UAB IRB
Approved
14-Feb-2022
until
13-Feb-2023

CONSENT FORM

TITLE OF RESEARCH: Interactions of Gut Microbiome, Genetic Susceptibility, and Environmental Factors in Parkinson's Disease

UAB IRB PROTOCOL NO.: IRB-300000941

INVESTIGATORS: Haydeh Payami, PhD, David Standaert, MD, PhD, Amy Amara, MD, PhD

SPONSOR: United States Department of Defense

Purpose of the Research

We are asking you to take part in a research study because you have either been (a) diagnosed with Parkinson's disease, (b) diagnosed with rapid eye movement sleep behavior disorder, or (c) you have no neurologic disorder and are willing to serve as a control.

The purpose of this study is to investigate the role of the gut microbiome in the development, progression and treatment of Parkinson's disease. The gut microbiome refers to the trillions of micro-organisms that live in the human gut. The gut microbiome is critical for human health, and abnormal microbiome can cause disease. In this study, we will investigate the interaction between the gut microbiome, human genes, and environmental factors in the development and progression of Parkinson's disease and related disorders. The gut microbiome is easily modifiable, therefore, this project may provide new and feasible means to predict, prevent and treat PD.

This study will enroll a total of 714 individuals with Parkinson's disease, 43 individuals with rapid eye movement sleep behavior disorder, and 428 control participants at UAB. Seventy individuals with rapid eye movement sleep behavior disorder will also be enrolled at the Research Institute of the McGill University in Montreal, Canada.

Explanation of Procedures

OPTION A:

If we are meeting in person, we will explain the study and answer your questions. If you agree to participate in the study, you will sign this Informed Consent Form. Your involvement will be in two parts:

1. During the visit, we will draw about 3-4 tablespoons (50 mL) of blood from a vein in your arm or we will collect about half a teaspoon (2 mL) of saliva. To collect saliva, we will ask you to spit into a tube. The blood and saliva will be used to extract DNA for genetic studies. This will take about 15-30 minutes.
2. We will give you a packet to take home to complete and return by mail. The packet will include an "Environmental and Family History Questionnaire," which asks about exposures to things such as caffeine and tobacco; a "Gut Microbiome Questionnaire," which asks about your recent diet and digestive health; a stool collection kit with detailed instructions, and a pre-stamped return envelope. Each questionnaire will take about 15-30 minutes. The stool collection procedure is simple and clean, and will take about 15 minutes.

OPTION B:

If we are unable to meet with you in person, we will explain the study over the phone, mail you the Informed Consent Form, and answer your questions at a follow-up call. If you agree to participate in the study, you will sign this Informed Consent Form and mail it back to us. Once we receive the signed Informed Consent

Form, we will mail you a packet to complete at home and return by mail. The packet will include an "Environmental and Family History Questionnaire," which asks about exposures to things such as caffeine and tobacco; a "Gut Microbiome Questionnaire," which asks about your recent diet and digestive health; a stool collection kit with detailed instructions, and a saliva collection kit with detailed instructions. Saliva will be used to extract DNA for genetic studies. A pre-stamped return envelope will be included to mail everything back to us. Each questionnaire will take about 15-30 minutes. The saliva and stool collection procedure are simple and clean, and will take about 10-15 minutes each.

In the unlikely event if we are unable to extract sufficient DNA from your saliva, blood or stool, we may ask you to provide another sample. You are free to refuse the additional sample.

The genetic study is purely for research and does not entail genetic testing for any disease, ancestry, or family relations. We will use the DNA that is in the blood (or saliva) to examine variations at about one million points along the chromosomes, which we will use as markers (like street signs) to map the length of the 23 human chromosomes, and to have as points of reference (like an address) when we correlate genetic markers with environmental factors or gut microbiome. We do not conduct whole genome sequencing or test for any genetic condition. Genetic data is used only for research and will not be given to you or your physician.

If you have been diagnosed with Parkinson's disease or rapid eye movement sleep behavior disorder, we will review your medical records which are available at UAB Medicine, and may review them again in the future unless you notify us in writing that you wish us to stop reviewing them. We may contact you in the future by phone or mail, unless you tell us you do not wish to be contacted.

As part of this study, we will store some of the blood, saliva, data and stool specimens collected from you for future research on Parkinson's disease and other age related disorders. The specimens may be used to extract genetic material (DNA and RNA). The future research may be conducted by Dr. Haydeh Payami, Dr. David Standaert, or by other researchers that obtain IRB approval for their research. The data and specimens will be labeled with a code that only Dr. Payami and her personnel can link back to you. These specimens will be stored indefinitely to be used in research or until the material are depleted. If you do not wish to allow your data and specimens to be stored for future research, then you should not participate in this study.

