Vigor and the LDR in Parkinson Disease

NCT04821830

Date of IRB Approval: December 13, 2023

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Vigor and the LDR in Parkinson disease

Company or agency sponsoring the study:
National Institute of Neurologic Disease and Stroke-National Institutes of Health

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):
Principal Investigator: Roger L. Albin, MD
Study Coordinator: Teresa Scerbak, BS, CCRP

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This is aimed at understanding how the most common treatment for Parkinson disease works in the brain.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include short periods of nausea or fatigue. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by leading to improved treatments of Parkinson disease. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be 4 days for Experiment 1, 5 days for Experiment 2 or 9 days if you choose to participate in both studies, over the course of 2 years.

You can decide not to be in this study. Alternatives to joining this study include continuing your routine care.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Parkinson disease is a common disorder in which reduced speed of movement results from inadequate brain production of the chemical dopamine. The most effective treatment for Parkinson disease is the drug levo-dopa, which partially replaces brain dopamine. Despite decades of successful use, the ways levo-dopa improves speed of movement in Parkinson disease is not understood. There is a very important component of levo-dopa action, the Long Duration Response (LDR), that lasts for days to weeks. We do not understand how the LDR works. The purpose of these experiments is to understand how levo-dopa treatment in Parkinson disease enhances movement speed. Understanding how the levo-dopa treatment produces the LDR may lead to improved treatment of Parkinson disease.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

To be eligible to participate:

- Diagnosis of Parkinson Disease
- Previously Untreated or treated for <4 weeks
- Age >45 and <91
- Mild to Moderate Parkinson disease (Hoehn & Yahr Stages I-II)
- About to start treatment with a L-Dopa preparation (Sinemet)

Subjects with any of the following are not eligible to participate in this study:

- The presence of other neurologic disease or findings on examination
- Depression: Geriatric Depression Scale score >11
- Use of dopamine agonists or stimulants
- Evidence of a stroke or mass lesion on prior structural brain imaging (MRI or CT)
- Evidence of any confounding medical or psychiatric problem that would preclude task participation.
- Participants with cognitive impairment that might impair their capacity to provide informed consent.
- Evidence of color vision deficiency (experiment 2 only)

3.2 How many people are expected to take part in this study?

Approximately 40 participants will take part in this study. If the study research site, the research sponsor, or you believe that going in to the study center might put you at risk of exposure to the novel coronavirus (COVID-19), then some of the procedures usually done at study visits may be done over the phone.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Participation in this study involves testing your ability to perform movements under different conditions. These evaluations are performed at 4 times, 2 times before the start of your routine treatment for Parkinson disease and 2 times after the start of your routine treatment for Parkinson disease. There are 2 experiments. Participants may take part in either one or both of these experiments.

Experiment 1 (see Table 1 below for Visit Schedule):

Standard Clinical Evaluation: At each study visit, all participants will undergo a standard clinical evaluation consisting of a physical examination by one of our physicians to assess severity of Parkinson disease, and a simple task to evaluate your speed of movement. You will be asked to alternatively tap two counters spaced about 1.5 feet apart as fast as you can. You will fill out questionnaires to assess aspects of mood and your thinking. These evaluations will take about 1.5 hours.

Movement Tasks:

You will be asked to perform 2 tasks assessing control of speed of movement. In the first task, you will be asked to squeeze a hand-held grip strength monitor in proportion to an offered small monetary reward. There will be a number of trials in which you are offered varying reward amounts. How hard you squeeze the grip strength monitor will be recorded in each trial. In the second task, you will move a joystick against varying resistance, again in proportion to a small monetary reward. Your speed and force of movement will be recorded. These tasks will take about 1.5 hours.

There will be 4 study visits for Experiment 1 (see Table 1 below for Visit Schedule). The first and second visits (baseline visits) will take place prior to your starting treatment for your Parkinson disease. The third and fourth visits (follow-up visits) will occur 2-3 months after you start treatment and when you have been on a stable dose of your Parkinson disease medication for weeks.

