

Study number: _____ **Principal Investigator (s):** _____
Title: _____

Informed Consent for Clinical Research

Georgetown University

INSTITUTION: _____ *(Name of all hospitals participating)*

INTRODUCTION

You are invited to consider participating in this study. The study is called ("*Title of Study*"). Please take your time to make your decision. Discuss it with your family and friends. It is important that you read and understand several general principles that apply to all who take part in our studies:

- (a) Taking part in the study is entirely voluntary;
- (b) Personal benefit to you may or may not result from taking part in the study, but knowledge may be gained from your participation that will benefit others;
- (c) You may withdraw from the study at any time without any of the benefits you would have received normally being limited or taken away.

The purpose and nature of the study, possible benefits, risks, and discomforts, other options, your rights as a participant, and other information about the study are discussed below. Any new information discovered, at any time during the research, which might affect your decision to participate or remain in the study will be provided to you. You are urged to ask any questions you have about this study with the staff members who explain it to you. You are urged to take whatever time you need to discuss the study with your physician, hospital personnel and your family and friends. The decision to participate or not is yours. If you decide to participate, please sign and date where indicated at the end of this form.

The research is being sponsored by *(name of agency/company)*. The *(name of agency/company)* is called the sponsor and *(Georgetown University)*, is being paid by *(name of agency/company)*, to conduct this study with *(name of investigator)* as the primary investigator.

WHY IS THE STUDY BEING DONE?

You are being asked to participate in this study because

You may not participate in this study if any of the following apply to you:

(List of exclusion criteria)

The purpose of this study is to _____.

(Choose applicable text:)

Observational Studies: Learn about the natural history of *(name of disease)* and its causes and treatments.



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Phase 1 Studies: Test the safety of (*drug/intervention*) and see what effects (*good and bad*) it has in your (*patient's condition*).

Or

Find the highest dose of (*drug*) that can be given without causing severe side effects.

Phase 2 Studies: Find out what effects (*good and bad*) (*drug/intervention*) has on you and your (*patient's condition*).

Phase 3 Studies: Compare the effect (*good and bad*) of the (*new drug/intervention*) with (*commonly-used drugs/intervention*) on you and your (*patient's condition*) to see which is better.

This research is being done because _____.

[Explain in one or two sentences. Examples are: "Currently, there is no effective treatment for this type of condition," or "We do not know which of these commonly-used treatments is better."]

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Participants in the study are referred to as subjects.

About ____ subjects will take part in this study worldwide; _____ subjects will be recruited at this site.

WHAT IS INVOLVED IN THE STUDY?

[Provide simplified schema and/or calendar.]

[For randomized studies:]

You will be "randomized" into one of the study groups: (*describe the groups*). Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by a computer. Neither you nor the researchers will choose what group you will be in. You will have an (*equal/one in three/etc.*) chance of being placed in any group. (*If blinded*) Neither you nor the investigator will know what group you are in.

You will be given a study medication and it will either contain (*name of drug*) or placebo (pills with no medicine)

[For nonrandomized and randomized studies:]

If you take part in this study, you will have the following tests and procedures:



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[List procedures and their frequency under the categories below. For randomized studies, list the study groups and under each describe categories of procedures. Include whether a patient will be at home, in the hospital, or in an outpatient setting. If objectives include a comparison of interventions, list all procedures, even those considered standard.]

Procedures that are part of regular care and may be done even if you do not join the study.

Standard procedures being done because you are in this study.

Procedures that are being tested in this study.

Please advise the researchers of any medications you are taking. In addition, if you are taking any over-the-counter drugs or herbal supplements which you have obtained from the drug store, grocery store, etc., you should advise the researchers.

HOW LONG WILL I BE IN THE STUDY?

We think you will be in the study for *(months/weeks, until a certain event)*.

[Where appropriate, state that the study will involve long-term follow-up.]

The researcher may decide to take you off this study if _____.

[List circumstances, such as in the participant's medical best interest, funding is stopped, drug supply is insufficient, patient's condition worsens, new information becomes available.]

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first.

[Describe any serious consequences of sudden withdrawal from the study.]

WHAT ARE THE RISKS OF THE STUDY?

For trials of drugs or devices/procedures, there may be risks. You should discuss these with the research doctor and/or your regular doctor.

Risks and side effects related to the (procedures, drugs, or devices) we are studying include:

[List by regimen the physical and nonphysical risks of participating in the study in categories of "very likely" and "less likely but serious." Nonphysical risks may include such things as the inability to work. Highlight or otherwise identify side effects that may be irreversible or long-term or life threatening.]

[Observational studies – describe risks and discomfort of procedures and questionnaire.]



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There may also be side effects, other than listed below that we cannot predict. Other drugs will be given to make side effects that occur less serious and less uncomfortable. Many side effects go away shortly after the (drug /intervention) is stopped, but in some cases side effects can be serious, long lasting or permanent.