Alternative
The alternative is to not participate in this study.

Risks and Discomforts
There is a slight risk of discomfort and bruising to nearby tissues when the blood is drawn. Rarely infection may occur at the site where blood is drawn and people may feel lightheaded or faint during blood draw.

Samples will be 'coded' to protect identity and confidentiality during the study.

As with any study of this nature, a possible risk is the loss of confidentiality about your medical and genetic information. We will take every precaution to protect your confidentiality, and very rigorous steps to ensure that the samples we analyze cannot be used to discriminate against you or your family in any possible manner.

Benefits
You may not directly benefit from the study. However, the study may help us better understand the connection between the gut microbiome and neurological disease, which may lead to safe and effective ways to prevent and treat disease.

By law, and because we are a research lab and not a clinical lab, we cannot disclose your individual results to you or to your doctor. However, if we make a discovery that might help improve heath, we will notify the participants of the study about the discovery, so that you can discuss it with your health care provider.

Confidentiality

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- The UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- The United States Department of Defense, which is funding the study.
- The Office for Human Research Protections (OHRP)

The information from the research may be published for scientific purposes; however, your identity will not be given out.

We will remove your name and identifiers from the samples you provide and replace them with a code. Only Dr. Payami and her study personnel can link the coded samples back to you. Laboratories that process your samples and researchers who work on the data cannot identify you or any of the research particpants.

We keep the data in a highly-secured database that is protected by two levels of password authetication, in addition to a firewall that meets IRB and HIPAA security criteria for restricted access.

Samples of your blood, saliva, DNA and stool may be sent outside of UAB for further analysis. However, no identifying information will be sent with your samples. It will not be possible for other institutions to link back information directly to you. These samples and data will be labeled with a code that only Dr. Payami and her study personnel can link back to you.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination by employers. We will take every precaution to protect your confidentiality, and very rigorous steps to ensure that the samples we analyze cannot be used to discriminate against you or your family in any possible manner.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution. Contact the study doctor if you want to withdraw from the study. If you are a UAB student or employee, taking part in this study is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this study.

Cost of Participation
There will be no cost to you for participating in this study. All procedures related to this study will be provided to you at no cost during your study visit. The kits and questionnaires will be provided to you with pre-stamped envelopes for mailing them back to UAB.

Payment for Participation in Research
You will not be paid for your participation in this research.

Payment for Research-Related Injuries
UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Significant New Findings
You will be told by your doctor or the study staff if new information becomes available that might affect your choice to stay in the study. If the study results reveal new information that may be of health benefit, we will notify you of the discovery so that you can discuss it with your health care provider.

Genomic Data Sharing
Genetic and other relevant study data, such as microbiome and health information, may be shared broadly in a coded form for future research or analysis. We may give this data about you to other researchers or companies not at UAB, including to a controlled-access government health research database. We will not give them your name, address, phone number, or any other identifiable information. Research results from these studies will not be returned to you.

Controlled-Access Databases: Your de-identified information may be put in controlled-access databases. This means only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your information stored in these databases will not include any identifying information. We will replace identifying information with a code number. We will keep a master list that links your code number to your identifying information here at the UAB. Only certain study personnel for this study at UAB will have access to this master list. Researchers approved to access information in the controlled-access database will agree not to attempt to identify you.

Risks: The risk of sharing your genomic data is that someone could link the information stored in the databases back to you. If your information suggested something serious about your health, it could be misused. For example, it could be used to make it harder for you to get or keep a job or insurance or be used to discriminate against you or your family. There may also be other unknown risks.

Benefits: There is no direct benefit to you from sharing your genomic data. Allowing researchers to use your data may lead to a better understanding of how genes and the gut microbiome affect health. This may help you and other people in the future.

If you do not agree for your de-identified genetic and other relevant study data to be shared broadly in a coded form for future research or analysis, then you should not participate in the study.

Questions
If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact Dr. Payami at 205-934-0371or Dr. Standaert at 205-934-0683.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights
You are not waiving any of your legal rights by signing this consent form.

Signatures
Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

_____ _____
Name of Participant (print) Phone Number

_____
Signature of Participant Date

_____
Signature of Person Obtaining Informed Consent Date

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____
Research Protocol: Interactions of Gut Microbiome, Genetic Susceptibility, and Environmental Factors in Parkinson's Disease

UAB IRB Protocol Number: IRB-300000941
Principal Investigators: Haydeh Payami, Ph.D., David Standaert, MD, PhD
Sponsor: United States Department of Defense

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: _____ Date: _____
or participant's legally authorized representative: _____ Date: _____
Printed Name of participant's representative: _____
Relationship to the participant: _____