Title:
Social Decision Making in Parkinson's Disease

NCT Number:
NCT04249544

Document date:
04/12/2023

VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Richard Ryan Darby, M.D. **Revision Date: 12/2/2020**
Study Title: Cognitive and Neural Mechanisms of Impaired Social Decision-Making in Parkinson's Disease Patients Taking Dopamine Agonists
Institution/Hospital: Vanderbilt University Medical Center

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Als. o, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

You are being asked to participate in this research study because you have Parkinson's disease and are taking a dopamine-related medication. The purpose of the study is to understand how dopaminergic medications influence your thinking. Over one screening and two study visits (three visits total), you will be invited to participate in a cognitive evaluation, answer some questionnaires, and have two non-invasive MRIs, which include a task which you will do while in the scanner. Each study visit should not take longer than 5 hours. By completing this consent form, you are not obligated to participate in the study. You may/ma not benefit from the study and some of the potential benefits if you have metal in your body that is not MRI compatible, if you're claustrophobic, or if you're uncomfortable slightly altering your medication regiment for the two study days. Risks can include that you will be uncomfortable answering questions, laying in the MRI, or taking a different type of dopamine agonist. Furthermore, you will be asked to withdrawal off of certain Parkinson's medications. This will be explained to you at the screening visit. When withdrawing from Parkinson's medications, you may experience an increase in tremor, rigidity, and other Parkinson's symptoms. Additionally, you may be asked to participate in some sub-studies. Deciding to participate or not participate in the sub-studies will not affect your ability to participate in this study. A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include any information that can identify you. At most, the website will include a summary of the results. You can search this Website at any time.

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 Parkinson's Disease and are taking a dopamine-related medication.

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.

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Procedures to be followed and approximate duration of the study:

You will be asked to take time out of your day to travel to the lab to take part in the study, which can be inconvenient. However, if you are traveling from outside of the Nashville area (greater than 15 miles), we will reimburse your fuel costs and possibly offer to pay for a hotel expense if you are traveling from a considerable distance, up to 150 miles. Other possible things that may make you uncomfortable are frustration and/or fatigue while doing the computer tasks and filling out the questionnaires. However, the staff will do everything they can (such as offering breaks) to make you as comfortable as possible.

The study procedures are described in detail below. The boxes will be checked for the procedures you will complete.

☐ Health Screen: The health screen will take place in Dr. Darby's lab, located on the 2nd floor of the Villages at Vanderbilt, and will involve an interview completed with the study doctor, study coordinator, or research staff. During the interview, you will be asked a series of questions about your medical history, personal background information (such as your handedness (left or right-handed), age, etc.), and information about any present or past psychiatric diagnoses or treatments. These questions come from a standard health background form that we use in all of our studies. You may skip any questions that you do not feel comfortable answering. If, after completing this interview, you do not fit our study criteria, you will not be asked to participate further. We will then destroy any information gathered about you immediately.

This part of the study will take between 5-10 minutes of your time.

☐ Questionnaires and Computer Testing: The questionnaires and computer study will be administered in Dr. Darby's lab, located on the 2nd floor of the Villages at Vanderbilt or in a quiet room in the Vanderbilt VUIIS. The questionnaires will take between 30 to 45 minutes of your time and include assessments about certain thinking and emotional difficulties that you may be experiencing. You will also complete a few measures of thinking abilities that will require you to read a list of words and perform some mental calculations. Additionally, your caregiver will fill out study questionnaires asking them questions about your thinking.

We are interested in how dopamine agonists (e.g., Mirapex, Requip, Neupro) affect learning and risk behavior. To determine this, we invite you to complete the Computer Testing on up to three separate visits. You will take certain medications and withhold taking other medications before your study visit. This allows us to determine how medications impact your thinking, speed, and skills. Computer tasks measuring reaction time will require you to make quick button presses with your left and right thumbs as you see objects appear on the computer screen. No computer experience is necessary to perform these tasks and rest breaks are provided frequently. These computer tasks should take between 1.5 to 2 hours of your time.