- Visit 1: For the Baseline Visit 1 session, you will not have taken any Parkinson disease medication.
- Visit 2: Baseline Visit 2 will take place within 2 weeks of Baseline Visit 1. For this Visit, you will take a standard dose of the preferred medication for Parkinson disease – carbidopa/levodopa 25/250 – wait approximately 1 hour and repeat the evaluations and tasks. First time use of carbidopa/levodopa occasionally produces nausea or lightheadedness. To reduce the chance of these side-effects occurring, we will ask you to take carbidopa for the prior 24 hours.
- Visit 3: Follow-up Visit 1 will be identical to the Baseline Visit with 1 exception. You will be asked not to take your usual Parkinson disease medication the morning of the Follow-up Visit. You will resume your usual Parkinson disease medications after the evaluations and tasks are complete.

- Visit 4: Follow-up Visit 2 will take place within 2 weeks of Follow-up Visit 1. It will be identical to Follow-up Visit 1 except that you will take your usual Parkinson disease medications on your usual schedule.

Experiment 1: Table of Visits

Visit Evaluations	Visit 1	Visit 2	Visit 3	Visit 4
Examination	X	X	X	X
Cognitive Tests	X	X	X	X
Mood Questions	X	X	X	X
Tapping Task	X	X	X	X
Grip Strength Task	X	X	X	X
Joystick Task	X	X	X	X

Experiment 1: Visit Schedule

Visit Component	Time Requirement
Clinical History; Neurologic Examination; Evaluation PD Severity; Tapping Task	0.5 Hour
Questionnaires for Thinking and Mood	1 Hour
Movement Tasks	1.5 Hour

Experiment 2:

Standard Clinical Evaluation: At each study visit, all participants will undergo a standard clinical evaluation consisting of a physical examination by one of our physicians and answer questions to assess severity of Parkinson disease. These evaluations will take about 30 minutes. In addition to the standard clinical evaluation, at the training visit, participants will be asked to complete questionnaires to assess aspects of your thinking and mood and look at a series of images designed to detect red-green color deficiencies. These tasks will take about 1 hour.

Eye Movement Task: This task has 2 components; a training component and a test component.
In the training component, you will be asked to look at a computer screen and move your focus of vision as quickly as possible from the center of the computer screen to visual targets around the screen. You will be rewarded for moving your vision towards some targets but not others. In the test component, you will be presented with the visual targets and asked to look quickly at some but not others. Where you look and how fast you move your vision from the center of the screen to the targets will be recorded. Both training and test sessions will take about 1 hour.

Movement Task: You will be asked to perform a task to assess control of speed of movement. In this task, you will move a joystick against varying resistance, in proportion to a small monetary reward. Your speed and force of movement will be recorded. This task will take about 30 minutes.

There will be 5 study visits for Experiment 2. The first, training visit, will take place before you start treatment for your Parkinson disease. The second and third visits will be test visits. They will take place before you start

treatment for your Parkinson disease. The third and fourth visits will occur 2-3 months after you start treatment and when you have been on a stable dose of your Parkinson disease medication for weeks.

- Training Visit: You will undergo training at this visit.
- Test Visit 1: For the First Test Visit, you will not have taken any Parkinson disease medication.
- Test Visit 2: Test Visit 2 will take place within 2 weeks of Test Visit 1. For this Visit, you will take a standard dose of the preferred medication for Parkinson disease – carbidopa/levodopa 25/250 – wait approximately 1 hour and repeat the evaluations and tasks. First time use of carbidopa/levodopa occasionally produces nausea or lightheadedness. To reduce the chance of these side-effects occurring, we will ask you to take carbidopa for the prior 24 hours.
- Test Visit 3: The Third Test Visit will be identical to the First Test Visit with 1 exception. You will be asked to take your Parkinson disease medication on your usual schedule or not to take your medication the morning of the Third Test Visit. The researcher will let you know whether you should take your Parkinson disease medication or not. If you are asked to not take your Parkinson disease medication the morning of your visit, you will resume your usual Parkinson disease medications after the evaluations and tasks are complete.
- Test Visit 4: Follow-up Visit 2 will take place within 2 weeks of Follow-up Visit 1. It will be identical to Follow-up Visit 1 with 1 exception. You will be asked to take your Parkinson disease medication on your usual schedule or not to take your medication the morning of the Fourth Test Visit. The researcher will let you know whether you should take your medication or not. If you are asked to not take your Parkinson disease medication the morning of your visit, you will resume your usual Parkinson disease medications after the evaluations and tasks are complete.

