate and side effects. You will also complete blood pressure and heart rate assessments, a carbon monoxide assessment to verify your smoking status, and the four computer-based tasks. There is no therapy at this visit. You will be given the last of your blister packs of study medication (for weeks 8-13) at this visit. The Week 7 visit will last about two hours.

Follow-Up Assessments

Finally, at Weeks 14 and 27 you will complete the treatment follow-up sessions. Week 14 is an in-person clinic visit that will take about two hours. You will have your height and weight measured and will complete a blood pressure assessment, a carbon monoxide assessment to measure your smoke exposure, and the four computer tasks. You will also complete paper and pencil assessments of your mood, smoking behavior and satisfaction with the program, a brief psychiatric interview, a recent medical history review and assessments of medication use, health behavior, caffeine use, smoking rate

and side effects. A 12.5 ml blood sample (about 2.5 teaspoons) will be drawn to obtain a second measurement of your cholesterol and glucose levels.

Week 27 is completed by phone and will last about 30-45 minutes. You will complete a brief psychiatric interview as well as assessments of your mood, smoking rate, medication use, outside treatments, health behavior and side effects. In addition, if you are quit at Week 27, you will be asked to attend a 30-minute clinic visit where your mood, health behavior, side effects, recent medical history and medication use will be assessed and you will have your carbon monoxide level blood pressure, heart rate and height and weight measured again.

What are my responsibilities if I take part in this research?

If you agree to participate in this research study, your responsibilities include:

- Attending study sessions, both in-person and phone, and completing all aspects of the sessions including assessments and questionnaires, computer tasks, specimen collection, and therapy homework
- Remaining compliant with the study treatment, both medication and therapy
- Maintaining open communication with study staff

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

You can leave the research at any time; it will not be held **against you.**

If you choose to be in this study, you have the right to be treated with respect, including respect for your decision whether or not you wish to continue or stop being in the study. You are free to choose to stop being in the study at any time.

If you decide to leave the research, contact the investigator so that the investigator can collect your study medication to be disposed of properly.

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. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment, your class standing (for students enrolled in a class at Northwestern), or your present or future employment (for employees at Northwestern or its affiliates).

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care.

If you agree, this data will be handled the same as research data.

Any new findings developed during the course of this research that may affect your willingness to continue in this study will be shared with you.

Detailed Risks: Is there any way being in this study could be bad for me?

Nicotine Withdrawal Syndrome. These feelings include:

- Sadness and mood changes
- Constipation
- Irritability
- Anger
- Restlessness and nervousness
- Insomnia
- Decreased heart rate
- Craving for nicotine
- Difficulty concentrating
- Appetite increase and weight gain
- Anxiety
- Muscle pain
- Headaches

Your therapist will work with you to develop strategies to help you deal with any withdrawal symptoms that you may experience. If you feel that your withdrawal symptoms are not lessening over time or are significantly interfering with your ability to function, you should contact the Principal Investigator whose contact information is on page 10 of this consent form under the section "If I have questions or concerns about this research study, whom can I call?"

Varenicline (Chantix®). The most common side effects are listed first; the rare potential side effects (e.g., allergic reactions, mood-related, etc.) follow:

More Common Side Effects. Potential side effects of taking the study drug are nausea, sleep disturbance, constipation, flatulence (gas), or vomiting. These can occur in more than 5% of people taking this medication.

Allergic Reactions. There have been rare reports of allergic and skin reactions to taking the study drug, including swelling of the face, mouth (tongue, lips, and gums), extremities, and neck (throat and larynx). These types of allergic reactions may be serious and life-threatening. The risk for these reactions is low, meaning about 1 out of 1000 people taking this medication. If you experience any difficulty breathing, stop using the study drug and seek medical help immediately. At the first appearance of any skin rash, you should also stop using the study drug immediately and contact your health care provider. If you experience any of these symptoms, contact the study staff as soon as possible after seeing your medical provider.

