NEW YORK STATE PSYCHIATRIC INSTITUTE

COMBINATION TREATMENT WITH L-DOPA AND EXERCISE FOR MOOD AND MOBILITY PROBLEMS IN LATER LIFE

Overview

Below is a summary of the study in which you are asked to take part in. This outline is meant to be a guide for you to use while considering the study and reading the consent form. It is not meant to replace the consent form, which you will have to sign if you decide to participate in the study. The study described is a double-blind placebo-controlled study, which means that you will be randomly assigned (like the flip of a coin) to study medication or else placebo (a sugar pill). You also will be assigned to one of two different types of physical training activities. Neither you nor the study doctor will be informed whether you are receiving study medication or placebo until the end of the study.

Participation is Voluntary

Participation in this research study is voluntary. If you decide not to participate, or if you later decide to stop participating, you will not lose any benefits to which you are otherwise entitled. A decision not to participate or withdraw your participation will not affect your current or future treatment at the New York State Psychiatric Institute or Columbia University Irving Medical Center.

Alternatives

You do not have to participate in this study to receive treatment for depression or slowed thinking and movement. Food and Drug Administration (FDA)-approved antidepressant medications such as Selective Serotonin Reuptake Inhibitors (SSRIs, e.g., Prozac, Zoloft, etc.) or Serotonin Norepinephrine Reuptake Inhibitors (SNRIs, e.g., Effexor, Cymbalta, etc.), in addition to other types of medications are effective in the treatment of depression. Additionally, psychotherapies that are supported by research such as Interpersonal Psychotherapy and Cognitive Behavior Therapy are available outside of this study to treat depression. Finally, exercise programs and cognitive remediation may be helpful for slowed thinking and movement and also are available outside this research project.

Procedures

- At the beginning of the study, you will be given a physical examination, an electrocardiogram (EKG), and have your blood drawn.
- Next you will have tests of your memory, concentration, and other thinking skills as well as a test of your walking.
- Half of study participants will undergo two (2) magnetic resonance imaging (MRI) scans of the brain, one at the beginning and one at the end of the study.

- MRI scans use strong magnetic fields and radio waves to take pictures of your brain.
- In the treatment part of the study, you will be randomly assigned to receive a medication called carbidopa/levodopa (Sinemet) or pill placebo (a sugar pill). We are using carbidopa/levodopa "off-label" in this study, which means that it is not approved by the FDA for the treatment of depression.
- In addition to taking the study pills, you will be randomly assigned to participate in an aerobic exercise regimen or a stretching program. These are programs you will complete at home under the direction of our research staff.
- You will be asked to speak to your study doctor, either in-person or remotely using the telephone or using WebEx, a Health Information Portability and Accountability Act (HIPAA) compliant video teleconferencing service, several times over the 12 weeks. You and the study doctors will talk about how you are feeling and have tests of your thinking and walking speed.
- The research study will end after 12 weeks. You will fill out some more thinking tests and have your walking speed tested again. If you received an MRI scan at the beginning of the study, you will have another at the end.

Risks

This study includes some risks and discomforts (please refer to the consent form for further details and explanations of these risks). The main risk to you in this study is that carbidopa/levodopa is an experimental treatment, and it is not known yet whether it will be effective in treating low dopamine levels or symptoms of depression. Other risks are worsening of depression while you are assigned to receive placebo, side effects associated with carbidopa/levodopa (such as nausea, headache, abnormal movements of arms and legs, muscle stiffness, and vivid dreams), and potential physical injury during the exercise treatment. There are also risks associated with COVID-19 and travel for research purposes.

Please alert study staff if you feel your depression is getting worse.

Benefits

This research study is not meant to benefit you directly. You may contact the study doctor, Dr. Bret Rutherford at 646-774-8660 with any questions.

