Metformin in Alzheimer's dementia Prevention
NCT04098666
Informed Consent Form
August 5, 2024

Participant ID _____

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Metformin in Alzheimer's dementia Prevention (MAP)

Screening and Clinical Assessment (SCA) Consent

JHM IRB Application No.: JHUSIRB00000013

Sponsor/Supporter/Funded By: National Institute on Aging (R01AG062624)

Principal Investigator:
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See "Site-Specific Consent Information" page(s) near the end of this consent form for contact information for your local study team.

You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

This study is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study, this informed consent form includes two parts. The first part of this document includes information that applies to all study sites. The second part of the consent form includes information specific to the study site where you are being asked to enroll.

1. Research Summary (Key Information):

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

The purpose of this study is to test whether the drug Glucophage® XR (generic name metformin extended-release tablets) can prevent cognitive decline among persons with mild cognitive impairment. Mild cognitive impairment is defined as the presence of cognitive complaints, such as forgetfulness, accompanied by mild deficits in tests of memory, and without affecting the ability to live independently. Metformin is approved by the Food and Drug Administration (FDA) for the treatment of type 2 diabetes but is also used "off-label" for the prevention of diabetes among persons at risk, for the treatment of fatty liver, and for the treatment of polycystic ovarian syndrome. Metformin is not approved for prevention of cognitive decline.

If you participate in this study, you will be randomly assigned (like flipping a coin) to receive either metformin or placebo. A placebo is an inactive substance that looks like the study drug but contains no medication. You will have an equal chance of receiving the study drug (metformin) or placebo, and neither you nor the research staff will know to which group you belong. We refer to study drug or placebo as study tablets in the rest of this document. Participants in this study are expected to take the study tablets for a maximum of 18 months.

The major risks and discomforts of this study are related to metformin. The most common side effect of metformin is gastrointestinal upset, including nausea, vomiting, diarrhea, abdominal pain, and loss of appetite. These side effects are most common when starting metformin and may resolve. Another common side effect is taste disturbance (metallic taste in the mouth).

2. Why is this research being done?

This research is being done to find out if metformin can help people who have mild cognitive impairment. Previous research has shown that metformin might prevent worsening of memory in persons with amnestic mild cognitive impairment who do not have diabetes, but this has not been proven definitively. This study intends to get more definitive evidence whether or not metformin is beneficial.

Amnestic mild cognitive impairment means that a person has memory complaints such as forgetfulness and mild deficits in memory tests but is still able to live independently.

Are there any investigational drugs/devices/procedures?

People in this study will receive either metformin or placebo (tablet without active ingredients).

Metformin is approved by the Food and Drug Administration (FDA) for the treatment of diabetes. It is not approved for use in people without diabetes. The FDA is allowing the use of metformin in this research study.

Who can join this study?

People ages 55-90 years with mild cognitive impairment, such as forgetfulness or memory loss, may join. You will be eligible to be in this study if you:

- do not have diabetes or take medications used for diabetes
- have vision and hearing sufficient for complying with testing procedures
- have a person who can attend study appointments with you or be available by telephone
- have no issues with taking the drug metformin
- do not have conditions that would prevent you from finishing the study.

How many people will be in this study?

This is a multicenter study. A total of 326 persons and their study partners will be enrolled at multiple study sites. Of those 326 participants, approximately 186 will take part in magnetic resonance imaging (MRI) of the brain. Once we reach 186 participants with MRI, we will stop enrolling participants for the MRI portion of the study.

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:

- We will ask that someone that knows you well (a study companion) accompanies you to study visits or be available by telephone for questions.

Telephone Screening Visit

- In order to assess if you are eligible, we will first ask screening questions over the telephone.
- This will take approximately 30 minutes.

