Signed consent forms must be faxed to 410-367-7382 for inclusion in the Epic medical record.

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: The MARK-PD study: Biomarkers for Parkinson disease (PD) and PD-related cognitive impairment (Parkinsonism participants)

Application No.: NA_00031749

Sponsor: **National Institute of Neurological Disorders and Stroke (NINDS)**

Principal Investigator: Liana Rosenthal, MD
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10751 Falls Road, Suite 250
Lutherville, MD 21093
Phone: 410-434-2561
Fax: 410-502-6737

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1. What you should know about this study:

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Please ask questions at any time about anything you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
- Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.
- The person being asked to be in this research study may not be able to give consent to be in this study. You are therefore being asked to give permission for this person to be in the study as his/her decision maker.
- During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study physician and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.

2. Why is this research being done?

This research is being done to find a test that can diagnose individuals with Parkinson disease (PD). To do this, we will collect and store clinical information, samples of blood, urine, DNA, and cerebral spinal fluid from people with Parkinson disease (PD), people with Parkinson-plus diseases, and from people without PD.

This information will be used to help develop biomarkers for PD and PD-related cognitive impairment. Biomarkers are measures that tell something about PD. We are working on biomarkers in PD because they may help to understand how the disease changes over time. Having good biomarkers for PD may also be useful in developing new treatments and may help to improve clinical care in the future. In this study we will test biomarkers that may be related to the way PD changes over time. We will store information about all the tests and samples of the different fluids, such as blood, urine, spinal fluid, and DNA, for future testing.

You are being invited to take part in this study because you are aged 30 years and older and have symptoms of Parkinsonism.

How many people will be in this study?

This study will enroll 80 individuals with PD and 80 individuals without a neurological disorder. Each participant will be asked to identify a study partner. We will also enroll 60 patients with a Parkinson-plus disorder. Each participant is asked to identify a study partner.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

Because this is a research study, we at Johns Hopkins Hospital will have a separate research chart for you. The information in that research chart will not be available to you until the research is completed. The research chart will not be made part of your routine medical records. You will be informed about the overall results of the study but, in general, you will not receive your own research test results.

Study Partner: You must have an individual (spouse, friend, or relative) who is willing to act as your Study Partner and:

- Accompany you to the screening and study visit
- Communicate changes in your health status over the period of this study
- Answer questions regarding your thinking and memory.

Screening

If you agree to take part in this study, you will first have a screening evaluation at Johns Hopkins Hospital. This visit may take approximately four hours. When appropriate, this screening visit will be combined with the baseline visit.

At this visit we will collect the following information to make sure you qualify to be part of the study:

- Review of you and your family's medical history
- A physical examination, including blood pressure and pulse
- A neurological examination and confirmation of diagnosis
- Information about your ability to perform daily activities and to measure your movement
- Review of any medications you are currently taking
- Blood tests to make sure there are no abnormal results and you are able to be in the study

- A blood sample that will have DNA removed for storage and research tests (DNA contains genetic information about the development and functioning of humans)

Baseline visit

If after screening, you are found eligible to be part of this study you will return to Johns Hopkins within 45 days of your screening visit. Again, if convenient for you, this visit will be combined with your screening visit. Together, the screening and baseline visit may about 6-8 hours, and will be spread over more than 1 day if more convenient.

We will collect the following information:

- Your blood pressure, pulse, temperature, height and weight
- Information about your health and medications you are taking
- Information about your neurological condition
- Information about your ability to perform daily activities and to measure your movement
- Questionnaires to measure your thinking, memory, moods and behaviors
- Questionnaires about your level of sleepiness
- Tests of your ability to smell
- A urine sample for storage and research tests
- A blood draw and for storage and research tests (see below)
- Lumbar puncture to collect cerebral spinal fluid for storage and research tests (see below).

Within 1 to 10 days after the study visit we will call you to ask how you are doing after having the lumbar puncture.

