VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Depressed Mood Improvement Through Nicotine Dosing 2 (Depressed Mind 2)
Version:	1.6
Date:	12/20/2021
PI:	Warren D. Taylor, 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:

What is the purpose of this study?

The purpose of this study is to better understand whether transdermal nicotine (a skin patch) can improve depression and memory performance in older individuals with depression. We also want to determine how nicotine affects brain function in order to cause these changes.

Depression in older adults can be difficult to treat, with some people not responding to currently approved antidepressant medicines. Additionally, depression in older adults is often characterized by problems with memory. There is no current medicine that is approved by the U.S. Food and Drug Administration (FDA) to treat memory and attention in depressed adults.

We are examining nicotine in this study because past research suggests that the stimulation of nicotine receptors in the brain may improve mood and depression. A previous pilot study in older adults with depression conducted at Vanderbilt found encouraging results. Also, in other populations, including older adults with memory disorders, nicotine and drugs that affect the brain's nicotine receptor have repeatedly shown to benefit memory.

In this study, we will use transdermal nicotine patches that are commercially approved by the U.S. Food and Drug Administration. Transdermal nicotine patches are approved for the cessation of smoking, but are not approved as a treatment for depression. We plan to enroll 32 individuals who will complete baseline procedures and start study patches.

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What will happen and how long will you be in the study?

If you agree to be in this study, you will first be asked to sign and date this consent form. The study takes place over the course of at least 15 weeks. After we determine you are eligible to participate in the study, the first 12 weeks will involve the use of transdermal nicotine patches.

To be eligible for this study, you will need to be taking a therapeutic dose of an allowable antidepressant medication. You will be asked to continue that medication throughout the study. If you are not taking an antidepressant medication, or are taking a medication that is not allowed, you may be eligible for a separate study that includes treatment with antidepressant medications.

You will have 7 in-person visits (about every 3 weeks) and 3 brain scans (at baseline, week 6 and week 12) over the course of the study. The brain scans are done using Magnetic Resonance Imaging (MRI) and do not involve radiation exposure. While not necessary for many people, to confirm it is safe for you to have an MRI we may ask you to have an x-ray, which does use radiation, to see if there is metal in your body.

Before starting the nicotine patches, you will have a clinical assessment, neuropsychological (memory) testing, and a brain MRI scan. This visit will take about 4.5 hours. You will repeat the brain scan after 6 and 12 weeks of receiving the patches. You will repeat the memory testing at the end of the 12-week study period. The week 6 visit will take about 4 hours and the week 12 visits will take about 5.5 hours. We will also have you return for a shorter visit at weeks 3 and 9, lasting 2 hours. You will have 4 blood draws every three weeks over the course of the study to monitor nicotine blood levels. We will collect 10 mL (about 2 tsp) of blood at each blood draw. You will not need to fast prior to each blood draw. The total amount of time you may spend at in-person study visits is about 21 hours. Study visits will be discussed in more detail in the next section of this document.

The last three weeks of the study will be used to safely reduce the patch dose and stop it. If you feel the nicotine patches have provided a benefit and would like to continue using them, you may purchase over-the-counter patches and we will not require that you stop them.

There is no cost to you for taking part in this research study. You will not have to pay for the study patches or the tests and treatments that are being done only for research. You are still responsible for paying for the usual care you would normally receive for the treatment of your illness, including

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the cost of your usual antidepressant medication. This will be discussed in more detail later in this document.

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 have depression and are age 60 years or older.

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. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

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

Nicotine and Patch Side Effects: Nicotine patches are currently FDA approved for over-the-counter sale for smoking cessation. Nicotine has effects that have been well studied for many years. Possible **common** side effects may include nausea, vomiting, dizziness or headaches Dizziness or lightheadedness may occur, especially with higher doses or after a dose increases. For many people, this effect is mild and short-lived, but can persist for others. For safety, you should avoid risky activities that could lead to falls, such as climbing on ladders. Nicotine patches can sometimes cause reddening or irritation of the skin where they are applied. **Uncommon** side effects include increased heart rate and blood pressure, irregular heartbeats, possible increase in anxiety, increased sweating, and occasionally shakes. In a recent study of older adults with memory problems, we found that nicotine patches may result in lower appetite that can cause slight weight loss (about 5-6 pounds on average over several months).