Experiment 2: Table of Visits

Visit Evaluations	Training Visit	Visit 1	Visit 2	Visit 3	Visit 4
Examination	X	X	X	X	X
Cognitive Tests	X				
Mood Questions	X				
Color Vision Test	X				
Joystick Task		X	X	X	X
Eye Movement Task	X (Training)	X	X	X	X

Experiment 2: Visit Schedule

Visit Component	Time Requirement
Clinical History; Neurologic Examination; Evaluation PD Severity	0.5 Hour
Questionnaires for Thinking and Mood	1 Hour
Movement Task	0.5 Hour
Eye Movement Task	1 Hour

Participants in Experiment 1 may also participate in Experiment 2.

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all of your scheduled appointments, take your study medication as directed, and report any adverse reactions you may have during the study.

Coronavirus (COVID-19) Procedures

It is possible you will not be able to go in to the study center for a scheduled visit because of the Coronavirus. If this happens, the study doctor may ask you to complete some of the visit procedures over the phone instead of face-to-face.

4.2 How much of my time will be needed to take part in this study?

Experiment 1 will consist of 4 study visits approximately 2-3 months apart. Each study visit will take approximately 3 hours.

Experiment 2 will consist of 5 study visits, with the second and third visits approximately 2-3 months apart. The training visit will take approximately 3.5 hours. Each remaining study visit will take approximately 3 hours.

4.3 When will my participation in the study be over?
Study participation will end after all testing is complete. However, you may withdraw from the study at any point in time.

4.4 What will happen with my information and/or biospecimens used in this study?
Your collected information may be shared with the National Institute of Neurologic Disease and Stroke – National Institutes of Health.
With appropriate permissions, your collected information may also be shared with other researchers, here, or around the world, or with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

- Confidentiality of Research Information: The research data to be collected from subjects will consist of confidential information relating to clinical, neuropsychological, mood, neuroanatomical, and neurochemical functions. These research data are not intended for entry into the subjects' clinical medical records. However, the data remain potentially discoverable. This may lead to violation of privacy and embarrassment of the subject. This is rare (<1% of participants).
- Clinical and Behavioral Testing: Risks in regard to the behavioral assessment are limited to fatigue, frustration and momentary embarrassment that may occur when one experiences difficulty disclosing information or during task performance. This is uncommon (<10% of participants). Risks of undergoing the motor testing in the (overnight) dopaminergic "off" state may result in some

discomfort and the possibility of worsened parkinsonian motor symptoms the morning of the research testing assessment (infrequent). Temporary withdrawal of dopaminergic medication will be required for >12 hours (overnight) prior to testing in the morning of the 3rd or 4th visit. There may be discomfort or transient worsening of Parkinson symptoms when participants are tested on a day when they withhold their their usual PD medications. In our experience, this is not common (<10% of participants). If you feel the need to take your regular PD medications at any point because of discomfort or for any other medical reason, please let us know and we can make sure that you get your regular medication at that time.

- Initial Use of Levodopa: Initial use of carbidopa/levodopa is sometimes accompanied by nausea or lightheadedness. This is uncommon (<10% of participants).

The researchers will try to minimize these risks by:

- Confidentiality of Research Information: The possibility of unintended disclosure of medical or research data is minimal, but not entirely impossible. We will employ stringent safeguards against unintended and inappropriate discovery and dissemination of personal medical and research data in our subjects by a multi-layered approach. All data bearing potential subject identifiers will reside solely in locked files in the offices of the study investigators. Original data collection documents will be maintained in secure files under the control of the investigators. Entries regarding details of the research project and its results will not be submitted to clinical medical databases. Electronic databases in the project will employ subject codes that cannot be linked directly to participants without a "key", possessed only by the study investigators in a secure location, and maintained separately from the databases. Databases will be housed on protected UM servers. Personal information that would directly identify study subjects will not be used in any publications or presentations resulting from this research study, unless separate written permission is given by the subject (or proxy). Any superfluous records will be shredded.
- Clinical and Behavioral Testing: Care will be taken to minimize distress. Subjects will be addressed in a courteous manner that does not infringe the patient's dignity. These individuals are prepared to respond to patient anxiety, concern and other behavioral changes as appropriate to the situation. Offering breaks and reassuring subjects will further minimize risks when necessary. The off-state testing at the 3rd visit (Experiment 1) or 4th visit (Experiment 2) will occur soon after the subjects arrive on the testing day so that they may be allowed to take their dopaminergic medications immediately afterwards. Any subjects that need to take their medications and reschedule the study visit will be able to do so any point should they like.
- Initial Levodopa Treatment: To reduce the risk of nausea or lightheadedness with initial Levodopa use, you will be asked to take carbidopa, a routine component of the standard treatment for Parkinson disease, for 24 hours prior to your Baseline (Experiment 1) or First Test (Experiment 2) Study Visit.