You will be asked to withdraw from some medications prior to testing. If you agree to withdraw from your Parkinson's disease medications, you will likely experience an increase in some symptoms associated with Parkinson's disease, such as tremor, rigidity, or slower movements. If these symptoms become too uncomfortable or you feel that you are at risk for falling, you can take your medications at any time. Your safety is most important to us. We do not want this to be a stressful or painful experience for you. There are no long-term effects of withdrawing from Parkinson's disease medications for the periods of time required for this study, and we will have a member of our movement disorders neurology team on site and available at all times should any complications arise.

☐ MRI Scans: This portion of the study consists of two MRI scans, on two separate visits. One visit will require you to have withdrawn from brain activity alerting medications (Amantadine, Selegiline, Rasagiline, Gabapentin, Entacapone, etc.) and to have taken your home dose of carbidopa/levodopa and 1mg of a placebo 1 hour before the start of the scan. The other will require the same medication withdrawal and for you to take your home dose of carbidopa/levodopa and 1 mg of pramipexole one hour before the scan. The pramipexole and placebo medications will be provided to you. You will remain blinded to the medication you take on each scan day, apart from the Carbidopa-Levodopa. We do this in order to attempt to control for how you might respond based on the knowledge of which medication you received. Dr. Darby and his colleague Dr. Claassen will oversee this medication administration. This will be explained to you in detail before you are enrolled in the study and a medication schedule will be given to you. Each MRI scan will take between 30 and 90 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.

You will not be able to have this scan if you have a device in your body, such as aneurysm clips in the brain, heart pacemakers or defibrillators, and cochlear (inner ear) implants. Also, you will 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).

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. You will also be able to hear the staff. They will be talking to you during your scan and may ask you to hold your breath, 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. But, if we see something that is not normal, you will be told and asked to consult your doctor.

Expected costs:

There is no cost to you for participating in this study.

However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non- research) further before choosing to be in the study. You may choose not to be in this study if your

insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

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.

If you use a transdermal patch (medicated patches applied to the skin), you may need to take it off 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 fMRI 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 MRI facility that you are using a patch. You should do this when making your appointment and during the health history questions you are asked when you arrive for your appointment.

There are no known risks of having MRI scans without contrast while pregnant. However, there may be risks that are unknown. To minimize these risks, you will not be able to have the scan if you are pregnant. To rule out pregnancy, if you are a female of childbearing potential, you will be required to take the serum BHCG pregnancy test.

Some questions that we ask you might seem unusual or make you uncomfortable. We will do everything we can to make you as comfortable as possible and you have the right to refuse to answer any questions. The cognitive tasks also might seem boring. We will offer you breaks as often as possible.

Unforeseeable risks:

We do not anticipate any unknown or unforeseeable risk associated with participation in this study.

Compensation in case of study-related injury:

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.

Good effects that might result from this study:

a) The benefits to science and humankind that <u>might</u> result from this study. The information we get from these studies may be helpful in evaluating and understanding how Parkinson's disease treatments affect thinking speed and abilities.
b) The benefits you might get from being in this study. There will be no direct benefit to you by taking part in this study. We will do our best to at the conclusion of your participation to explain the study in detail and comment on how you performed.

Study Results:

We provide an option to schedule a return visit to receive MRI results from the study investigator, Dr. Darby. If an incidental finding is discovered on an MRI, you will be alerted and your MRI image will be sent to a radiologist for review. These results will be shared with you by the study investigator, Dr. Darby. Furthermore, results will be shared on clinicaltrials.gov. This website will not include information that can identify you.

Alternative treatments available:

There are no known alternative treatments available.

Compensation for participation:

- ☐ Computer Study: You will be paid $10 per hour for participating in the computer studies. You will receive the full amount even if the last hour is incomplete.
- ☐ MRI Study: You will be paid $50 ($25 per hour) for participating in the MRI study. You will receive the full amount even if the last hour is incomplete.
- ☐ Travel Reimbursement: You will be reimbursed for fuel/travel costs if you are traveling from outside of the Nashville area greater than 15 miles. You will be reimbursed at a standard mileage reimbursement rate, currently at $0.57.5/mile up to 150 miles. If you are traveling from a considerable distance and participating in a medication withdrawal or stimulation withdrawal study, we will discuss the option of having you stay overnight in Vanderbilt's Clinical Research Center or be provided with or reimbursed for staying in a hotel.