There is no evidence that using nicotine patches would prompt a non-smoker to become a cigarette smoker or to abuse nicotine products. The likelihood that participation in this study may cause participants to begin to use nicotine products (like tobacco, cigarettes, cigars) is extremely low. There have been no cases reported in the medical literature of abuse by non-smokers of nicotine

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replacement products. We have given nicotine and nicotinic drugs over the years to several hundred non-smoking participants including older adults, and have not had any participants take up tobacco or nicotine use as a consequence of study participation.

Studies have shown that nicotine by itself does not appear by itself to be cancer causing.

Diagnostic, Cognitive, and Clinical Interviews: You may experience boredom or discomfort during the clinical interview and evaluations when discussing symptoms and recent life events. You may also experience frustration with some cognitive tasks. Should you wish to stop or take a break, the study coordinator will allow it.

Should you express suicidal ideation at any time during the interview, Dr. Taylor or another study doctor will be contacted to assess you and to determine the appropriate course of treatment. Thoughts of suicide will be taken very seriously.

Blood sampling: We will draw 10mL (about 2 teaspoons) of blood to measure levels of nicotine and nicotine metabolites four times over the 12-week trial. Pain, redness, soreness, bruising, or infection may occur at the needle stick site. However, this risk is low. Blood will be drawn by a phlebotomist using sterile technique. Rarely some people faint. The study staff may put some cream (called EMLA) on your skin to numb the area so you will not feel the needle stick as much. The numbing cream may make your skin or the area have a change in skin color, but this is rare.

Worsening Depressive Symptoms: If you do not experience benefit with the patch, it is possible your depressive symptoms would worsen and suicidal ideation develop. We are reducing this risk by requiring that all participants be on a stable therapeutic dose of a FDA-approved antidepressant medication. We will safeguard against this risk by frequent monitoring and availability for phone calls or urgent in-person visits for worsening depression. If you exhibit worsening depressive symptoms, you may be withdrawn from the study and referred for appropriate clinical care.

Radiation Risks: This research study may involve exposure to radiation from up to 1 x-ray in a part of the body before an MRI scan to see where a metal object is located. This radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation that you may receive by participating in this study is equal to your body receiving 8 months of radiation from your natural surroundings, or about 4.2% of the amount allowed in a year for people who are exposed to radiation as part of their work.

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Risks of Magnetic Resonance Imaging (MRI): There are no known major risks with an MRI scan. But, it is possible that harmful effects could be found out in the future. Even though the tunnel is open, it may bother you to be placed in a tight space (claustrophobia), and to hear the noise made by the magnet during the scan. You will be given earplugs to reduce the noise. You may also feel the table vibrate and/or move slightly during the scan. It may be hard to lie on the table during the scan. If you have any metal pieces in your body, they could move during the scan and damage nearby tissues or organs.

You will need to take off your transdermal nicotine patch, and any other medication patches you may be taking, during the MRI scan. Transdermal patches slowly deliver medicines through the skin. Some patches have metal in the layer of the patch that is not in contact with the skin (the backing). You may not be able to see the metal in the backing of these patches. Patches that contain metal can overheat during an MRI scan and cause skin burns in the immediate area of the patch. Tell the study doctor that you are using a patch and why you are using it (such as, for pain, smoking cessation, hormones). Ask your doctor for guidance about removing and disposing of the patch before having an fMRI scan and replacing it after the procedure. Tell the fMRI facility that you are using a patch during the health history questions you are asked when you arrive for your appointment.

End of Study Procedures: During the course of the study we will work with you to identify providers who will continue their care at the end of the study. After completion of the 12-week final assessments, you will undergo a three-week patch taper. You will then return for a final safety visit. We will then communicate to your physician about study procedures, your study participation, and if you benefited from your participation.

Loss of Confidentiality: There is also the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however this cannot be guaranteed.

Risks that are not known:

As with any research, there may be risks of participation or from the study medication that we cannot predict. Because this treatment is investigational, meaning non-FDA approved, there may be risks that we do not know about at this time. If you experience any unpleasant effects during this study not mentioned in this consent form, please contact a study coordinator or study doctor as soon as possible.