Once all procedures are completed at this baseline visit and you are enrolled in the study, you will be asked to return every 6 months for a total of 11 study visits (5 years).

Follow Up Visits (Month 6 to Month 60)

From month 6 to month 60 you will return to Johns Hopkins for study visits that will include collection of the information listed below.

- Your blood pressure, pulse, temperature, height and weight
- Information about your health and medications you are taking
- Information about your neurological condition
- Information about your ability to perform daily activities and to measure your movement
- Questionnaires to measure your thinking, memory, moods and behaviors
- Questionnaires about your level of sleepiness
- Tests of your ability to smell
- A urine sample for storage and research tests
- A blood draw and for storage and research tests (see below)

At each yearly follow-up visit, the following additional tasks listed below will be done. These visits will take about 6-8 hours and may be conducted over more than 1 day:

- Blood tests to make sure there are no abnormal results
- Many more tests and questions about your thinking and memory
- A urine sample for storage and research tests
- Lumbar puncture to collect cerebral spinal fluid for storage and research tests (see below).

DESCRIPTION OF PROCEDURES

Blood Samples

Blood samples will be collected from a vein in your arm to test for abnormalities and also for research purposes. At screening or at the study visit about eight and a half tablespoons of blood will be collected.

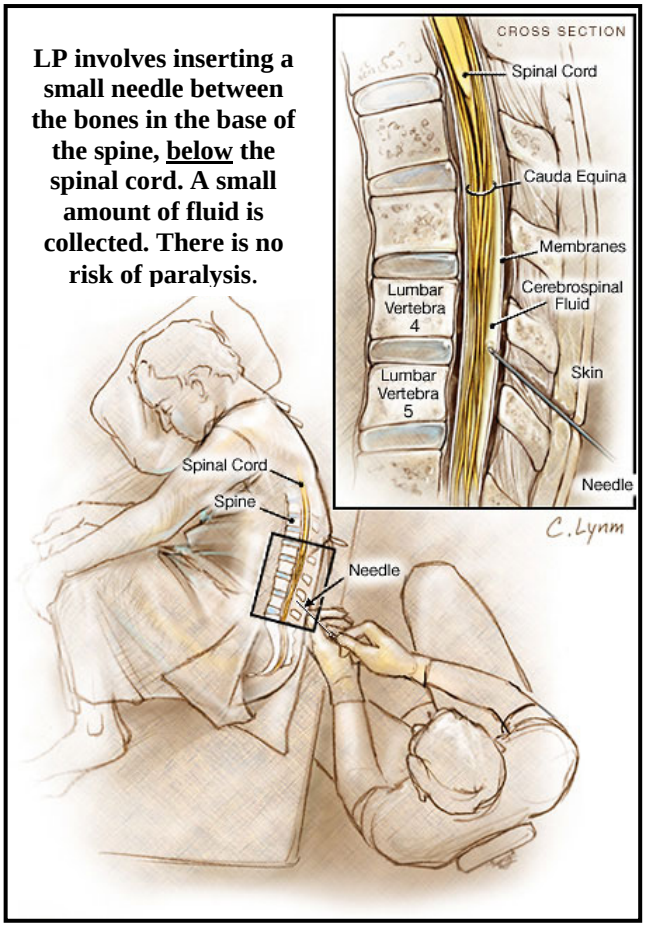
The blood samples that are collected for storage in a central repository for research purposes will be tested now and in the future for the following reasons:

- Measure the amount of proteins and other molecules found in blood that may reflect brain function or indicate changes in brain function. For example, the amount of alpha-synuclein in blood may be an early sign to help diagnose PD and track disease progression.
- Look at the genetic material in people with PD compared to people without PD.
- Identify genes that may be important in the progression of PD.
- Prepare DNA and make cell cultures, from which DNA will be prepared
- Use the blood to look at other measurements that have not yet been identified (see below).