Informed Consent for Participation in Research

COMBINATION TREATMENT WITH L-DOPA AND EXERCISE FOR MOOD AND MOBILITY PROBLEMS IN LATER LIFE

PURPOSE OF STUDY

The purpose of this research study is to understand whether a combination of two different treatments can be helpful for older adults who struggle with depression and slowed thinking and/or movement. Participants in this study will receive two things—a pill (which will be either a medication called carbidopa/levodopa or placebo) and a physical training program (which will be either aerobic exercise or a stretching and toning program). Carbidopa/levodopa is approved by the Food and Drug Administration (FDA) for the treatment of Parkinson's Disease. We are using carbidopa/levodopa "off-label" in this study, which means that it is not approved by the FDA for the treatment of depression. We are interested in studying whether the addition of physical training may help the carbidopa/levodopa work better for people.

Half of the people participating in this study will have brain scans using magnetic resonance imaging (MRI). We are performing these scans to understand more about how the brain's dopamine system may be different in older adults who are depressed. The MRI scans involve some parts where you will be asked to lie quietly in the scanner without doing anything and some parts where you will be asked to look at a screen and accomplish tasks by pressing buttons

This study is supported by a grant from the National Institute of Mental Health.

VOLUNTARY

Participation in this study is voluntary. If you do not wish to participate in this study or decide to discontinue your participation in this study later, you will not lose any benefits to which you are otherwise entitled, including current or future treatment at New York State Psychiatric Institute or Columbia University Medical Center. We will notify you of any significant new findings that may relate to your willingness to continue to participate.

ALTERNATIVE TREATMENT

You do not have to participate in this study. The alternative to participating in this study is to seek treatment outside the research project so that you would be certain of receiving a treatment approved for treatment of depression. Approved medications for depression are available (e.g., fluoxetine (Prozac), sertaline (Zoloft), etc.), and evidence based psychotherapies (Interpersonal Psychotherapy, Cognitive Behavior Therapy) also

may be helpful with depression, whether on their own or combined with medication.

Although no treatments for mental and physical slowing have been formally approved by the FDA, other treatment approaches include exercise programs and cognitive training.

Information being collected is for research purposes only and is to learn more about changes in the brain's dopamine system with aging, not about you. It is not necessary to participate in this research study to have an MRI, and the MRI done as part of this study is not the same as one done for medical purposes.

STUDY PROCEDURES

This study will follow all applicable policies of the New York State Psychiatric Institute to ensure the safety of research participants and staff during the COVID-19 pandemic. We have reduced in-person visits to the minimum needed. Some of your visits may be conducted remotely using the telephone or video teleconferencing. When it is necessary for your participation for you to come to the New York State Psychiatric Institute, research staff will ask screening questions about your health beforehand, and it is required that you wear a face covering when in the building. We offer transportation via car services to reduce risks inherent in public transportation.

Evaluation: If you decide to participate in this study, you will have blood drawn, complete some tests, and have your walking measured using a special mat. The total amount of blood taken at this study visit is about four tablespoons. Results of these blood tests will be available to you, should you request them. The tests measure thought processes such as memory, language, reasoning, and attention. These tests are paper-and- pencil as well as computer-based and take about two hours to complete. The results of these tests are for research purposes only and will not be shared with you.

Based on these tests, it will be determined whether you are eligible for the treatment portion of the study. If you are not eligible, you will be referred to appropriate options for further treatment. If you are eligible and continue to wish to participate, you will proceed with the next part of the study.

MRI scans: Half of the participants in this study will be offered the opportunity to have an MRI scan at the beginning of the study (before you receive any carbidopa/levodopa or placebo) and again after the medication/physical training part of the study. You may still participate in the medication and exercise part of the study even if you are not eligible for or do not desire to do the MRI scan. Some parts of the MRI scans involve completing tasks while you are lying in the scanner machine. You will be trained for about 1 hour before each scan in the performance of two computer tasks by one of the study's research assistants. These tasks involve sitting at a desk, looking at pictures on a computer screen, and pressing buttons with your finger. You then will be asked to undergo the MRI scans,

each of which lasts approximately one hour.

