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| **MedStar Health Research Institute Informed Consent for Clinical Research** |

##

## **INTRODUCTION**

We invite you to take part in a **[choose one only if IND/IDE product study** (investigational/experimental)**]** research study called *(“Title of Study”)*. You were selected as a possible participant in this study because (state why the participant was selected). Please take your time to read this form, ask any questions you may have and make your decision. We encourage you to discuss your decision with your family, friends and your doctors.

This following text will be included by the site if there is LAR. If this text is not submitted do not include it.

This form is for use in a research study that may involve participants who may or may not have the capacity to consent to take part in the study. Accordingly, pronouns “you” and “your” should be read as referring to the participant rather than the person (legally authorized representative) who is signing this form for the participant.

## **WHAT IS THE PURPOSE OF THIS STUDY?**

This study is being done to **[choose applicable text category below by deleting all other categories, category text and aligning the remaining verbiage behind the word “to” in this sentence]**

**[Outcomes/Observational/Other Studies]**

study the natural history of (name of disease/condition) and its causes and treatments.

**[Phase 1 Drug Studies]**

test the safety of(drug/treatment) and see what effects, good and bad,it has on **[choose one: normal healthy volunteers like yourself or people with your (participant's condition)].** This is a Phase I study, which means that this drug is either being studied for the first time in humans or has been tested a limited number of times in humans.

**[Phase 2 Drug Studies]**

find out what effects, good and bad, (drug/treatment) has on you and your (participant's condition) **[choose one]** (and/or) find the highest dose of (drug),which can be given without causing severe side effects.

**[Phase 3 Drug Studies]**

compare the effect, good and bad, of the (new drug/treatment) with **[insert comparison reference - i.e. commonly-used drugs/treatments, placebo, etc.]** (comparison reference) on you and your (participant's condition) to see which is better.

**[Devices]**

study the (device name) on persons with (participant's condition) to determine **[insert question to be answered by study]** (study question).

**WHAT ELSE SHOULD I KNOW ABOUT THIS RESEARCH STUDY?**

It is important that you read and understand several points that apply to all who take part in our studies:

* Taking part in the study is entirely voluntary and refusal to participate will not affect any rights or benefits you normally have;
* You may or may not benefit from taking part in the study, but knowledge may be gained from your participation that may help others; and
* You may stop being in the study at any time without any penalty or losing any of the benefits you would have normally received.

The nature of the study, the benefits, risks, discomforts and other information about the study are discussed further below. If any new information is learned, at any time during the research, which might affect your participation in the study, we will tell you. We urge you to ask any questions you have about this study with the staff members who explain it to you and with your own advisors prior to agreeing to participate.

**WHO IS IN CHARGE OF THIS STUDY?**

The investigator is (**insert name of investigator**). The research is being sponsored by (**insert name of agency/company or the word ”investigator”, if applicable)**. MedStar Health Research Institute is being paid by (insert name of agency/company/grant, i.e., intramural, fellowship, etc.), to conduct this study with (i**nsert name of investigator**) as the primary investigator.

**WHO CANNOT PARTICIPATE IN THIS STUDY?**

You cannot be in this study if any of the following apply to you: **[Bullet point list of exclusion criteria in lay language]**

##### **[insert if interventional study].** **WHAT IF I AM PRESENTLY PARTICIPATING IN ANOTHER RESEARCH STUDY?**

##### Are you presently participating in any other research studies? Yes [ ]  No [ ]

If yes, please state which study(ies)\_\_\_\_

While participating in this study, you should not take part in any other research project without approval from the people in charge of each study. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, interaction of research drugs, or similar hazards.

**HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?**

About **(#)** people will take part in this study, worldwide. **(#)** people will be recruited at this site.

**WHAT HAPPENS IF I AGREE TO BE IN THE STUDY?**

**[For randomized studies:]**

If you agree to take part in this study, 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. Neither you nor the investigators will choose what group you will be in. You will have **(insert description of chance - an equal/one in three/etc.)** chance of being placed in any group.

**[Insert if doubled blinded]**

Neither you nor the investigator will know what group you are in.

**[Insert if single blinded]**

You will not know what group you are in.