Mood-related Side Effects. Rare serious mood-related effects have been reported in a small number of persons taking the study drug. These include, but are not limited to, depression, agitation, hostility, suicidal thoughts, suicide attempts, and completed suicide. Some reported cases may have been complicated by the symptoms of nicotine withdrawal in patients who stopped smoking. Depressed mood may be a symptom of nicotine withdrawal. Depression, rarely including suicidal thoughts, has been reported in smokers undergoing a smoking cessation attempt without medication. However, some of these symptoms have occurred in patients taking the study drug who continued to smoke. When symptoms are reported, most occurred during treatment with Chantix®, while some followed after stopping Chantix® therapy. All patients being treated with the study drug will be assessed for such symptoms. These events have occurred rarely in patients with and without pre-existing psychiatric disease. Although patients with serious psychiatric illness, such as major depression, schizophrenia, or bipolar disorder, did not participate in the pre-marketing studies of the study drug, recent clinical trials that targeted these populations have demonstrated safety of varenicline use in these populations.

These studies found no significant differences in mood-related side effect rates or an exacerbation of psychiatric symptoms between those taking Chantix® versus placebo. Our research staff and therapists

follow strict procedures to help monitor for the presence of these side effects, including asking you repeatedly during each study session about your reactions to the study medication. They will work closely with the study physicians/psychologists to make sure that you can safely take the study drug.

You should stop taking the study drug and contact a healthcare provider immediately if agitation, hostility, depressed mood, or changes in behavior or thinking that are not typical of you are observed, or if you develop suicidal thoughts or behavior. In many cases, resolution of symptoms was reported after stopping Chantix® therapy, although in some cases the symptoms persisted; therefore, ongoing monitoring and supportive care should be provided until symptoms resolve.

Cardiac Side Effects. The study drug may be associated with an increased risk for certain cardiac (heart) and vascular (blood vessel) side effects, including chest pain, heart attack, stroke, shortness of breath, calf pain when walking or sudden onset of weakness, numbness or difficulty speaking. One study showed that these risks are rare (~1% or 1 out of 100 people using the study drug) but a later study found no difference between placebo and the study drug in terms of these cardiac risks. Our study staff follow strict procedures to help them monitor for the presence of these side effects, including asking you repeatedly during the study about your reactions to the study medication and assessing your blood pressure.

Somnambulism. Cases of somnambulism (sleep walking) have been reported in patients taking varenicline. You should notify research staff as soon as possible if you experience somnambulism.

Brief Cognitive Side Effects. The study drug may cause noticeable drowsiness, dizziness, headache, loss of consciousness or difficulty concentrating that may impair your ability to perform tasks requiring judgment or motor and cognitive skills such as driving a car and operating machinery. You should proceed with caution in this regard until you are certain that the study drug does not affect your performance. *Risk of Seizure.* The study drug may be associated with new or worsening seizures during the first month of treatment. Some patients had no history of seizures, whereas others had a history of seizure disorder that was remote or well-controlled. You should not take the study drug if you have an unstable, untreated history of seizures.

Potential Interaction with Alcohol. The study drug may increase the intoxicating effects of alcohol. Some individuals have reported lower alcohol tolerance, aggressive behavior, or impaired memory following drinking alcohol while taking Chantix®. In these cases, which number less than 30 across the United States, the amount of alcohol consumed was not sufficient to explain the symptoms. Minimize or reduce your alcohol intake, with no more than 3 drinks per occasion or within a 24-hour period, while you are taking the study drug or until you know whether the study drug affects your tolerance of alcohol.

A thorough list of medical and psychiatric eligibility requirements will be used to further limit the possibility of the above-listed side effects. For your safety, if you are found to be at risk for experiencing cardiac events, you will be unable to participate in this study.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

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

The research may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. [The effect of the study drug on human sperm and eggs has not been studied. The effects on the developing fetus using the study drug during pregnancy and the risk of birth defects are also unknown or may be unforeseeable. Therefore, you should not attempt pregnancy and should not be pregnant or breastfeeding while taking part in this study. Before entering this study all women will be asked to take a urine pregnancy test to determine if you are pregnant. You may not enroll in this study if you are pregnant or breast-feeding.