The MRI uses strong magnetic fields and radio waves to take pictures of your brain. MRI involves lying on a table that slides into a large magnet shaped like a cylinder. Before beginning the imaging procedure, we will determine whether you have a pacemaker or any unsafe metallic implants such as an aneurysm clip or heart valve and certain tattoos, and you will be asked to remove any metal or magnetized objects (such as keys, chains, jewelry, retainers, medication patches, hairpins and credit cards). You will be asked to lie flat on your back in the MRI scanner for about 60 minutes and to remain as still as possible. You will not feel anything, but you will hear a knocking noise. This is a normal sound produced by the MRI scanner and does not indicate that anything is wrong. If you feel nauseated during scanning, please immediately alert the MRI staff member. It could be dangerous to vomit while in the scanner due to a risk of aspiration.

Medication portion: In the medication part of the study, you will be randomly assigned to one of two different treatment options (like by flipping a coin). If you are assigned to the first option, you will receive the starting dose of carbidopa/levodopa (37.5mg/150mg). This dose will be increased to the final dose of carbidopa/levodopa 112.5mg/450mg. Taking the medication in this study will involve taking three pills per day, one in the morning, one at lunchtime, and one at night. If you are assigned to the second option, then you will receive pill placebo. The placebo looks like the other treatments/pills, but does not contain any medicine (it is sometimes called a "sugar pill"). Neither you nor the researchers will know if you are getting the placebo, but they can find out in an emergency. You will receive free medication or placebo for the duration of the study.

You will take the study pills for 12 weeks. If you have trouble tolerating the study medication, we will lower your dose to one you previously tolerated. If you cannot tolerate any dose of the medication, your participation in the study will be discontinued. If the study doctor feels your condition worsens significantly, the current treatment will be stopped, and you will be offered different treatments for your slowed thinking and walking.

Exercise portion: At the beginning of the study, you will have an exercise test that will measure your exercise capacity and determine the proper heart rate range for you to target during aerobic exercise. You will then be assigned to participate in a four times per week home aerobic exercise program (using a manual walking treadmill) or else a regimen of stretching and muscle toning.

Manual Walking Treadmill

You will be trained in the proper use of this equipment by a research staff member and then have the equipment delivered to your home. You will keep logs of your exercise and upload information from a heart rate monitor you will wear while doing the exercise. A research team member will serve as your "coach" and will review this information to ensure you are exercising safely and properly. You will be allowed to keep the exercise equipment following your participation in the study.

If you are assigned to the stretching and toning regimen, you will also be trained in the proper performance of the exercises, and a research "coach" will monitor your progress. At the end of the 12 week study, you will again return to our clinic to have your exercise capacity re-tested.

The study doctor may stop your participation in the study at any time without your consent if you do not comply with the study procedures or for other reasons. You will return to our clinic several times to speak with the study doctor and have some tests. These appointments will last about 45 minutes. Between these visits you may have phone check ins with the study doctor and other research staff. The research study will end after 12 weeks, when you will again complete the tests you performed at the beginning of the study and have another MRI (if you are in the MRI part of the study).

Following the study, you will still receive 3 months of free doctor visits in the clinic. The medication used in this study is available from pharmacies, so it is an option to continue taking the medication following the study if you feel you have benefited from it. You will receive at least 1 month of free medication if you wish. Every effort will be made to provide free medication for 3 months total, but we cannot guarantee the availability of free medication beyond 1 month. If you do not wish to continue the medication after the study, the dose will be gradually decreased over 3 days before stopping it.

RISKS

Carbidopa/levodopa risk: The main risk to your participation in this study is that carbidopa/levodopa is an experimental treatment, and it is not known yet whether it will be effective in treating low dopamine levels or symptoms of depression. The most common side effects reported for carbidopa/levodopa are nausea, headache, and vivid dreams. You should be careful about drinking alcohol, since it may have a greater effect on you in combination with medication.

In addition, you may be assigned to receive placebo for 12 weeks during the study. Therefore, you will not receive Food and Drug Administration (FDA) approved medication for your condition until after the 12 week study is over. There will be a delay of 12 weeks (the time you are doing the study) before you will receive a treatment that is known to be effective for the treatment of depression (e.g., antidepressant medication). There is a chance your depression may worsen during the time you are receiving carbidopa/levodopa or placebo in this study.