Screening and Baseline Visit

- If you are considered to be potentially eligible, you will be asked to complete further screening assessments. Some of these assessments may be done remotely immediately following your telephone screening, at a separate time, or could be all done in person. Some of the assessments, such as physical measurements and cognitive testing, can only be done in person.
- A member of our research staff will review this consent form with you. After all your questions have been answered, you will be asked to sign the consent form.
- Our research staff will ask you questions related to your past medical history, review the study inclusion and exclusion criteria, test your cognitive (thinking) abilities, and draw blood for blood tests. You will be required to fast (no food or drink) before this visit. Approximately four tablespoons of blood will be drawn.
- We will perform a physical exam, including taking your blood pressure, weight, and body measurements.
- If you are eligible for the study based on the results of the in-person screening visit, you will be asked to participate for the study's full duration (18 months). The screening assessments will also be part of the baseline visit if you are finally deemed eligible.
- A computer will assign you to receive the study drug (metformin) or placebo by chance (like flipping a coin). Neither you nor the study investigators or staff will know whether you are taking metformin or placebo. Only a few persons in the data coordinating center of the study, located at John Hopkins University, will have access to the information on whether you are taking metformin or placebo. In the case of an emergency, the study doctor can quickly find out which drug or intervention you are assigned to receive.
- You will receive a supply of study tablets to take home and begin taking one study tablet a day.
- We will provide directions as to how to take the medication.

This baseline visit will take approximately 4 hours.

Medication Adjustment

In the first month after the baseline visit, you will be contacted approximately every 10 days to adjust the study tablets as tolerated.

- Every 10 days the dose will be increased by one study tablet as tolerated, until you reach a maximum of four study tablets.
- You will stay on the maximum number of study tablets that you can tolerate, which may be none. You will be asked to remain in the study even if you do not tolerate any study tablets.

6-Month Study Visits

- You will have a study visit every 6 months (months 6, 12, and 18)
- During the study visits we will repeat the blood tests, questionnaires, physical exam, and cognitive tests, similar to the baseline visit. Approximately four tablespoons of blood will be drawn at each study visit. Just as for the screening/baseline visit, some of the questionnaires may be conducted remotely, or all may be done in person. The physical measurements and cognitive testing must be done in person.
- You will be given a new supply of study tablets during these visits. You may receive a 3-month or a 6-month supply depending on your preference and that of your site's study team. If you receive a 3-month supply, the rest may be mailed to you or given to you in person after 3 months.
- You will also return any unused study tablets from the previous supply you received.
- Each study visit will take approximately 4 hours.

Monthly contacts

- In between the in-person study visits, a member of our research staff will call you once per month to make sure you are safe, ask how you are doing, and answer any study related questions. You may conduct this monthly contact in person if you prefer.
- Each contact will last approximately 15-30 minutes.
- The study coordinators and investigators will be available to be contacted by you at any time during the study.

Will research test results be shared with you?

We will share with you only results that may impact your medical care, such as blood tests with information on your kidneys, liver, and blood counts.

How long will you be in the study?

You will be in this study for a maximum of 22 months, with four scheduled in-person study visits (screening/baseline, and three visits every 6 months), and possibly two extra visits for brain MRI (optional).

4. What happens to data and biospecimens that are collected in the study?

Our research partners work to advance science and public health. The data and biospecimens we collect from you are important to this effort.

The biospecimens collected in this study will be from blood. Blood contains DNA, which contains the genetic code for each person.

If you join this study, you will not own the data and/or biospecimens collected from you as part of this research study. If researchers use them to create a new product or idea, including those that may have commercial value, you will not benefit financially from these efforts.

What testing or procedures may be done with your biospecimens?

Your biospecimens may be used for a variety of research purposes. The specific testing that will be part of this study includes genetic testing for APOE-ε4, which may modify the effectiveness of metformin and the risk of cognitive impairment.

This study involves genetic testing on samples that you provide. The Genetic Information Nondiscrimination Act (GINA) is a federal law that helps reduce the risk of discrimination by health insurers or employers based on your genetic information. GINA does not protect you from discrimination if you apply for other types of insurance (such as life, disability or long-term care). GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Genetic information is unique to you and your family. Even without your name or other identifiers, it may be possible to identify you or other members of your family with your genetic information. Our collaborators follow procedures so that people who work with your DNA information for research cannot discover it belongs to you, unless you have given consent. However, new techniques may be developed that in the future make it easier to link your genetic data to you, so we cannot promise that your genetic information will never be linked to you.

How will your data and/or biospecimens be shared now and in the future?

Sharing data and/or biospecimens is part of research and may increase what we can learn from this study.

Often, data/biospecimen sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas.

Your data and/or biospecimens may be shared:

- directly with research collaborators, other researchers, sponsors, government agencies, publishers of papers and other research partners
- through government or other databases/repositories

Data/biospecimen sharing could change over time and may continue after the study ends.