For more information about risks and side effects, ask the researcher or contact _____.

[Reference and attach drug sheets, pharmaceutical information for the public, or other material on risks.]

Avoidance of Pregnancy: The medicines and procedures used in this study may be unsafe for an unborn baby, an infant, sperm, and eggs. If you, as a subject of study, are a woman of child bearing potential, you must agree to avoid pregnancy during your participation in this study and for *three months* after the completion of the study (**include when appropriate**); if you, as a subject, are a man, you must agree to not conceive a child during your participation in this study and for *three months* after the completion of the study (**include when appropriate**). If you do become pregnant during the study or if you father a child during the study, you should immediately notify Dr. _____ at 202-_____. In addition, if you are already pregnant or are breast feeding, you cannot participate in this study.

Fill in the blanks.

Risks associated with the genetic information:

Risks of being in genetic testing include the misuse of personal, genetic information. All personnel who will have access to genetic information about you are ethically and legally obligated to maintain the confidence of that information. However, there can be no absolute guarantees. Although rare, misuse of such information has caused problems for persons related to their employment and/or their life and/or health insurance and other benefits or entitlements. Also, there is a risk that being in a genetics study can cause psychological distress or experience tension with other family members. Even when the information is kept secret, if you are asked if you have ever been tested for a genetic disorder, answering “yes” could cause benefits to be denied or could cause other problems including discrimination.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

[If possible benefits are expected, use:] If you agree to take part in this study, there may or may not be direct medical benefit to you.

[If no possible benefits are expected, use:] If you agree to take parting this study, there will be no direct medical benefit to you.

We cannot promise that you will experience medical benefits from participating in this study. We hope the information learned from this study will benefit others in the future.



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WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you have these options:

[List alternatives including commonly used therapy(ies)]

Whether you participate in this study or not, you will receive care to manage your symptoms and keep you comfortable.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Medical records of research study participants are stored and kept according to legal requirements. You will not be identified in any reports or publications resulting from this study. Organizations that may request to inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as:

(the name of the sponsor), Food and Drug Administration, Georgetown University, Georgetown University Institutional Review Board (IRB), (name of Clinical Research Organization - CRO), federal research oversight agencies.

[Please include only if subjects are being paid for participation]

Please note that administrative personnel involved in processing your payment for participation will be aware of your identity.

CERTIFICATE OF CONFIDENTIALITY

(* NOTE: THIS IS ONLY AN INSTRUCTION FOR THE PI - DO NOT INCLUDE THIS SECTION IF IT DOES NOT APPLY TO YOUR STUDY*)

A Certificate of Confidentiality can be granted by the Department of Health and Human Services (DHHS). This Certificate will protect the investigators (project staff) from being forced to release any research data in which the subject is identified even under a court order or subpoena. This protection is not absolute. It does not, for instance, apply to any state requirement to report child abuse to the appropriate authorities.

DATA SECURITY

If information about your participation in this study is stored in a computer, we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage:

State here whether you are keeping data on a computer that will identify the subjects in the study. If you are, explain how you are protecting this information. Give details: for example, is the computer in a locked room, is it part of a network, is a password required for getting onto the system, who has access to these data, etc.



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WHAT ARE THE COSTS?

Qualified study subjects will/will not have to pay for the study drug/treatment. You or your insurance company will have to pay for _____.

Taking part in this study may lead to added costs for you or your insurance company. Please ask about any expected added costs or insurance problems.

Note to Researchers: Be as specific as possible about additional costs.

You or your insurance company will be charged for continuing medical care and/or hospitalization that are not a part of the study.

Include the following paragraph if this study will be done at Georgetown University Hospital

Call the Georgetown University Clinical Trials Office at 202-444-0381 with any questions or concerns about expected costs, bills you have received from the hospital or your study physician that you feel may be related to your participation in this research study.

POLICY/PROCEDURES FOR RESEARCH RELATED INJURY

The Policy and Procedure for the Sponsor **[always insert the name of the sponsor here]** are as follows:

[Include the Sponsor's statement here---the sponsor will or will not pay for care necessitated by a research related injury]

The Policy and Procedure for Georgetown University:

We will make every effort to prevent study-related injuries and illnesses. If you are injured or become ill while you are in the study and the illness or injury is due to your participation in this study, you will receive necessary medical care at the usual charge. The costs of this care will be charged to you or to your health insurer. No funds are available from Georgetown University, Georgetown University Hospital, MedStar Research Institute, or their affiliates, the District of Columbia government or the federal government to repay you or compensate you for a study related injury or illness.

PAYMENT FOR PARTICIPATION

You will/will not be paid for participating in this study. **(If paid, state payment schedule/amount).**

You should not expect anyone to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research study.