**[Describe what is involved in the study. Consider inserting a simplified schema and/or calendar informing the participant of their requirements. Include whether a participant 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]**

The procedures/treatments in this study that are considered experimental/investigational are:

For procedures/treatments that are not experimental/investigational,

* The following procedures are part of the research study and would not normally be done as part of your routine care:
* The following procedures would normally be done as part of your routine care whether or not you are enrolled in the study:

**[For nonrandomized studies:]**

If you agree to be in this study, you will have the following tests and procedures:

**[Describe what is involved in the study. Consider inserting a simplified schema and/or calendar informing the participant of their requirements. Include whether a participant 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]**.

The procedures/treatments in this study that are considered experimental/investigational are:

For procedures/treatments that are not experimental/investigational,

* The following procedures are part of the research study and would not normally be done as part of your routine care:
* The following procedures would normally be done as part of your routine care whether or not you are enrolled in the study:

**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 either short or long-term follow-up or require responding to a questionnaire]**

The investigator may decide to take you off this study if it is believed to be in your best interest, you fail to follow instructions, new information becomes known about the safety of the study, or for other reasons the investigator or sponsor believes are important.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the investigator and your regular doctor first so they can help you decide what other options may be best for your medical care once you are off study.

If you suddenly withdraw from the study, **[Describe any serious consequences of sudden withdrawal from the study]** and we may not be able to use any of the information gathered from your participation.

**WHAT ARE THE RISKS AND SIDE EFFECTS OF THIS STUDY?**

If you decide to participate in this study, you should know there may be risks. You should discuss these with the investigator and/or your regular doctor and you are encouraged to speak with your family and friends about any potential risks before making a decision. Potential risks and side effects related to this study include:

**[List below all reasonably foreseeable physical and nonphysical risks,(e.g. the inability to work, emotional distress, etc.) and discomforts (e.g. sitting in one place for a long time, being in a confined space, reliving painful memories, receiving multiple injections, etc.) associated with the study, and describe how they will be managed, being explicit about severity and reversibility. In addition to physiological and psychological risks/discomforts, describe any social, legal or financial risks that might result from participating in the research]**.

Risks and side effects ***that may occur*** include:

* **[If appropriate insert "occurs in approximately X-Y% of participants"]**

Risks and side effects ***that are less likely to occur*** include:

* **[If appropriate insert "occurs in approximately X-Y% of participants"]**

Risks and side effects ***that rarely occur*** include:

* **[If appropriate insert "occurs in approximately X-Y% of participants"]**

**[If applicable]**

**[If a placebo will be used, you must clearly define the term placebo and you may want to state the risk that the condition under study may not improve or may become worse during the study].**

**[If applicable]**

Please tell the investigator about all medications including over-the-counter drugs or herbal supplements you are taking, even if you don’t think they are important.

**[If this protocol involves self-administration of a drug, add the following paragraph]**

Only you can take the study drug. Do not share it with anyone else. It must be kept out of reach of children and persons who may not be able to read or understand the label.

**[If applicable]**

Avoidance of Pregnancy: Because the (**drugs/devices/procedures**) in this study may affect an infant, unborn baby, sperm or eggs you should not become pregnant or nurse a baby while taking part in this study or for \_\_\_\_ months after the study. If you are a man, you should not father a baby while taking part in this study or for \_\_\_\_ months after the study. If you or your partner could become pregnant, you should ask about counseling and more information about preventing pregnancy. If you do become pregnant during the study or if you father a child during the study, you should immediately notify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at ( )\_\_\_\_\_\_\_\_\_\_\_\_.

**[If appropriate, include a statement about possible sterility]**.

**[If appropriate, include additional information about contraception, etc.]**.

 **[When appropriate, reference and attach drug sheets, pharmaceutical information for the public or other material on risks].**

There may also be risks and side effects other than those listed above that we cannot predict. Many side effects go away in a short time after the **(drug/device/procedure)** is stopped, but, in some cases, side effects can be serious, long lasting and/or life threatening. If you have any unwanted side effects, you should ask the investigator whether there are any medications or other things that may be done to make the side effect less uncomfortable.

For more information about risks and side effects, please ask (insert name of the investigator).