We will do our best to protect and maintain your data/biospecimens in a safe way. Generally, if we share your data/biospecimens without identifiers (such as your name, address, and date of birth) further review and approval by an Institutional Review Board (IRB) is not needed. However, when we share data/biospecimens, we limit the uses of the information and whether these data/biospecimens can be shared with another research team. If data/biospecimens are shared with identifiers, further IRB review and approval may be needed, and the IRB will determine whether additional consent is required.

Genomic Data Sharing

Genomic studies, including genome-wide association studies (GWAS), examine genetic differences in the entire human genome (the complete set of human genes) and the association between these genetic differences and health conditions.

As part of this study, we will collect information about your health and your individual genes. This information may be sent to a National Institutes of Health (NIH) designated data repository that includes genomic and other data from studies funded by the NIH.

The aim of collecting this information is to look for genetic connections that may:

- Increase the likelihood of getting a certain disease (such as asthma, cancer, diabetes, heart disease or mental illness) or a condition (such as high blood pressure or obesity);
- Affect the progress of a certain disease or condition;
- Affect treatments (medicines, etc.) that work for certain diseases in some people, but not in others.

We or our collaborators will remove direct identifiers (such as your name or date of birth) and instead code your information before sending it to the repository. The NIH will never receive this code or the identifiers we have removed.

The repository is a controlled-access repository. This means that your individual de-identified data is only available to researchers who apply to the NIH. The NIH will review data requests for scientific merit and for methods to protect data and methods to ensure data will be used for the approved purpose. We will not always know what types of health-related research will be done with the data that are sent to the repository.

Genomic summary results (GSR) data for non-sensitive studies may be made available by NIH without controlled access. GSR data does not include information about you as an individual but consists of statistical information calculated using your data combined with data from other people.

What are the risks to your privacy?
There may be risks to your privacy and the privacy of your relatives from storing your information in the repository. Although the NIH takes measures to protect privacy, we do not know how likely it is that your identity could become re-connected with your genetic and health information.

If your genetic information were re-identified, personal information about you, your health and your risk of disease could become known to others. This could present unknown risks. Current federal law will help protect you from genetic discrimination in health insurance and employment.

Are there benefits to sharing your genetic information?
There is no direct benefit to you from placing your genetic information in the repository. Allowing researchers to study your genetic information may lead to a better understanding of how genes affect health. This may help other people in the future.

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

Risks from Metformin

- Very common (greater than 1 in 10 participants)
    - Gastrointestinal disorders such as nausea, vomiting, diarrhea, abdominal pain and loss of appetite. These undesirable effects occur most frequently during initiation of the drug and resolve spontaneously in most cases. A slow increase of the dose may also improve gastrointestinal tolerability. Gastrointestinal disorders are the most common reason for metformin non-tolerance.
- Common side effects (greater than 1 in 100 participants)
    - Metallic taste in the mouth.
- Very rare side effects (less than 1 in 10,000 participants)
    - The most severe but very rare side effect of metformin is lactic acidosis, which is a buildup of toxic substances in your blood.
    - Vitamin B12 (cobalamin) deficiency and decrease in serum B12 levels that can lead to anemia. We will monitor your B12 levels throughout the study and provide you with the results.
    - Liver test abnormalities. We will monitor liver tests throughout the study and provide you with the results.
    - Skin reactions such as redness and itching
    - Fast heart rate.

Due to potential kidney function complications and lactic acidosis, metformin should be discontinued the day before any surgery or administration of contrast agents and resumed 48 hours after the procedure.

We will make sure that you do not have conditions that predispose you to severe side effects, such as advanced kidney, liver, and heart disease. Excessive alcohol intake can also increase the risk of severe side effects.

Blood Draw

- Drawing blood may cause discomfort, pain, bleeding, or bruising where the needle enters the body. In rare cases, it may result in fainting.
- There is a very small risk of infection.

Interviews or questionnaires

The memory and cognitive testing have been used in thousands of people.

- You may get tired or bored when we are asking you questions, or you are completing questionnaires.
- The interviews and cognitive testing may cause you stress and fatigue. Tell the staff if you feel uncomfortable during interviews or testing.
- You do not have to answer any question you do not want to answer.
- You may discontinue your study participation if you do not wish to carry out further testing.