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Good effects that might result from this study:

The benefits to science and humankind that might result from this study: You will be adding to the understanding of whether nicotine therapy may help treat depression in older adults, as well as the effects of nicotine on memory and cognition. This information will help us determine if nicotine may be a useful approach to treating depression or memory problems.

The benefits you might get from being in this study: By receiving transdermal nicotine patches, you may experience an improvement in depression. In addition, you may experience an improvement in your memory or cognitive functioning as well. However, as people respond differently to treatments, personal benefit cannot be guaranteed.

Procedures to be followed:

Screening Visit (Total Time: 2 to 2 ½ hours):
During the initial visit, you will meet with both the study coordinator and a study doctor. Your medical and psychiatric history will be carefully reviewed to make sure that you are eligible for the study. Additionally, we will assess your current depressive symptoms and your current and past medication use. You do not have to answer any questions you do not feel comfortable answering. The interview with the study coordinator will take 60 to 90 minutes. Your visit with the study doctor will take about an hour.

For your safety, you must tell a study doctor about all the medications you are taking, including over-the-counter drugs and herbals, before you start the study and before taking any new medications while you are in the study. If there is a problem where you cannot be in the study because of one of the medications you are taking, a study doctor will discuss that with you.

As part of this visit, we will carefully evaluate you to determine if you have any metal in your body that could stop you from having the MRI. If you have had any surgeries that used implanted metal objects, we will need to request medical records to assure your safety before you could proceed to MRI. If you have had surgeries where records are not available, and you do not think those surgeries included metal, we may ask you to have an x-ray of that part of your body to make sure there is no

metal in that site. If it is deemed necessary for you to have an x-ray, this will take place before your next visit.

During this visit, you will also have an option to complete a "mock" MRI scan. Although no actual scan is taken, you will be able to experience the process (getting on and off the table, being inside the tube, and hearing the sounds the machine produces during a scan) to make sure you are comfortable having an MRI scan.

At the end of the screening visit, you will be emailed a link to complete a series of questionnaires. These questionnaires will be completed in REDCap. REDCap is a secure web platform created for researchers were data for this study will be collected and stored. If you do not have an email address, or if you prefer to complete the questionnaires on paper, you will be given a take-home packet of questionnaires to complete. We will ask you to complete them as soon as possible and, if you are given paper questionnaires to complete, you will return them to us via the addressed, stamped envelope we will provide. If you have any questions, you can contact us at any time.

Baseline Visit (Total Time: 4.5 hours)
After we are sure that you are safe to complete the MRI, this will be an in-person visit. You will meet with a study doctor who will again assess your depressive symptoms. During this visit, you will complete the neuropsychological (memory) testing and the MRI scan. This visit can last about 4 hours. If needed, we can spread the procedures out over two days as long as both visits occur within 7 days of each other.

Neuropsychological (Memory) Testing: We will ask you to complete some tasks that measure your attention, memory, and cognitive abilities. Most of these tasks will be done on the computer, but some of these tasks will be done using pencil and paper. These tasks will take about two hours, and will be completed at the beginning and end of the 12-week study period.

The memory tests are completed for research purposes only. They are not administered by a licensed clinical psychologist and thus, we are not able to provide a clinical interpretation of the results.

MRI: You will complete three brain scans using Magnetic Resonance Imaging (MRI) – one before starting the patch, one after 6 weeks of being on the patch, and one after 12 weeks of being on the patch.

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Each MRI scan will take about 60 minutes. An MRI scan is taken in a large machine that is shaped like a tunnel. This scan does not use x-rays. Instead, they use a strong magnet and radio waves, like those used in an AM/FM radio to make pictures of your body.

During the scan, you will be asked to complete two tasks. One measures attention during the MRI. This task shows pictures of faces and words, and you will be asked to identify the face's emotion.

During the other task, you will see pictures of indoor and outdoor scenes as well as faces. Some of these images will be scrambled. You will be asked to detect certain target images during this task.

You will be able to practice both tasks and ask questions about them before entering the MRI.

You may not be able to have this scan if you have a device in your body, such as aneurysm clips in your brain, heart pacemakers or defibrillators, or cochlear (inner ear) implants. Also, you may not be able to have this scan if you have iron-based tattoos or pieces of metal (bullet, BB, shrapnel) close to or in an important organ (such as the eye). If we determine that you cannot safely complete the MRI, we will withdraw you from the study.