It is not fully known how the normal slowing down that occurs during aging relates to the type of slowing that occurs in patients with Parkinson's disease. Some individuals who experience slowing with age may be at increased risk for Parkinson's disease. carbidopa/levodopa is a treatment for Parkinson's disease, but in patients with the illness it can be associated with increased risk for developing abnormal movements over time.

You do not have Parkinson's disease right now. However, if you were to go on to develop Parkinson's disease later on and need treatment with carbidopa/levodopa, there is a small possibility that your participation in this study could increase your risk of developing abnormal movements. It is difficult to know the exact chances of your needing carbidopa/levodopa in the future or your risk of abnormal movements, but we would estimate the chances of this study causing you problems in the future as less than 1%.

Exercise risks: You may experience physical injury, muscle soreness, and/or fatigue due to the study assessments of balance and gait as well as the increased physical activity if you are assigned to receive exercise. Most such injuries are minor and resolve on their own with time, but it is possible for more serious injuries to occur including broken bones or joint dysfunction. Additionally, an exercise-induced cardiovascular event (such as a stroke or heart attack) is a potential risk, although the study team seeks to minimize this risk by clearing your study participation with your primary doctor and not allowing individuals with serious cardiovascular problems to participate in the study. The study team will provide training on how to safely exercise or perform stretching movements, and we will closely monitor your heart rate during the study.

MRI risks: The long-term effects of being placed in a magnet of this strength (3 Tesla) are unknown, but you should be aware that there have been no reports of any ill long-term effects caused by magnets of the same or even higher strength, either here or elsewhere. Also, although there are no known risks associated with pregnancy, we will not scan someone who is pregnant. Therefore, you should understand that if you are a woman in your childbearing years, pregnancy testing will be used to assure that you are not pregnant.

Some people have reported sensations during MRI scans, such as "tingling" or "twitching" (or, very rarely, a painful sensation), which are caused by changes in the magnetic field that can stimulate nerves in your body. If you experience sensations and feel that these are uncomfortable, you can tell the MRI technologist, and he or she will stop the scan immediately. Occasionally, some people experience nervousness or claustrophobic feelings due to the scanner's small space. If you encounter any discomfort, you can tell the MR technologist, and he or she will stop the scan immediately. Despite these experiences, no one has ever had sensations from the scanning that did not stop as soon as the scanning stopped.

Except for pacemakers and some types of metallic implants, we know of no health hazard from the MRI scan. The MRI scan is not painful, but lying still on the scanning table may be slightly uncomfortable.

Other risks: When your blood is drawn, there is a small risk you may be left with a bruise that will resolve within a few days. Results of blood tests taken for research purposes will remain confidential.

Furthermore, specifically for in person visits to NYSPI, individuals are at increased risk for exposure to COVID-19 both in transit to NYSPI as well as during their time at NYSPI. Procedures are in place to minimize this risk. We plan to offer car transportation subject to a maximum of $50 each way, which minimizes exposure to public transportation for those participants. At NYSPI, personal protective equipment such as masks will be utilized at all times both by staff and participants, and social distancing will be adhered to when possible (exceptions exist for procedures such as blood draws and EKGs). Screen shields between patient and staff will be used during neuropsychological testing to further minimize exposure risk.

BENEFITS

You may not benefit from this study, and no benefit is in any way guaranteed as a result of your participation.

RESULTS OF YOUR MRI

While MRI scans are sometimes done for clinical purposes, the kind of MRI scans you will have as part of this study is for research purposes only. This means that the scans are not designed to provide clinical information that might be helpful to you or your doctor and they may not show problems that would normally be found in an MRI ordered to evaluate a specific medical problem. It is likely that the MRI scan will not have the quality of those done for clinical purposes.

However, within a month of the MRI scans, the scans will be read by a neuroradiologist for evidence of any obvious irregularities requiring your follow-up. You, or a physician whom you may designate, will be informed only when significant abnormalities are detected. If you wish, we can also inform you if there were no obvious findings. Given the nature of the scans, the absence of a finding does not mean that one is not present.