Lumbar Puncture:

You will undergo a lumbar puncture (LP) to obtain cerebral spinal fluid (CSF) samples. CSF is the fluid that surrounds the brain and spinal cord. Studying this fluid may help researchers learn about what is going on in the brain.

LP involves inserting a small needle between the bones in the base of the spine, below the spinal cord. A small amount of fluid is collected. There is no risk of paralysis.



A lumbar puncture involves inserting a small needle in your lower back. For this procedure, the study staff will help position you either on your side or sitting up, whichever is most comfortable for you. First your skin will be cleaned with antiseptic. The study doctor or his/her team member will inject a small amount of local anesthetic to numb the area. To avoid an allergic reaction, please let the study staff know if you have ever had a reaction to a local anesthetic (such as while at the dentist). Once numb, a very thin needle will be inserted into the spinal canal in your lower back. About 20-25 milliliters (about one and a half tablespoons) of spinal fluid will be removed for analysis and storage. *Your body replaces this spinal fluid within 1-2 hours.*

After the lumbar puncture is completed, you will remain in the clinic for about 20 minutes. You will be given something to eat and drink before you leave. You should not do any strenuous physical activity for the next 24 hours. This includes lifting, bending, doing housework and gardening, or doing exercise such as jogging or bicycle riding.

Use and Storage of Research Data and Biological Samples

Blood samples that are collected to test for abnormalities are sent to a central lab for processing and testing. This sample will be destroyed once the test is completed.

This study involves the collection of blood, urine, DNA, and CSF as well as research data to be used for current study analysis and stored for future research. The purpose of storing these samples and research data is to make them available to scientists who are trying to develop new tests, treatments, and ways to prevent diseases. These samples and research data may be shared with other scientists for studies of PD, other neurological conditions, other types of disorders, or other biomedical research studies. These studies may be at research centers other than Johns Hopkins.

The Genetic Information Nondiscrimination Act (GINA) may help protect you from health insurance or employment discrimination based on genetic information.

The law provides that health insurance companies and group health plans

- may not ask for genetic information from this research and
- may not use genetic information when making decision about eligibility or premiums

The law will not stop health insurance companies from using genetic information to decide whether to pay claims. The law also will not help you get other types of insurance (such as: life, disability or long-term care).

The clinical research data collected from you will be will be stored indefinitely for research purposes. There will be no personal identifiers attached with your research data that is shared with other researchers.

Blood samples, urine samples, DNA, and CSF that are collected for research purposes will be stored in a freezer at Johns Hopkins and some samples will also be sent to Coriell Laboratory. There is a risk that someone could use information from the sample you submitted, via DNA, to identify you if it were matched with another DNA sample provided by you. However, any user of this sample must agree not to use it for that purpose, and the risk, while real, is small. These samples will not be destroyed once the study is completed (they will be stored indefinitely). Prior to storage and analysis, your DNA, urine, blood, and CSF samples will be labeled with a unique code. Your name or other information that may identify you will not be attached to the stored samples. No personal identifying information will be sent to Coriell Laboratory.

You will not receive the results of research done with your specimens. This is because research can take a long time and must use specimen samples from many people before results are known. Also, all samples and data are de-identified, which means that personal information will not be tied to that sample. Results from research using your specimen may not be ready for many years and will not affect your care right now, but they may be helpful to people like you in the future. You will only receive results of research assessments, and blood tests if the study team finds something that needs further medical attention and you will be referred to the appropriate physician.

You can change your mind at any time about the storage of your samples. Just contact the principal investigator, in writing, and let her know that you no longer want your samples stored and they will be removed and destroyed. However, in some cases, it may be impossible to locate and stop such future research on your specific sample if all identifiers were stripped from your sample prior to the sample being provided to other researchers.

Your samples and study data will only be used for research and will not be sold. Requests by other researchers to access coded samples and clinical research data will be scientifically reviewed.

Successful research by individuals or organizations using the samples or other parts of the sample could result in a commercial or therapeutic product with significant value, such as a product for the medical treatment or diagnosis of PD or other disorders. You will not share in any financial benefits of these uses.