If you are sexually active, both men and women should use at least one effective means of birth control while participating in this research study. According to the World Health Organization and the United States Center for Disease Control and Prevention, the most effective forms of birth control include complete abstinence, surgical sterilization (both male and female), intrauterine devices (IUDs), and the contraceptive implant. The next most effective forms of birth control include injectables, oral contraceptive pills, the contraceptive ring, or the contraceptive patch. Acceptable but least effective methods of birth control include male condoms (with or without spermicide) and female condoms.
If you or your partner become pregnant while participating in this research study or for _____ months after you complete the study, it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other treatment options will be discussed with you at that time if necessary.
If you or your partner [are/is] considered to be postmenopausal, you are not required to use contraception while participating in this research study. Postmenopausal women rarely become pregnant. If you or your partner become pregnant while participating in this research study, it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other treatment options will be discussed with you at that time if necessary.

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

Taking part in this research study will not lead to any costs to you.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Will being in this study help me any way?

We cannot promise any benefits to you or others from taking part in this research. However, potential benefits include the opportunity to safely and effectively stop smoking with the support of professionals that are sensitive to your difficulties. Additionally, taking part in this study may help scientists better understand and handle the treatment of smoking cessation in people who also struggle with major depression.

What happens to the information collected for this research?

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. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

If we learn about current or ongoing child [or elder] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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 information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include

- The Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you would be informed if such a decision was made and the reason for this decision.
- You have not followed study instructions (e.g., repeatedly no-showing to all your study visits without calling staff to cancel/reschedule)
- The Sponsor or Principal Investigator has decided to stop the study.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

If you have an injury or illness from the study device, taking the study drug, or the procedures required for this study, the reasonable medical expenses required to treat such injury or illness may be paid for by the study sponsor.

The coverage for such injury or illness is only available if the Northwestern University principal investigator and study sponsor, if applicable, have decided that the injury/illness is directly related to the study drug, device, or procedures and is not the result of a pre-existing condition or the normal progression of your disease, or because you have not followed the directions of the study doctor. If your insurance is billed, you may be required to pay deductibles and co-payments that apply. You should check with your insurance company about any such payments.

Will I receive payment for participation in this study?

If you agree to take part in this research study, we will pay you for your time and effort needed for completing assessments. You may earn up to $140 for taking part in this research study. You will receive $15 for completing the intake session, $15 for each in-person session for which you complete the computer tasks (Weeks 1, 7, and 14), and$10 for all other sessions. It will be paid to you in cash at the end of each study session. Phone session payments will accrue and be paid to you at the following in-person session. If you complete the week 27 phone visit but are not asked to come in for the week 27 in-person visit, you will be sent an electronic gift card (i.e., e-voucher) of $10 to the retailer of your choice (Target, Walmart, or Amazon.com) to reimburse you for the week 27 phone session. A link to activate the e-gift card will be sent to your email address. For each in-person session you attend, you will also be reimbursed $10 for transportation/parking expenses. If at any point during the intake session, you are deemed ineligible for this study, we will compensate you $10 to cover your travel costs. If you withdraw from the study, you will be paid for the portions that you completed for which you have not already been paid. The payment schedule, including travel and parking reimbursement, is detailed in the table below:

You will be given a validated parking voucher and/or reimbursement up to $10 at the end of each in-person study visit for expenses related to travel (e.g., train fare, bus fare, roadway tolls, etc.) and parking. If you do not drive or park in one of the qualifying Northwestern garages, you will still be reimbursed $10 for transportation expenses. If you do park in one of the qualifying Northwestern garages (Erie-Ontario Garage: 321 E. Erie St., Chicago; or Huron-Superior Parking: 222 E. Huron St., Chicago), you will be provided with a parking voucher (value: $5.75) plus $4.25 in cash. If at any point during the intake session you are deemed ineligible for this study, we will compensate you $10 to cover your travel/parking costs.

Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Study Session	Session Compensation	Travel/Parking Compensation
Intake Session	$15	$10
Week 1 (pre-quit 1)	$15	$10
Week 3 (target quit day)	$10	$10
Week 4 (phone)	$10	-
Week 6 (phone)	$10	-
Week 7 (in-person assessment)	$15	$10
Week 8 (phone)	$10	-
Week 10 (phone)	$10	-
Week 12 (phone)	$10	-
Week 14 (in-person assessment)	$15	$10
Week 27 (phone)	$10	
Week 27 (clinic/if quit)	$10	$10
Subtotal:	**$140**	**$60**
	Total: $200	

HIPAA Authorization We are committed to respecting your privacy and keeping your personal information confidential. When choosing to take part in this study, you are giving us 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. Your health information we may collect and use for this research includes:

- Name, address, and telephone number
- Email address
- Date of birth
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well as questionnaires
- Records about study medication or drugs
- Substance abuse information: Smoking, alcohol use and psychoactive substance use history
- Mental health information: psychological and psychiatric history

You have the right to inspect and copy the mental health and developmental disabilities records that will be collected as part of this study.

This consent expires on 5/14/2020. After this date, Northwestern University may not gather new information about you, use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless Northwestern University obtains permission to do so from you. Illinois State Law permits use and disclosure of your mental health information only to the extent specified in this document.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- The National Institute of Health, who is sponsoring the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

However, Illinois law does not allow the re-release of HIV/AIDS, genetic testing, mental health and developmental disabilities information by the receivers of the information except in precise situations allowed by law.

The results of this study may also be used for teaching, publications, or presentation at scientific meetings.

Also, Federal Confidentiality Rules, 42 CFR Part 2, prohibit making any further disclosure of substance use disorder information unless further disclosure of this information is expressly permitted by written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2.

Unless you revoke your consent, it will expire on 5/14/2020.

If you are assessed as being at high risk of harming yourself or others, it may be necessary to break confidentiality to notify emergency services, your healthcare provider or your nominated family member or friend (whose details will be collected at your next appointment). This would include disclosure of your personal details, medical and mental health information for the purpose of providing you with appropriate care. Study personnel will keep you informed of this if it occurs and as it occurs.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:
Dr. Brian Hitsman
Department of Preventive Medicine
Northwestern University Feinberg School of Medicine
680 N. Lake Shore Dr., Suite 1400
Chicago IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

Optional Study 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.

Audiotaping:

I agree	**I disagree**	
_____	_____	The researcher may audio record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team.

Can we notify your healthcare providers?

If you are found eligible and choose to enroll in this research study, we would like your permission to inform your current treatment providers that you are a study participant. This would be beneficial for your overall healthcare management because good communication between treatment providers can help improve the quality of healthcare delivered. Therefore, if you agree, a brief letter will be sent to your nominated healthcare or mental healthcare providers as a courtesy, notifying them of your enrollment in this study. The letter will contain a brief summary of the research study and description of what is required of study participants. You are able to view a template of this letter. We may also communicate with your healthcare provider regarding significantly worsening symptoms of depression (including high risk of self-harm), changes in your use of study medication, smoking status, and enrollment status (if your participation in the study ends).

I agree **I disagree**

_____ _____ The study team may contact my primary mental healthcare provider as described above.

_____ (Initial) Not applicable. I do not have a primary or mental healthcare provider.

If you consent to allow research staff to notify your primary mental healthcare provider of your participation in this study, please nominate the physician that you would like notified:

	Name of Provider	**Contact Details (Phone & Address)**
1		
2		

If you are not currently in active treatment for Major Depressive Disorder, we recommend that you see a mental healthcare or primary care provider who can conduct an assessment of depression symptoms and recommend whether treatment is needed. We will provide a list of mental health and primary care referrals. If you form a relationship with a mental healthcare provider, we ask that you inform research staff and consider offering permission for us to communicate with your provider about your participation in the study.

_____ (initial) I do not currently have a mental healthcare provider, and have been provided with the referrals noted above.

_____ (initial) Not applicable. I currently have a healthcare provider who is aware of my symptoms.

Consent Summary:

Version Date: V16 – August 21, 2019

Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

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

My signature below documents that the information in the consent document and assent process and any other written and verbal information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____ _____ _____
Signature of Witness to Consent/Assent Process Date

_____
Printed Name of Person Witnessing Consent/Assent Process