Subject Name & ID#: _____ **Date:** _____

IRB#: Pro00001441

Title of Study: GPR109A and Parkinson's Disease: Role of Niacin in Outcome Measures

Principal Investigator: Dr. Chandramohan Wakade, PhD, MBBS **VAMC:** Charlie Norwood Augusta, GA

Subinvestigators: Dr. Raymond Chong, Dr. John Morgan, MD, PhD, Banabihari Giri, PhD, Marissa Seamon

DESCRIPTION OF RESEARCH BY INVESTIGATOR

PRINCIPLES CONCERNING RESEARCH

You are being asked to take part in a research study. It is important that you read and understand these principles that apply to all individuals who agree to participate in the research project below:

1. Taking part in the research is entirely voluntary.
2. You may not personally benefit from taking part in the research but the knowledge obtained may help the health professionals caring for you better understand the disease/condition and how to treat it.
3. You may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.
4. If during your participation in the research study, new information becomes available concerning your condition (disease) or concerning better therapies which affect your being in the research study your doctor will discuss this new information with you and will help you make a decision about continuing in the research.
5. The purpose of the research study, how it will be done, and what your part in the study will be, is described below. Also described are the risks, inconveniences, discomforts, and other important information which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions you have about this research with the staff members.
6. Veteran and non-Veteran subjects will not be required pay for medical services received as a subject in an approved VA research study. Some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to VA-provided medical care and services that are not a part of the study.

Introduction

Please read the following information about this and ask any questions you may have. If you do not understand something you read, be sure to ask what it means.

Purpose

The purposes of this study are to (1) examine the blood, urine and spinal fluid of persons with Parkinson's to look for evidence of inflammation and; (2) whether 6 months of vitamin B3 supplements may reduce the inflammation and/or improve your symptoms. If you do not have

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Parkinson's, you will serve as a control subject. You will be tested twice: before and after the supplement. About 100 people are expected to participate in the study. This study is sponsored by the VA.

Procedures

We will do the following research procedures: we will use questionnaire forms to document your health status such as existing medical problems, medications, details of your daily food intake, quality of life, mental status, sleep quality, postural stability and conduct basic physical examination for strength, speed, coordination, tremor, flexibility, rigidity and reaction time. We will acquire blood, urine and spinal fluid samples from you. Certain biological markers will be analyzed in the samples. We will use a computer program to randomly assign you to either the niacin or the placebo group. The randomization ensures that the researchers cannot pick and choose who is placed in the groups.

In order to assess your symptoms, we will ask you to do some or all of the following (depending on your capability):

1. Walk several feet at a time at your normal pace or faster than normal;
2. Get up from a chair with or without support;
3. Turn around while walking;
4. Stand still for 60 seconds on a firm or soft surface with eyes open, closed or count backwards;
5. Write a sentence;
6. Point or tap targets with eyes open or closed;
7. Wear non-invasive painless sensor on your body during the tests or while you sleep at night to record your brain activities

The items will be repeated several times in each session. We may also ask you to combine items, e.g., get up from a chair, walk, turn around and return to the chair.

The specimens and other information we collect from you will be kept indefinitely so that additional analyses can be carried out if necessary to strengthen or confirm the results of the initial analyses. It will also allow us to conduct additional analyses if we come across information from other researchers that are relevant to this study. The specimens and other information will be coded and stored in a locked facility and accessible by members of the research team.

Permission

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• I give permission for my information to be entered into the database and used in the future in research studies that would not identify me.

□ Yes □ No Signature _____

• I give permission for someone to contact me in the future to update specific information entered into the database.

□ Yes □ No Signature _____

Subject Payment
You will receive a $50 gift card if you complete the 6-month study. You will receive an additional $100 if you also participate in the spinal fluid sampling.

Risks
There is a minimal risk that the physical and cognitive tests may cause you to experience undue anxiety, frustration, fatigue, and/or discouragement. To minimize the chance of this happening, you will be provided with frequent breaks and encouragements.

There is always a risk of breach of confidentiality. This will be minimized by securing data in a locked office and on a VA-protected server with limited access to the study team and others required to monitor compliance with regulations.

The risks associated with lumbar puncture may include following:

- Discomfort or pain during the procedure
- Bleeding into the spinal cord, particularly in people who take blood thinners or have a low platelet count (thrombocytopenia)
- Headache as a result of CSF leakage
- Infection
- Nerve damage
- Cerebral herniation
- Back pain

There will be minor pain with the needle stick while obtaining the blood sample. We will observe all the standard safety precautions under the guidelines of Biological Safety at CNVAMC. Although

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procedures involve are considered minimal risk, any procedure may involve risks to the subject, some of which are currently unforeseeable. We ask that you check the needle stick site daily and inform Dr. Morgan or Dr. Wakade if you think there is an infection. You will be advised on what do to. If necessary, we will arrange to see you for treatment.