Physical Exam

Measurement of vital signs and body measurements may cause psychological distress.

Identifiable private information

There is the risk that information about you may become known to people outside this study.
We will try to respect your privacy and protect your confidentiality throughout the study. We do this by keeping your tracking information (name, medical record number, address, and phone number) separate from your study file. In your study files, you are identified by a study ID number. We also share the information gathered in the study only with the people who need to know this information. However, there is the risk that psychological, emotional, financial, social, and legal risks might result if this confidentiality cannot be maintained.

Please see the **"Site-Specific Consent Information"** (Part 2 of this consent) for other details on how your privacy will be protected.

Unknown risk

There may be side effects and discomforts that are not yet known.

6. 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 others in the future. The results of this study may help prevent or lessen cognitive decline associated with Alzheimer's disease.

7. 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 the study site will not be affected.

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

You will not need to pay for any tests and procedures that are done just for this research study. We will pay for your local transportation costs according to the conditions covered in the second part of this consent form.

However, you and/or your health plan will need to pay for all other tests and procedures that you would normally have as part of your regular medical care. These tests and procedures are those required by your physician for a clinical assessment.

If you have billing or insurance questions, contact the study team listed in the site-specific consent information section located towards the end of this form.

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

You will be paid for your participation in this study. **Please see the site-specific consent information section of this consent for additional information on payments at your study site.**

10. 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, our researchers may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. 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.
- You are unable to attend scheduled study visits.
- 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, our researchers may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

12. What is a Certificate of Confidentiality?

This study is protected by a Certificate of Confidentiality that helps keep your information private when stored in the U.S. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

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

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. 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. If you would like to review the information for this study, or a summary of the results, the ClinicalTrials.gov study registration number is NCT04098666.

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 primary doctor and other physicians who treat you.

What is the Institutional Review Board (IRB) and how does it protect you?
This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study.

For this multi-site study, Johns Hopkins has agreed to serve as the single IRB (sIRB) providing oversight for all sites. You may contact the Johns Hopkins IRB at 410-502-2092 or jhmeirb@jhmi.edu with your questions or concerns.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?
Call the principal investigator for your study site, which is listed in the **"Site-specific Consent Information"** (Part 2 of this consent).

If you have an urgent medical problem or think you are injured or ill because of this study, call 911 or go to your local emergency department.

If you wish to contact the main study principal investigator, Jose Luchsinger, M.D., call 212-305-4730. You may contact the principal investigator by letter or email at jal94@cumc.columbia.edu. The mailing address is 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 410-502-2092.

14. Optional Components:

This part of the consent form is about optional component(s) of the study that you can choose to take part in or not. You can still take part in the main study even if you say "no" to this/these optional component(s).

Future use of biospecimens
If you agree, our researchers may use the biospecimens collected in this study for future research purposes, which may include gene sequencing and genetic testing. Each cell contains your complete DNA. Gene sequencing of your DNA provides researchers with the code to your genetic material. This future research may be unrelated to the current study and may include outside collaborators.

Because science constantly advances, we do not yet know what future testing may include. If biospecimens are tested/used in ways not described above, further IRB review and approval may be needed, and the IRB will determine whether additional consent is required.

The specimens will be stored in a facility affiliated with and approved by the study principal investigator and Columbia University.

Future testing of your DNA sample is optional. You may decline the use of biospecimens for future research.

Will you allow us to use the biospecimens we collect for this study for future research?

Please sign and date your choice below:

YES ☐ _____ _____
Signature of Participant Date

NO ☐ _____ _____
Signature of Participant Date

Future Contact

We would like your permission for our research team to contact you in the future. Please note that your decision below does not prevent other researchers at the research institution from contacting you about other research.

Please sign and date your choice below:

YES ☐ _____ _____
Signature of Participant Date

NO ☐ _____ _____
Signature of Participant Date

MRI

We would like your permission for our research team to arrange for an MRI for you in the future. Having an MRI as part of this research study is optional. Not having the MRI will not affect your participation in the study.