CONFIDENTIALITY

Your records will be stored in a locked file. Records will be available to research staff, and to Federal, State and Institutional regulatory personnel (who may review records as part of routine audits). There are legal advocacy organizations that have the authority under State Law to access otherwise confidential records, though they cannot be redisclosed without your consent. All records will be kept confidential to the extent permitted by law. Your name and other personal identifying information will be stored in an electronically secure database at New York State Psychiatric Institute. Electronically stored data will be accessible only by password known to the study investigators and research assistants. For participants with email access, self-report measures will be sent via

encrypted email.

Your MRI will be interpreted and the results will be shared with you or a physician who you may designate. Your MRI report will be maintained as part of the clinical database at the New York State Psychiatric Institute or the Columbia University Medical Center along with your name and will be accessible to clinicians at the Medical Center. Your psychiatric diagnosis will not be a part of the report.

The data obtained for this study and biospecimens could be used for future research studies or may be distributed to another investigator for future research studies, however all information including biospecimens will be de-identified (this means information cannot be linked back to you) and will not include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). Biospecimens will not be used for commercial profit. Clinically relevant research results, including individual research results may be available to you at you request but such request will be granted under the discretion of the study doctor. You may be contacted in the future by the study team for future studies.

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share de-

identified information with each other. A data repository is a large database where information from many studies is stored and managed. De-identified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

During and after the study, the researchers will send de-identified information about your health and behavior to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to your de-identified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers around the world treat future children and adults with mental illnesses so that they have better outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at http://data-archive.nimh.gov.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information

A description of this clinical trial will be available on 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.

COMPENSATION AND ECONOMIC CONSIDERATIONS

You will not be charged for any procedures that are a part of this study, including the study medication or the exercise equipment and coaching.

To compensate you for the time required for each study visit, we offer $35 for your initial screening visit and $100 for each of your two main assessment sessions (beginning and end of study). This money will be paid by cash at the conclusion of each of these visits.

For those individuals doing MRI scans, we offer $50 for each MRI scan ($100 total if you attend both scans). This money will be paid in 1 lump sum payment at the end of the study. Payments typically require 1-3 weeks to process and will be mailed in the form of a check.

Thus, the maximum compensation in this study will be $335 for participants attending all study visits and doing all neuroimaging procedures.

IN CASE OF INJURY

Federal regulations require that we inform participants about our institution's policy with regard to compensation and payment for treatment of research-related injuries.

In case of injury, New York State Psychiatric Institute will provide short term emergency medical treatment, which has been determined to be necessary by New York State Psychiatric Institute's doctors, and which is within the capability of New York State Psychiatric Institute to provide. In addition, we will provide assistance in arranging follow up care in such instances.

New York State Psychiatric Institute and Research Foundation for Mental Hygiene do not provide compensation or payment for treatment of research related injuries. However, you should be aware that you do not give up your legal right to seek such compensation through the court by participating in this research.

Please be aware that:

1. The Research Foundation for Mental Hygiene, The New York State Psychiatric Institute, Columbia University and New York Presbyterian Hospital will furnish that emergency medical care determined to be necessary by the medical staff of this hospital
2. You will be responsible for the cost of such care, either personally or through your medical insurance or other form of medical coverage.
3. No monetary compensation for wages lost as a result of injury will be paid to you by the New York State Psychiatric Institute, Columbia University or by New York Presbyterian Hospital.
4. By signing this consent form, you are not waiving any of your legal rights to seek compensation through the courts.

QUESTIONS

If you have further questions about the research procedures, or about your response to the procedures research staff members are available to answer them to the best of their ability. You can reach Dr. Bret Rutherford at 646-774-8660 during general business hours.

In an emergency, you may reach the on call doctor at 917-786-6940, 24 hours per day. If you have general questions, you may contact the research coordinator at 646-774-8664. We will notify you of any significant new findings that may relate to your willingness to continue to participate.

If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of human subjects in research studies). You may call the IRB Main Office at (646) 774-7155 during regular office hours.

You will be given a copy of this consent form to keep.

DOCUMENTATION OF CONSENT

I have read the above and voluntarily agree to participate in the research study described above. To the best of my knowledge, I am not pregnant. I have been informed that my participation is voluntary, and that I can withdraw from the study at any time without penalty or loss of benefits to which I am otherwise entitled.