Benefits
The possible benefits of the study are that your symptoms may improve. It is possible that society may gain knowledge from the results of this study. You may or may not gain a better understanding of your symptoms and postural control abilities. At the end of the study, we will offer you the supplement at no cost and invite you to return for an optional follow-up assessment.

Alternatives
Your alternative to participating in the study is to refuse. If you refuse, no information about you will be collected. Additionally, your refusal will not result with any penalties or loss of care or other benefits to which you are otherwise entitled.

Withdrawal
Your participation in this database is voluntary. You may revoke your consent and authorization and withdraw now or at any time in the future without penalty or loss of care or other benefits to which you are otherwise entitled.

The research team may stop your taking part in the research study without your consent for various reasons. Some examples are:

- The sponsor or study doctor decides to stop the study.
- The study doctor stops your taking part in the study for your safety.
- You are no longer eligible to take part in the study.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow the instructions.

Privacy Notice
The researchers are asking for your written authorization before using your health information or sharing it with others in order to conduct the research as described. However, under certain circumstances, the researchers may use and disclose your health information without your written

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authorization if they obtain approval through a special process to ensure that research without your written authorization poses minimal risk to your privacy. Under no circumstances, however, would the researchers allow others to use your name or identity publicly. The researchers may also disclose your health information without your written authorization to people who are planning a future research project, so long as any information identifying you does not leave our facility. Information about people who have died may be shared with researchers using the information of deceased persons, as long as the researchers agree not to remove from our facility any information that identifies these individuals.

Confidentiality
Only the investigator, the members of the research team, and authorized officials from state and federal governments and accrediting bodies, and authorized representatives of Augusta University and the Augusta Veterans Affairs Medical Center will have access to confidential data, which would identify you unless specifically required to be disclosed by state or federal law. You will not be identified in any reports or publications resulting from the study. If you do not sign this authorization, you will not be a part of the study. This authorization has no expiration date. If you wish to revoke this authorization, you may obtain a revocation letter from the investigator. If you revoke this authorization, Dr. Wakade and his research team can continue to use information about you that has been collected. No new information will be collected after you revoke your authorization.

Indemnity
The VA will provide any neccessary medical treatment should you be injured by participation in this study and you will be treated for the injury within this facility, with limited exceptions, at no cost to you. An exception would be situations where this facility would not be capable of furnishing the care or services the subject requires. This requirement does not apply to treatment for injuries that result from noncompliance by a research subject with study procedures.

Telephone Numbers
In case there are any medical problems, questions, or complaints, you should call Dr. Chandramohan Wakade at 706-589-4171 during during or after work hours. If you have any questions about your rights as a research subject, you may also contact the Augusta University Institutional Review Board at (706) 721-1483. You may also report any questions, problems, and/or complaints to the Augusta VA Research Compliance Officer at (706) 733-0188 ext 2571. If you have questions concerning the privacy of your information, please contact the VA Privacy Officer at (706) 733-0188 ext 7603.

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Research Subject's Rights

I have read or have had read to you all of the above. Dr. John Morgan or a member of the research team has explained the study to me and answered my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. My participation in this study is voluntary and I do not have to take part in this study. My refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. No promises have been given to me regarding this study since the results and the risks of a research study are not always known in advance. However, every reasonable safety measure will be taken to protect my well-being. I have not released this institution from liability for negligence. The results of this study may be published, but my records will not be revealed unless required by law. I voluntarily consent to participate in this.study. I have been told what the study is about and how and why it is being done. I have been given a chance to ask questions about this research study and such questions have been answered to my satisfaction. I agree to participate in this study. I will receive a copy of this consent form for my own records.

Research Participant:		
Print	Sign	Date/Time

Phone and email: _____

Investigator Statement: I acknowledge that I have discussed the above study with this participant and answered all of his/her questions. He/she has voluntarily agreed to participate. I have documented this action in the subject's medical record, source documents or research chart source documents, as applicable. A copy of this document will be placed in the subject's electronic medical record or research chart source, as applicable. A copy of this document will be given to the subject.		
Investigator Obtaining Consent:		
Print	Sign	Date/Time

Subject's Initials: _____ **Version Date**: 8/25/15; 1/15/16; 5/27/16; 8/14/17; 06/26/18; 5/22/19; 9/19/19; 1/21/2020

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