- If you are eligible for magnetic resonance imaging (MRI), we will ask you to have a brain MRI. Please note that once the study reaches 186 participants with MRI across all the sites, enrollment for MRIs will be stopped.
- We anticipate that half of the study participants will undergo a brain MRI.
- If you decide to do the MRI, it will be done twice, within a month of the baseline visit, and within a month of the 18-month visit.
- MRI scans create images of the body using a magnet and radio waves. There is no radiation involved in an MRI exam.
- You may not take part in this study if you have any metal or device in your body which is not compatible with MRI. Examples include certain pacemakers, defibrillators, aneurysm clips, or certain other implanted electronic or metallic devices, shrapnel, or other metal. If you have a history of metal in your head or eyes, you cannot take part in the MRI portion of this study.
- The MRI machine periodically makes loud banging noises. We will provide earplugs or headphones for you to wear during the MRI exam.
- A member of our study team will escort you in and out of the MRI facility.
- The MRI exam(s) in this study will take 45-60 minutes.

Incidental Findings

- A qualified professional will review the research brain MRI. This research brain MRI will not include the full diagnostic information that you would get if your primary doctor referred you for an MRI of the brain for medical (not research) purposes.
- There is a possibility that while reviewing your MRI we may see an unexpected abnormality. This is called an "incidental finding." An incidental finding may include something like a benign tumor that requires non-urgent attention, or something more serious, like a new stroke or a more serious tumor that requires immediate attention.
- We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail, email, or phone. In the case of a potential serious emergency, someone may go to your home if you cannot be contacted by telephone.
- A qualified person (usually a member of the research team) will talk to you if there is an incidental finding. <u>You do not have an option to decline information about an incidental finding from the MRI procedure.</u>
- If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.
- What could happen if there is an incidental finding?
    - An incidental finding may cause you to feel anxious.
    - Since a report of the incidental finding will be part of your medical record, it will be available to those accessing your medical record for your clinical care and may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved.
- The costs for any care that may come from the incidental finding, such as the need to see a doctor to diagnose or treat an incidental finding, will not be paid for by this research study. These costs would be your responsibility and/or the responsibility of your medical insurance.

MRI Risks

- While no significant risks have been found from the use of MRI scans, you may be bothered by the MRI machine noise and by feelings of being closed in (claustrophobia).
- Some people have reported sensations during MRI scans, such as tingling or twitching (or, very rarely, a painful sensation) caused by changes in the magnetic field that can stimulate nerves in your body.
- If you experience any discomfort and wish to stop the scan, you can inform the MRI technologist and the scan will stop immediately.
- In our experience, no one has had ongoing sensations from the MRI scan once the scanning has stopped.
- There is a potential risk of a loss of privacy due to collection of identifying personal information that will be used to identify the MRI scan. This risk may be minimized by deletion of all identifying information before releasing the images to the research team from the MRI service. Your scan will be assigned a study number. The list of study participants/numbers will be kept on a password-protected computer with limited access. This information will be entered into a secure database at the Data Coordinating Center at Johns Hopkins University.

Please sign and date your choice below:

YES ☐ _____ _____
Signature of Participant Date

NO ☐ _____ _____
Signature of Participant Date

SITE-SPECIFIC CONSENT INFORMATION

Site Name: Columbia University Irving Medical Center

Study Title: Metformin in Alzheimer's Dementia Prevention (MAP)

JHM IRB Application Number: JHUSIRB00000013

Consent Version: v1.2

Site Principal Investigator: José A. Luchsinger, MD MPH

Site Principal Investigator Contact Information:

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Emergency Contact: Study Team Contact / (P): 646-946-9158

Introduction

This is a multi-site study, meaning it will take place at several locations around the United States. Because this is a multi-site study, the consent form has two parts: **1)** the first part includes information that applies to all study sites; **2)** the second part includes information specific to your study site.

This part of the consent form includes information about your site and is specific to participation at your site only. Before making your decision, both the site-specific information and general study information will be reviewed with you. You will have the opportunity to discuss any questions, including questions about this portion of the consent document, with your site's study team.

Payment for Study Participation:

You will be paid $50.00 (fifty dollars) for initial screening with a pay card. You will be paid $200.00 (two hundred dollars) for each in person study visit with a pay card.

You will be paid up to $50.00 (fifty dollars) for your travel costs to the in-person and MRI study visits. Documentation of these costs, including mileage and toll receipts, may be required.