See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. You will be directly monitored during all study visits. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

If you become ill, are hurt or injured, or feel you are experiencing a medical emergency at any point during or after the study, immediately dial 911 or visit your nearest emergency room. First aid and emergency care is readily available and will be provided to you by the University of Michigan Health System in case any

complications, adverse effects, or health threatening events may arise during the course of testing. If at a later point in the time you believe the study has made you sick or caused you injury, contact one of the people listed in section 10 of this document (Contact Information) after seeking care from your doctor or the emergency room.

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. Results from this study may be useful in improving treatment of Parkinson disease.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

You do not have to participate in this study. You may discontinue your participation from the study at any time without penalty. Taking part in the research is not a treatment or part of your routine medical care.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

There is no harm in leaving the study before it is finished. However, if you decide to leave the study during some of the procedures we may ask you to stay until it is deemed safe to leave.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

There is the potential that the research evaluations may have caused you anxiety or worries about your health. You may need or want to investigate these health concerns further for an appropriate diagnosis. However, any procedures or tests should be obtained separately if your doctor believes that you require those tests for your diagnosis. These additional studies and appropriate treatment, if necessary, will not be paid for by this study.

The study team has given you instructions about this research study. It is important that you follow these instructions carefully. If you get sick, have a medical complication, or are injured as a result of your being in the study, page Dr. Albin immediately, at 734-936-6267. The doctor will either treat you or send you to another doctor for treatment.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

Yes. To compensate for travel expenses, you will receive $50 at the first study visit, regardless of whether you complete the study. For completing either Experiment 1 or Experiment 2, you will receive an additional $150. For completing both experiments, you will receive an additional $250. The total compensation possible for participation in both Experiments 1 and 2 is $300.

Study Payment Schedule

Study Component	Compensation
Study Enrollment	$50
Complete Experiment 1 or Experiment 2	$150
Complete Both Experiment 1 and Experiment 2	$250

8.3 Who could profit or financially benefit from the study results?

Neither the researchers conducting the study nor the University of Michigan will have financial profit from the study results.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

Your research records will be stored in a secure location to which only the investigators have access. All research records will be stored under code numbers, without attached names or other identifying information. The "key" linking these records to subject names will be stored in a separate, locked (electronic) file. Your research records will not be part of your medical records.

A description of this clinical trial will be available on www.ClinicalTrials.gov (http://www.clinicaltrials.gov/), as required by US 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 website at any time.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others].

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- HIV/AIDS status
- Sexually transmitted disease and/or other communicable disease status
- Genetic counseling/genetic testing records
- Health plan/health insurance records
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- Demographic information
- Personal identifiers
- Other information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.

- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

9.5 Will I be contacted for other studies?

No, unless you indicate by initialing below that you may be contacted by other researchers at the University of Michigan for studies for which you may eligible. If you agree to be contacted for other studies we will keep your name and contact information in a separate password-protected database.

I agree to be contacted about other research studies for which I may qualify. If I cancel my permission for this study I will not be contacted for other studies.

YES / NO (circle one) Initials: _____

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Roger L. Albin, MD
Mailing Address: 5023 BSRB, 109 Zina Pitcher Place, Ann Arbor, MI, 48109-2200
Telephone: 734-764-1347

Study Coordinator: Teresa Scerbak
Mailing Address: NCAC, 2901 Hubbard Drive, Suite 2722, Ann Arbor, MI 48109-2435
Telephone: 734-936-9115

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file*

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-D

Consent/Assent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable data for use in future research. I understand that it is my choice whether or not to allow future use of my specimens. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the study team keep my identifiable data for future research.

_____ No, I do not agree to let the study team keep my identifiable data for future research.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____