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COMMERCIAL INTEREST (if applicable)

For your information, the (name of institution) holds a patent for this device or drug and has a potential financial interest in the outcome of this study. (Institution or individual investigator)

Materials obtained from you in this research may be used for commercial purposes. It is the policy of Georgetown University not to provide financial compensation to you should this occur.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part in or leave the study at any time. If you choose to not take part in or to leave the study, your regular care will not be affected nor will your relations with your physicians, other personnel and the hospital or university. In addition, you will not lose any of the benefits to which you are entitled.

We will tell you about new information that may affect your health, welfare, or participation in this study.

[Please include the following when a Data Safety and Monitoring Board exists:]

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

By signing this form you do not lose any of your legal rights.

NEW FINDINGS

Throughout the study, we will tell you about new information we receive about treatments that may be appropriate for you, about the experimental treatments under investigation in this study, and any information that may affect your interest in remaining in the study.

For studies involving Center Functional and Molecular Imaging:

Throughout the study, we will tell you about new information we receive about treatments that may be appropriate for you and any information that may affect your interest in remaining in the study. The investigators for this project are not trained to perform radiological diagnosis, and the scans performed are not optimized to find abnormalities. The investigators are not responsible for failure to find existing abnormalities in your MRI scans. However, on occasion the investigator may notice a finding on a MRI scan that seems abnormal. When this occurs, a neurologist will be consulted as to whether the finding merits further investigation, in which case the investigator or the consulting neurologist would contact you and your primary care physician to inform you of the finding. The decision as to whether to proceed with further examination lies with you and your physician. The investigators, the consulting neuroradiologist or neurologist, and Georgetown are not responsible for any examination or treatment that you undertake based upon these findings. **Because images in this study do not comprise a proper clinical MRI series, these images will not be made available for diagnostic purposes.**



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WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call (*name*) at (*telephone number*) or the [*Department name, e.g., Neurology*] fellow on-call at (*telephone number*). Be sure to inform the physician of your participation in this study.

Note to Researchers: Please note that this must be a 24 hour telephone number. The on-call number should be provided in addition to the PI number.

If you are a participant at Georgetown University and have questions about your rights as a research participant, contact the Georgetown University IRB Office. Direct your questions to:

Institutional Review Board at:

Address: Georgetown University Medical Center Telephone:
(202) 687-1506
3900 Reservoir Road, N.W.
SW104 Med-Dent
Washington, D.C. 20057

Withdrawal by investigator, physician, or sponsor

The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, if you need additional or different medication, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.



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[please use this section if you are doing tissue banking]

THINGS TO THINK ABOUT

The choice to let us keep the collecting left over tissue and blood for future research is up to you. No matter what you decide to do, it will not affect your care or follow-up.

If you decide now that your tissue can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your tissue. Then any tissue that remains will no longer be used for research and will be destroyed.

In the future, people who do research on your samples may need to know more about your health. Reports will not have your name, address, phone number, or any other information that will let researchers know who you are. They will be identified by unique numbers that do not allow the researcher the ability to identify who the samples were obtained from.

Your tissue will be used only for research and will not be sold. The research done with our tissue may help to develop new products in the future. You will not profit from any new product developed from research done on your specimens.

MAKING YOUR CHOICE

Please read the sentence below and think about your choice. Please circle “Yes” or “No” then add your initials and date after you answer. **No matter what you decide to do, it will not affect your care.** If you have any questions, please talk to your study doctor or nurse, or call the Institutional Review Board at 202-687-1506

Please note: this section of the informed consent form is about additional types of research studies that may be done with in addition to basic studies of _____. Some of these studies may not be related to **cancer**. We would like to use any leftover samples for these types of studies. You will not have any extra procedures. You may take part in these additional studies if you want to. You can still be a part of the basic study even if you say ‘no’ to taking part in any of these additional studies.

NOTE: If the subject was on a therapeutic trial that already consented for banking and future contact then they should not be presented with these options a second time!

Your samples will only be used by qualified researchers. Each proposed project is reviewed by a group of scientists. Every project is also reviewed by a group that protects your rights as a person joining a research study. Once you’ve answered the instructions below, you will not be asked again about participation in the specific studies using your banked samples:

Instruction 1: *[Please provide a brief description of the first tissue study/experiment]*



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#1

YES

NO

Initials	Date

Instruction 2: *[Please provide a brief description of the first tissue study/experiment]*

#2

YES

NO

Initials	Date

Instruction 3: *[Please provide a brief description of the first tissue study/experiment]*

#3

YES

NO

Initials	Date



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RESEARCHER'S STATEMENT

I have fully explained this study to the subject. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

Signature of person obtaining the consent

Print Name of Person

Date

I, the undersigned, have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way effect my future treatment or medical management and you will not lose any benefits to which you are otherwise entitled. I agree to cooperate with (*name of principal investigator*) and the research staff and to inform them immediately if (*I / the patient name*) experience any unexpected or unusual symptoms.

Signature of Subject

Print Name of Subject

Date

If appropriate, include the following section:

Signature of Legally Authorized Representative
And Relationship To Participant (When Appropriate)

Date