You will be offered free Amazon Prime membership during your participation in the study or an Amazon gift card or TruCentive physical or electronic gift card of equal value. This gift card will be sent to you by mail or email. The TruCentive physical or electronic gift card will be a VISA gift card. Please note, for physical gift cards, information about you (including physical address) will need to be entered into a secure third-party system. There are protections in place to safeguard your information and the research team will not have access to any of the information you provide for compensation purposes.You will not be paid for time missed from work or other activities.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from the study site exceed $600 per year, you will need to fill out a W-9 form, the study site will report these payments to the Internal Revenue Service, and you will receive a 1099-MISC form from the institution.

Compensation for Research-Related Injury:

Taking part in this research study may result in injury or harm to you. In the event of an injury resulting from your participation in this study, you should seek appropriate medical care and inform the study doctor. In the event of an emergency you should go to an emergency room.

If you are injured or harmed as a result of participating in the study and receive medical care through the New York-Presbyterian Hospital (NYPH), a Columbia doctor, or any other health provider, you will be sent a bill for whatever medical care you receive. All or part of your bill may be paid by your health insurance.

Columbia University and New York-Presbyterian Hospital (NYPH) are not offering to provide you the drug/device after the termination of the study or to pay you for pain, worry, lost income, the cost of your medical care or non-medical care costs that might occur as a result of your taking part in this study. However, you do not waive any of your legal rights in signing this form.

Site IRB Contact Information:

If you have any questions about your rights as a research participant, or if you have a concern about this study, you may contact the office below.
Human Research Protection Office
Institutional Review Board
Columbia University Medical Center
154 Haven Avenue, 1st Floor
New York, NY 10032
Telephone: (212) 305-5883
irboffice@columbia.edu

HIPAA Authorization for Disclosure of Protected Health Information:

Access to your health information is required to be part of this study. If you choose to take part in this study, you are giving us the authorization (i.e. your permission) to use the protected health information and information collected during the research that can identify you. The health information that we may collect and use for this research may include medical history that may be considered sensitive.

Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care that is needed for this research purpose.

The research information that is shared with people outside of Columbia University Medical Center and New York-Presbyterian Hospital will not include your name, address, telephone number or any other direct identifier unless disclosure of the information is required by law or you have authorized the disclosure.

The following individuals and/or agencies will be able to look at, copy, use and share your research information:
- The investigator, study staff, Columbia University staff, New York-Presbyterian Hospital staff] and medical professionals who may be evaluating the study or providing services for the study
- Authorities from Columbia University and New York-Presbyterian Hospital, including the Institutional Review Board ('IRB'). An IRB is a committee organized to protect the rights and welfare of people involved in research.
- The Federal Office of Human Research Protections ('OHRP') and/or the United States Food and Drug Administration ('FDA');
- The sponsor of this study, the National Institute on Aging, including persons or organizations working with or owned by the sponsor may review your data for accuracy but may not copy information with your name on it.

Your authorization to use and share your health information does not have an expiration (ending) date.

Once your health information has been disclosed to a third party (for example, a pharmaceutical company participating in a study), federal privacy laws may no longer protect it from further disclosure.

You may change your mind and revoke (take back) this consent and authorization at any time and for any reason. To revoke this consent and authorization, you must contact the Principal Investigator at the address listed on the first page of this consent.

However, if you revoke your consent and authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this consent and authorization, the Researchers and the Sponsor (if applicable) may continue to use and disclose the information they have already collected.

Your participation in this research study will be documented in your electronic medical record. This record can be viewed by authorized personnel from Columbia University Irving Medical Center, Weill Cornell Medical Center and New York-Presbyterian Hospital and its affiliated institutions, because these institutions share the electronic medical record system. Study monitors and others who provide oversight of the study may also need to access this record.

Additional information about your local site:
Statement of consent and HIPAA Authorization:
I have read the consent and HIPAA authorization form and talked about this research study, including the purpose, procedures, risks, benefits and alternatives with the researcher. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent and HIPAA authorization form to keep for my records.

Documentation of Consent/Signatures

Your signature on this form means that:
You understand the information given to you in this form, you accept the provisions in the form, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS CONSENT FORM

_____

Signature of Participant Print Name Date

_____

Signature of Person Obtaining Consent Print Name Date

_____

Signature of Legally Authorized Representative Print Name Date
(Required only if participant loses capacity during the course of the research)

_____

Relationship of LAR to Participant
(Indicate why the LAR is authorized to act as a surrogate health care decision-maker under state or applicable local law)