FUTURE USE OF YOUR RESEARCH DATA AND BIOLOGICAL SAMPLES

If you choose to participate in this study, you agree to the collection of your blood, urine, DNA and CSF samples for storage at Johns Hopkins Hospital. These samples will be kept at Johns Hopkins indefinitely and may also be stored at Coriell laboratories. All identifying information will be removed from the samples submitted to Coriell Labs. You also agree to the collection of your research data for storage at Johns Hopkins and Coriell laboratories. The research data and samples will be stored indefinitely. Your research data and samples will be made available (with no personal identifying information) for future research studies at Johns Hopkins and other institutions in PD as well as other biomedical research studies that may not be related to Parkinson disease. Your research data will be shared with other researchers through an online repository, also called a database. No personal identifying information will be in this shared database. We will be keeping your personal identifying information in our records, which are both paper records and a secure, HIPAA approved, online database.

How long will you be in the study?

You will be in the study for approximately 5 years.

4. What are the risks or discomforts of the study?

Your participation in this study may involve risks that are currently unforeseeable due to the investigational nature of this study. However, if any new risks become known in the future you will be informed of them. Participation in this study may involve some added risks or discomforts, which are outlined below.

Risk of Lumbar Puncture: The lumbar puncture may cause pain at the site where the needle goes in and the spinal fluid is taken. There is a small risk of infection or bleeding. After the lumbar puncture, you may get a headache. To minimize the risk of a headache, the doctor will use a small needle and may prescribe bedrest for one or more hours after the procedure. If a headache occurs, it is usually mild and can be controlled by bedrest, drinking lots of fluids, and a pain pill, such as Tylenol. Rarely, the headache is severe and may require additional treatment with a "blood patch." In this procedure, a small amount of your own blood is injected into the lumbar puncture site. This procedure is generally effective in stopping the headache.

You must inform your study doctor if you are allergic to local anesthesia (lidocaine) or to Betadine. Although very rare, it is possible to have an allergic reaction to the local anesthetic used for the lumbar puncture. Signs of an allergic reaction include swelling and/or a rash on your skin where the anesthetic was injected. To minimize any possible risk, the lumbar puncture will be done by a staff person who is specifically trained in the procedure.

Risk of Blood Draws: Blood draws may cause pain and bruising at the site where the blood is taken. Sometimes people can feel lightheaded or even faint after having blood drawn. There is a risk that someone could use information from the DNA sample you submitted, to identify you if it were matched with another DNA sample provided by you. However, any user of this sample must agree not to use it for that purpose, and the risk, while real, is small.

The Genetic Information Nondiscrimination Act (GINA) generally protects employability and the ability to obtain health insurance. However, in spite of the protections provided by GINA and the best efforts of the research team, there may still be a slight risk if information about you were to become known to people outside of this study.

Evaluations: You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

Loss of Confidentiality: Despite the GINA protections and the best efforts of the research team, there may still be a risk if information about you were to become known to people outside of this study. It may not be in your best interest if, for example, insurance companies or your employer become aware of such information. Every effort will be made to maintain your confidential information and protect personal information obtained as a result of this study.

Research information is kept in locked offices and on password protected computers.

Questions: Some of the questions you will be answering are personal and may make you feel uncomfortable or upset. You do not have to answer any questions that you do not want to. You may get frustrated or feel tired when completing some of the questionnaires or other study activities.

5. Are there benefits to being in the study?

There is no direct benefit to you from being in this study. If you take part in this study, you may help to develop a biomarker for Parkinson disease and Parkinson disease-related cognitive impairment. Biomarkers may be helpful in the diagnosis of PD and PD-related cognitive impairment or in developing future therapies for PD and PD-related cognitive impairment.

6. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected. You will be told about any new information that might change your decision to be in this study.