Certain metal objects like watches, credit cards, hairpins, writing pens, etc. may be damaged by the machine or may be pulled away from the body when you are getting the scan. Also, metal can sometimes cause poor pictures if it is close to the part of the body being scanned. For these reasons, you will be asked to remove these objects before going into the room for the scan.

You will hear "hammering," clicking, or squealing noises during the scan. You will be given earplugs to reduce the noise. You will also be told how to alert the staff if you need them.

During the scan, the MRI staff is able to hear and talk to you in between scans. You will also be able to hear the staff in between scans. They will be talking to you during your scan and may ask you to not move or other simple tasks. You may be asked to lie very still throughout the scan.

In this study, the MRI scan is for research only. However, if we see something that is not normal, you will be told and asked to consult your doctor. The scans will not be routinely examined by health professionals for potential abnormalities. However, in the event an abnormality is detected by the investigators or the MRI technologist, the scans will be further examined by a radiologist and the investigator may encourage you to consult your physician or provider referrals for further evaluations.

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This MRI scanner has been used with research animals. For your safety, we clean the scanner with bleach before and after your scan as we do with scanners used only for patients.

Study Nicotine Patches: After the MRI is complete, you will receive transdermal nicotine patches. You will initially start with half of a 7m patch (3.5mg), and gradually move to a higher dosage. You will be instructed to start wearing a new study patch each day when you wake up, then take it off at night before bed.

Follow-Up Visits: We will schedule in-person follow-up visits at weeks 3, 6, and 9. Visits at weeks 3 and 9 will take about 2 hours. The week 6 visit will take about 4 hours as you will be having a second 60 minute MRI. At each follow-up visit, will assess depressive symptoms and see if you are having any side effects. Vital signs such as blood pressure, weight, and pulse will be taken and recorded during each of these visits. You will also complete a variety of questionnaires to assess depression symptoms and any side effects. These assessments will be completed during each in-person follow-up visit. At each follow-up visit you will have a blood draw to measure levels of nicotine in your blood (10 mL, which is about 2 tsp). At the week 6 visit, you will complete the questionnaires you completed after your screening visit again. These will either be completed on the computer or on paper depending on your preference.

Visit	Approximate Time	Study Doctor Visit	Questionnaires	Blood Draw	MRI	Memory Testing
Screening	2-2.5 hours	X	X			
Baseline	4.5 hours	X	X		X	x
Week 3	2 hours	X	X	X		
Week 6	4 hours	X	X	X	X	
Week 9	2 hours	X	X	X		
Week 12	5.5 hours	X	X	x	x	X
Week 15	30 minutes	x	x			

Nicotine Patches and Dosage: The nicotine patch dose will be increased 4 times during the study. During week 1, the dosage will be 3.5 mg. During weeks 2-3, the dose will be increased to 7mg. During weeks 4-6, the dose will be increased to 10.5mg. During weeks 7-9, the dose will be increased to 14mg. During weeks 10-12, the dose will be increased to 21 mg. At week 12, the dosage will be decreased from 21mg to 14mg to 7mg by week 15 before stopping. You will wear each nicotine patch for approximately 16 hours during the day and remove it at night.

Dosages can be adjusted if you develop side effects. If you develop any side effects, you should contact the study doctor to discuss the problem.

Week 12 (Total Time: 5.5 hours): During week 12, another study visit will be scheduled. During this visit, the memory testing will be repeated. You will also have a third 60 minute MRI. There will be a final blood draw to measure levels of nicotine in your blood (10 mL, which is about 2 tsp), and vitals will be taken. After this, we will begin to reduce dose of the nicotine patch. If you feel the nicotine patches have provided a benefit and would like to continue using them, you may purchase over-the-counter patches and we will not require this discontinuation. You will complete the questionnaires you completed after your screening and week 6 visits again. These will either be completed in REDCap or on paper depending on your preference.

Week 15 (Total Time: 30 minutes): Week 15 will be your final visit for this study. This visit is a final safety visit and will include a recording of vital signs. You will discuss any side effects from tapering with a study doctor. This can be done in person or by telephone.

Other treatments you could get if you decide not to be in this study:

You do not have to participate in this study to receive treatment for depression. There are many antidepressants that are commercially available and may be prescribed by your physician. Talk therapy is also available, which is a treatment for depression that does not require medications. You can also purchase nicotine patches at your local pharmacy. If you have any questions about these options, a study doctor will discuss them with you.