If you do not complete the study, you will be paid for those procedures you completed.

As an identifier for our own purposes, your social security number is needed because you are receiving payment for taking part in this study. Vanderbilt University Medical Center is required to tell the IRS of any payments to you as a subject in research studies in a given calendar year totaling $600 or more. If that occurs, you will receive a 1099 form at the end of the year. No information identifying why you received payment is given to the Hospital's accounting department or the government. This information is kept strictly confidential.

Circumstances under which the Principal Investigator may withdraw you from study participation:

Dr. Darby can remove you from the study at any time if it is in your best interest or the best interest of the study. For example, if you are having a lot of motor symptoms while off of your medications, or if you are experiencing high levels of anxiety or frustration during the study, he may decide that it is better for you to stop the testing. Dr. Darby will tell you why you are removed from the study. Also, if there is a new finding that may make you change your mind about taking part in this study, you will be told right away.

What happens if you choose to withdraw from study participation?

Being in this study is voluntary. You may refuse to be in the study or quit at any time and this will not affect the medical care you will receive at Vanderbilt. If you choose to quit, you should tell Dr. Darby or the research staff. Dr. Darby reserves the right to use any data gathered from you before your withdrawal of the study. However, if this data is not usable, Dr. Darby will destroy the information.

Contact Information. If you should have any questions about this research study or possibly injury, please feel free to contact **Katie Hay** at **Vanderbilt University Medical Center** or my Faculty Advisor**, Ryan Darby** at **615-875-7403.**

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. All information and results gathered during your participation will be kept in a secure place available only to the researchers involved in this study. Participant confidentiality will be maintained in this study by isolating the data being collected from the true identity of the participant. Electronic databases containing identifiable participant information will be password encoded. Written information containing participant identifiers (informed consent, lab results, subject payment, etc.) will be stored in file cabinets in offices within the Department of Neurology. Participants will be given a code that will be used to label all research data including all questionnaires and MRI data. This study is funded, in part, by the Department of Defense. The DoD reserves the right to access these records as a part of it's regulatory oversight activities.

Dr. Darby, his study team, and/or Vanderbilt may share your information including the results of this study and/or non-study linked research study test results, and medical records, without identifiers, to the Department of Defense, or use it for other research projects not listed in this form. Vanderbilt, Dr. Darby 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.

Furthermore, this study may have some support from the National Institutes of Health (NIH) and the Department of Defense. If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means

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.

Privacy:

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Darby and his study team may share the results of your study and/or non-study linked research study test results, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, National Institutes of Health, and regulatory authorities in other countries. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

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.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

Procedures to be followed and approximate duration of the study:

You will be asked to take time out of your day to travel to the lab to take part in the study, which can be inconvenient. However, if you are traveling from outside of the Nashville area (greater than 15 miles), we will reimburse your fuel costs and possibly offer to pay for a hotel expense if you are traveling from a considerable distance, up to 150 miles. Other possible things that may make you uncomfortable are frustration and/or fatigue while doing the computer tasks and filling out the questionnaires. However, the staff will do everything they can (such as offering breaks) to make you as comfortable as possible.

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In this study, the MRI scan is for research only. But, if we see something that is not normal, you will be told and asked to consult your doctor.

Expected costs:

There is no cost to you for participating in this study.

However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non- research) further before choosing to be in the study. You may choose not to be in this study if your

insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

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.

If you use a transdermal patch (medicated patches applied to the skin), you may need to take it off 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 fMRI 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 MRI facility that you are using a patch. You should do this when making your appointment and during the health history questions you are asked when you arrive for your appointment.

There are no known risks of having MRI scans without contrast while pregnant. However, there may be risks that are unknown. To minimize these risks, you will not be able to have the scan if you are pregnant. To rule out pregnancy, if you are a female of childbearing potential, you will be required to take the serum BHCG pregnancy test.

Some questions that we ask you might seem unusual or make you uncomfortable. We will do everything we can to make you as comfortable as possible and you have the right to refuse to answer any questions. The cognitive tasks also might seem boring. We will offer you breaks as often as possible.

Unforeseeable risks:

We do not anticipate any unknown or unforeseeable risk associated with participation in this study.