7. Will it cost you anything to be in this study?

No

8. Will you be paid if you join this study?

You will be paid $170 for completing the screening/baseline visit and for the yearly visit that includes the lumbar puncture (visit 1, visit 3, visit 5, visit 7, visit 9, and visit 11). You will be paid $50 for completing the other study visits (visit 2, visit 4, visit 6, visit 8, visit 10). You will receive a parking coupon for each visit. You will be provided lunch on the visit days. You may be required to provide your Social Security number to be paid. If your payment for study participation exceeds $600 per year, this information must be reported to the Internal Revenue Service.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.
- If you leave the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities.

10. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities**.**

11. How will your privacy be protected?

Johns Hopkins has rules to protect information about you. Federal and state laws also protect your privacy.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and other details.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Johns Hopkins may see or give out your information. These include people who review research studies, their staff, lawyers, or other Johns Hopkins staff.

People outside of Johns Hopkins may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and companies that sponsor the study.

We cannot do this study without your permission to use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Hopkins who receive your information may not be covered by this promise. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee this.

The use and disclosure of your information has no time limit. You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

12. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

13. What treatment costs will be paid if you are injured in this study?

Johns Hopkins and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

- If you have health insurance: The costs for any treatment or hospital care you receive as the result of a study-related injury will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you.

- If you do not have health insurance: You will be billed for the costs of any treatment or hospital care you receive as the result of a study-related injury.

By signing this form you will not give up any rights you have to seek compensation for injury.

14. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Liana Rosenthal at pager number 410-434-2561. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

Call Dr. Liana Rosenthal at pager number 410-434-2561 if you have an urgent medical problem related to your taking part in this study. **After the tone, enter the phone number where you can be called, press the # key, and hang up.**

d. What happens to Data, Tissue, Blood and Specimens that are collected in the study?

Scientists at Johns Hopkins work to find the causes and cures of disease. The data, tissue, blood and specimens collected from you during this study are important to both this study and to future research.

If you join this study:

- You will not own the data, or the tissue, blood, or other specimens given by you to the investigators for this research.
- Both Johns Hopkins and any sponsor of this research may study your data and the tissue, blood or other specimens collected from you.
- If data, tissue, blood, or other specimens are in a form that identifies you, Johns Hopkins may use them for future research only with your consent or IRB approval.
- If data, tissue, blood or any other specimens are in a form that we believe does not identify you, they may be shared with other academic medical centers, non-profit organizations, corporate sponsors and other commercial companies without your consent or IRB approval.
- You will not own any product or idea created by the researchers working on this study.
- You will not receive any financial benefit from the creation, use or sale of such a product or idea.

e. What are the Organizations that are part of Johns Hopkins?

Johns Hopkins includes the following:

- The Johns Hopkins University
- The Johns Hopkins Hospital
- Johns Hopkins Bayview Medical Center
- Howard County General Hospital
- Johns Hopkins Community Physicians.
- Suburban Hospital
- Sibley Memorial Hospital

15. What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

CONSENT TO BE CONTACTED ABOUT FUTURE RESEARCH

Is it okay to contact you in the future to see if you are interested in participating in more research that may or may not be related to the current study?

☐ **Yes** ☐ **No** **DATE and INITIAL_____**

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

_____

Signature of Participant Date/Time

_____

Signature of Person Obtaining Consent Date/Time

_____

Signature of Legally Authorized Representative (LAR) for **ADULTS NOT CAPABLE of GIVING CONSENT** (*Persons from the following categories in order of priority may be a Legally Authorized Representative: Health Care Agent; Legal Guardian; Spouse; Adult child; Parent; Adult sibling; Friend or other relative)* Date/Time

_____

Relationship of LAR to Participant (indicate why the LAR is authorized to act as a surrogate health care decision-maker under Maryland Law) Date/Time

NOTE: **A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; AND A COPY OF THE CONSENT FORM MUST BE FAXED TO 410 367-7382 FOR INCLUSION IN THE EPIC MEDICAL RECORD.**

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.