Print name: _____

Signed: _____

Date: _____

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions and in my opinion is capable of freely consenting to participate in this research.

Print name: _____
Person Designated to Obtain Consent

Signed: _____

Date: _____

New York State Psychiatric Institute (NYSPI)
Authorization to Use or Disclose Health Information during a Research Study

Protocol Number: **Principal Investigator:** Bret R. Rutherford, MD

Name of Study: Combination Treatment with L-DOPA and Exercise for Mood and Mobility Problems in Later Life

Before researchers can use or share any identifiable health information ("Health Information") about you as part of the above study (the "Research"), the New York State Psychiatric Institute (NYSPI) is required to obtain your authorization. You agree to allow the following individuals and entities to use and disclose Health Information about you as described below:

- New York State Psychiatric Institute (NYSPI), your doctors and other health care providers, if any, and
- The Principal Investigator and his/her staff (together "Researchers"). Researchers may include staff of NYSPI, the New York State Office of Mental Health (OMH), Research Foundation for Mental Hygiene, Inc. (RFMH), and Columbia University (CU), provided such staff is a part of the study, and
- Providers of services for the Research at CU, NYSPI and/or RFMH, such as MRI or PET, or Central Reference Laboratories (NKI), if indicated in the consent form**.**

1. The Health Information that may be used and/or disclosed for this Research includes:

☑ All information collected during the Research as told to you in the Informed Consent Form.
☑ Health Information in your clinical research record which includes the results of physical exams, medical and psychiatric history, laboratory or diagnostic tests, or Health Information relating to a particular condition that is related to the Research.
☑ Additional information may include:
MRI scans

2. **The Health Information listed above may be disclosed to:**

☑ Researchers and their staff at the following organizations involved with this Research:
The New York State Psychiatric Institute, Columbia University Irving Medical Center, The Nathan Kline Institute for Psychiatric Research

☑ The Sponsor of the Research,
National Institute of Health
and its agents and contractors (together, "Sponsor"); and
☑ Representatives of regulatory and government agencies, institutional review boards, representatives of the Researchers and their institutions to the level needed to carry out their responsibilities related to the conduct of the research.
☐ Private laboratories and other persons and organizations that analyze your health information in connection with this study

☐ Other (family members or significant others, study buddies, outside agencies etc.) Specify:

3. By giving permission to release your Health Information as described above, you understand that your Health Information may be disclosed to individuals or entities which are not required to comply with the federal and state privacy laws which govern the use and disclosure of personal Health Information by NYSPI. This means that once your Health

Information has been disclosed to a third party which does not have to follow these laws (e.g., a drug company or the Sponsor of the Research), it may no longer be protected under the HIPAA or NYS Mental Hygiene Law requirements but is subject to the terms of the consent form and may be subject to other state or federal privacy laws or regulations.

4. Please note that:

- You do not have to sign this Authorization form, but if you do not, you may not be able to participate in the study or receive study related care. You may change your mind at any time and for any reason. If you do so, you may no longer be allowed to participate in the study. If you withdraw this Authorization the research staff and the Sponsor, if this is sponsored research, may still use or disclose Health Information containing identifying information they already have collected about you as needed to maintain the reliability of the research. Any request to withdraw this Authorization must be made in writing to (enter name and contact information below):

  Bret R. Rutherford, MD
  1051 Riverside Drive, Box 98
  New York, New York 10032
- While the Research is going on, you may not be allowed to review the Health Information in your clinical research record that has been created or collected by NYSPI. When this research has been completed you may be allowed to see this information. If it is needed for your care, your Health Information will be given to you or your Doctor.

5. This Authorization does not have an end date.

6. You will be given a copy of this form after you have signed it.

I agree to the use and disclosure of Health Information about me as described above:

_____ _____

Signature of Participant/ Legal Representative Date

_____

Printed Name of Participant

_____

Relationship of Legal Representative to Participant (if applicable)

We also ask you or your legal representative to initial the statements below:

☐ **I have received a copy of the NYSPI/OMH Notice of Privacy Practices.**