Payments for your time spent taking part in this study or expenses:

You will be compensated for your participation based on how many visits/assessments you attend. You can receive up to $600. The table below shows how much you will receive for completing each visit:

Visit	Amount
Screening Visit	$25
Week 0 – Assessment visit with MRI	$150

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Week 3 – Clinic visit with blood draw	$50
Week 6 – Assessment visit with blood draw and MRI	$150
Week 9 – Clinic visit with blood draw	$50
Week 12 – Assessment visit with blood draw and MRI	$150
Week 15 – Final safety visit	$25
Total	**Up to $600**

We will ask for your Social Security number and address before you are compensated for taking part in this study.

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 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 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 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 the study coordinator, Sarah Siddiqi at [redacted] or the study doctor, Dr. Warren Taylor, at [redacted] If you cannot reach the research staff, please page the study doctor at [redacted]

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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:

Your study doctor may withdraw you from study participation if he or she determines that, based on the initial study interview, you are not eligible to continue the study. He or she may also withdraw you if you are having difficulty completing study procedures, if you need an immediate referral for clinical care, or if he/she decides that it is not in your best interest to continue in the study. If you are taken out of the study, you will be told the reason.

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. We may ask you to come in for a final study visit. Because you are receiving study medication, it is important to discuss a safe and effective plan for continuing, altering, or stopping the medication. If you withdraw or are withdrawn from the study early, you will be compensated for the parts of the study you have completed.

All participation in the study is voluntary, and there is no penalty for refusing to participate or for early withdrawal. Deciding to not be part of the study will not change your regular medical care in any way.

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 reasonable efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. Your records will be kept in locked filing cabinets within locked rooms, and only the research team will have access. Your

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information may be shared with institutional and/or governmental authorities, such as the Vanderbilt University Institutional Review Board, if you or someone else is in danger or if we are required to do so by law.

All data are labeled and coded for protection and confidentiality. Data are kept on secure, password protected networked computers and in locked offices. Identification numbers are used instead of names for additional protection. Only research staff will have access to participant data. Source materials will be labeled and coded with an identification number that is not linked in any way to participant personal identifying information for purposes of additional protections and confidentiality. This number will be used to identify participants' self-reported questionnaires, memory test results, and MRI/fMRI computerized data.

A list linking names to identification numbers will be available only to authorized personnel and will be kept separately from research charts. Only research personnel authorized by the Principal Investigator will have access to these records. The link between your identity and your identification number will not be shared with researchers in other institutions and will not leave VUMC.

During the study, if we learn you are having thoughts about suicide or hurting yourself or others, the research staff will ask you more questions about your thoughts. Based on your response, the staff may provide you with help to get treatment. This may include:

- working with you to contact your doctor,
- contact a trusted family member, or a therapist to discuss your thoughts,
- or work with you on a plan that may include getting you to a hospital for safety.

In these cases, the research team may share information about your condition with other health care providers.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Taylor and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

This study is supported by the National Institutes of Health (NIH) and 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.

Blood samples will be leaving Vanderbilt University Medical Center for analyses of levels of nicotine and nicotine metabolites. They will be sent to Dr. Rachel Tyndale at the Center for Addiction and Mental Health at the University of Toronto. These samples will be deidentified. This means they will only include your study-created identification number, initials (first, last), and date of sample collection.

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.

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

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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 know now that you do not want your data in the NDA, please tell the study researcher before leaving the clinic today. 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.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

Study Results:

You will not receive results from the study. However, you will know how the nicotine patches affect you. If it would help your medical care, we can provide copies of your MRI scan to your physician. This would be a copy of the images, not a radiologist report.

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.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

What if you change your mind?
Unless told otherwise, your consent to use or share your PHI does not expire. 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. The mailing address is 1601 23rd Avenue South, Nashville, TN 37212. At that time, we will stop getting any more data about you. 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. The health data we stored before you withdrew your consent may still be used for reporting and research quality.

Study Title:	Depressed Mood Improvement Through Nicotine Dosing 2 (Depressed Mind 2)
Version:	1.6
Date:	12/20/2021
PI:	Warren D. Taylor, MD

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.

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: _____