**[If applicable - for research involving genetic or related testing, participants must be informed of any risks associated with the genetic information that may result- ADDITIONAL FORM REQUIRED]**

As part of this study, you will be asked to participate in genetic testing.

[if applicable, state whether the participant can participate in the main study without participating in the genetic portion.

If yes, include the following question:

 Do you want to participate in the genetic sub-study? Yes \_\_\_\_\_\_\_\_, No: \_\_\_\_\_\_\_\_\_\_\_

If the answer is YES, you will be asked to sign a separate consent form to be in this part of the study involving genetic testing.

**ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?**

**[If there is no intended benefit to any participants, insert the following statement: "This study is not designed to provide direct benefits to any participants."]**.

You may or may not get any direct benefit from being in this study. We cannot promise that you will experience any benefits from participating in this study. We hope the information learned from this study will benefit others in the future.

**WHAT OTHER OPTIONS ARE THERE?**

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

**[Bullet point the list of alternatives including standard of care, or other investigational products or procedures and disclose any of their important potential benefits and risks]**

* You always have the option to not be in this study or to refuse any medical treatment.

**WHAT ABOUT CONFIDENTIALITY?**

Your personal health information (PHI) will be kept private to the extent allowed by law. Study records identifying you will be kept confidential and will not be made publicly available. You will not be identified by name in any publications resulting from this study. You will be asked to sign a separate form that will give permission to the investigator, representatives from government agencies, including the Food and Drug Administration (FDA), institutional review boards, the sponsor and/or the sponsor’s representative(s), and certain other people, agencies or entities, to look at and review the records related to this study including your personal health information and the information discovered during this study. This separate form explains in greater detail who will have access to your records, what type of information will be reviewed and for what purposes, how long your permission for others to review and release your records will last, and how you may withdraw your permission if necessary. If you do not wish to sign this permission form you will not be allowed to participate in this study.

Information, that does not include personally identifiable information, concerning this clinical trial has been or may be submitted, at the appropriate and required time, to the government-operated clinical trial registry data bank, which contains registration, results, and other information about registered clinical trials. This data bank can be accessed by you and the general public at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov). Federal law requires clinical trial information for certain clinical trials to be submitted to the data bank.

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

A Data Safety and Monitoring Board, which is a group of experts not connected to the study, 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.

**WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?**

You **[choose one]** (will/will not) be paid for being in this study. **[If participant is compensated]** (state payment schedule/amount; and state that payments of $600 or more in one year will be reported to the IRS).

Materials and information obtained from you in this research may be used for commercial or non-commercial purposes. It is the policy of (insert Hospital name/site), MedStar Health Research Institute, MedStar Health, Inc. and its affiliated entities not to provide financial compensation to you should this occur.

**WHAT ARE THE COSTS?**

You do not have to pay anything to be in this study. However, if taking part in this study leads to procedures or care not included in the study, it may lead to added costs for you or your insurance company. You will not be charged for **(insert appropriate tests, procedures, medications, etc.)** that are part of this research study.

However, you, or your insurance company, will be charged for any other portion of your care that is considered standard of care. You may be responsible for any co-payments and deductibles that are standard for your insurance coverage. This may include: (**Describe what may be included)**

**WHAT IF I’M INJURED OR BECOME ILL DURING THE STUDY?**

We will make every effort to prevent injuries or illness from occurring while you are in the study. In the case of an injury, illness, or other harm occurring to you during, or resulting from, the study, you should seek medical treatment. You should also contact the study doctor as soon as possible. You or your insurance company will be charged for any continuing medical care and/or hospitalization that are not a part of the study.

If you suffer an injury related to the study drug or study procedures, the reasonable costs of necessary medical treatment of the injury **(Select one: will/will not)** be reimbursed by the **[insert sponsor name]** to the extent these costs are not covered by your insurance or other third party coverage.

No funds have been set aside, by the **(name of hospital/site)**, the MedStar Health Research Institute, MedStar Health, or its affiliated entities to repay you in case of injury, illness, or other harm occurring during, or resulting from the study, and their current policies do not provide for payments for lost wages, cost of pain and suffering, or additional expenses. By agreeing to this you do not give up your rights to seek compensation in the courts.