Compensation in case of study-related injury:

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.

Good effects that might result from this study:

a) The benefits to science and humankind that <u>might</u> result from this study. The information we get from these studies may be helpful in evaluating and understanding how Parkinson's disease treatments affect thinking speed and abilities.
b) The benefits you might get from being in this study. There will be no direct benefit to you by taking part in this study. We will do our best to at the conclusion of your participation to explain the study in detail and comment on how you performed.

Study Results:

We provide an option to schedule a return visit to receive MRI results from the study investigator, Dr. Darby. If an incidental finding is discovered on an MRI, you will be alerted and your MRI image will be sent to a radiologist for review. These results will be shared with you by the study investigator, Dr. Darby. Furthermore, results will be shared on clinicaltrials.gov. This website will not include information that can identify you.

Alternative treatments available:

There are no known alternative treatments available.

Compensation for participation:

- ☐ Computer Study: You will be paid $10 per hour for participating in the computer studies. You will receive the full amount even if the last hour is incomplete.
- ☐ MRI Study: You will be paid $50 ($25 per hour) for participating in the MRI study. You will receive the full amount even if the last hour is incomplete.
- ☐ Travel Reimbursement: You will be reimbursed for fuel/travel costs if you are traveling from outside of the Nashville area greater than 15 miles. You will be reimbursed at a standard mileage reimbursement rate, currently at $0.57.5/mile up to 150 miles. If you are traveling from a considerable distance and participating in a medication withdrawal or stimulation withdrawal study, we will discuss the option of having you stay overnight in Vanderbilt's Clinical Research Center or be provided with or reimbursed for staying in a hotel.

If you do not complete the study, you will be paid for those procedures you completed.

As an identifier for our own purposes, your social security number is needed because you are receiving payment for taking part in this study. Vanderbilt University Medical Center is required to tell the IRS of any payments to you as a subject in research studies in a given calendar year totaling $600 or more. If that occurs, you will receive a 1099 form at the end of the year. No information identifying why you received payment is given to the Hospital's accounting department or the government. This information is kept strictly confidential.

Circumstances under which the Principal Investigator may withdraw you from study participation:

Dr. Darby can remove you from the study at any time if it is in your best interest or the best interest of the study. For example, if you are having a lot of motor symptoms while off of your medications, or if you are experiencing high levels of anxiety or frustration during the study, he may decide that it is better for you to stop the testing. Dr. Darby will tell you why you are removed from the study. Also, if there is a new finding that may make you change your mind about taking part in this study, you will be told right away.

What happens if you choose to withdraw from study participation?

Being in this study is voluntary. You may refuse to be in the study or quit at any time and this will not affect the medical care you will receive at Vanderbilt. If you choose to quit, you should tell Dr. Darby or the research staff. Dr. Darby reserves the right to use any data gathered from you before your withdrawal of the study. However, if this data is not usable, Dr. Darby will destroy the information.

Contact Information. If you should have any questions about this research study or possibly injury, please feel free to contact **Katie Hay** at **Vanderbilt University Medical Center** or my Faculty Advisor**, Ryan Darby** at **615-875-7403.**

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. All information and results gathered during your participation will be kept in a secure place available only to the researchers involved in this study. Participant confidentiality will be maintained in this study by isolating the data being collected from the true identity of the participant. Electronic databases containing identifiable participant information will be password encoded. Written information containing participant identifiers (informed consent, lab results, subject payment, etc.) will be stored in file cabinets in offices within the Department of Neurology. Participants will be given a code that will be used to label all research data including all questionnaires and MRI data. This study is funded, in part, by the Department of Defense. The DoD reserves the right to access these records as a part of it's regulatory oversight activities.

Dr. Darby, his study team, and/or Vanderbilt may share your information including the results of this study and/or non-study linked research study test results, and medical records, without identifiers, to the Department of Defense, or use it for other research projects not listed in this form. Vanderbilt, Dr. Darby 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.

Furthermore, this study may have some support from the National Institutes of Health (NIH) and the Department of Defense. If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means

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.

Privacy:

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Darby and his study team may share the results of your study and/or non-study linked research study test results, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, National Institutes of Health, and regulatory authorities in other countries. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

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.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title