**[If applicable]**

**What Consultative or Financial Interests are Involved in this Study?**

**[Identify Consultative or Financial Interests - If applicable]**

For your information, (Insert the name of the Investigator) has a reportable financial interest in this study. (Describe the nature of the investigator’s financial interest or potential conflict of interest).

***Examples****:*

*Dr. A is a paid consultant to the company sponsoring this study and an immediate family member has significant financial interest in the company.*

*Dr. B is a paid consultant, paid member of the Advisory Board, and receives payment for lectures from the company sponsoring this study.*

*Dr. C is an unpaid consultant to the company sponsoring this study, but has other interests in the company or its products (such as patents, trademarks, copyrights, licensing agreements, or stock options).*

*Dr. D is a founder of the company, has stock in the company, and is a paid consultant to the company sponsoring this study.*

**[Identify other Financial Interests - If applicable]**

For your information, **(Insert the name of the investigator)** has a reportable financial interest in this study. (Describe the nature of the investigator’s financial interest or potential conflict of interest).

**WHAT ARE MY RIGHTS AS A PARTICIPANT?**

* You have the right to be told about the nature and purpose of the study;
* You have the right to be given an explanation of exactly what will be done in the study and given a description of potential risks, discomforts, or benefits that can reasonably be expected;
* You have the right to be informed of any appropriate alternatives to the study, including, if appropriate, any drugs or devices that might help you, along with their potential risks, discomforts and benefits;
* You have the right to ask any questions you may have about the study;
* You have the right to decide whether or not to be in the study without anyone misleading or deceiving you; and
* You have the right to receive a copy of this consent form.

By signing this form, you will not give up any legal rights you may have as a research participant. 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 and you will not lose any of the benefits you would have received normally. We will tell you about new information that may affect your health, welfare, or willingness to be in this study.

**WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

For questions about the study or a research-related injury, contact the investigator, **(insert name)**, at **(telephone number)**. If you are having a medical emergency, you should call 911 or go directly to the nearest emergency room.

For questions about your rights as a research participant, contact the MedStar Health Research Institute. Direct your questions to the Office of Research Integrity at:

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| --- | --- | --- | --- | --- |
| Address: | MedStar Health Research Institute |  | Telephone: | (301) 560-2912 |
|  | 6525 Belcrest Rd. |  | Toll Free: | (800) 793-7175 |
|  | Suite 700 |  | Fax | (301) 560-7336 |
|  | Hyattsville, MD 20782 |  |  |  |

THIS SPACE INTENTIONALLY LEFT BLANK **[Signatures should all be on one page – not split between two pages]**

SIGNATURES

**STATEMENT OF CONSENT**

I 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 be in this study. I am free to stop being in the study at any time without need to justify my decision and if I stop being in the study I understand it will not in any way affect my future treatment or medical management. I agree to cooperate with (**name of principal investigator**) and the research staff and to tell them immediately if I experience any unexpected or unusual symptoms.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participants signature Date of Signature

Printed Name of Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PERSON EXPLAINING CONSENT**

I have explained the purpose, the procedures, the possible 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 Consent Date of Signature

Printed Name of Individual Obtaining Consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**LEGALLY AUTHORIZED REPRESENTATIVE**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Legally Authorized Representative (if appropriate) Date of Signature

Printed Name of Legally Authorized Representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship of Legally Authorized Representative to Participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**[NOTE: Is the LAR signature required? If so, please justify in the application form. If the LAR signature is not required, please delete this signature line.]**

**WITNESS**

On this date, I have witnessed the consent process and signatures for this study:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Witness (If applicable but not required) Date of Signature

Printed Name of Witness: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness signature is required when: Required by IRB or consenting physically disabled.

**STATEMENT OF PRINCIPAL INVESTIGATOR (or designee)**

As the Principal Investigator (or designee) for this research study, I attest that I have reviewed the consent documentation and confirm requirements for obtaining informed consent have been met.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator’s Signature Date of Signature

If not the principal investigator, a sub-investigator who has delegation of authority or who may adjudicate adverse events should sign for the PI; must be signed within 5 business days of consenting the participant.