## Informed Consent for Participation in a Research Study

## Title of Research Study: [insert title of research study here]

## Investigator: [insert name of Principal Investigator and Department]

## Key Information:

## {Should not exceed one page}

## You are being asked to take part in a research study about … (include general description of study). This page will give you key information to help you decide whether or not you want to participate in this study. More detailed information can be found on the next pages. Ask the research team questions during the consent process, and use the contact information on this form to ask questions later.

**WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?**

***Briefly*** *describe the purpose if the study and the procedures to be followed in lay terms. Put detailed descriptions in the main consent document (next pages).*

By doing this study, we hope to learn …Your participation in this research will last about *{hours, days, months, years}.*

**WHAT ARE THE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?**

*State the* ***most important*** *reasons {benefits} a person may want to participate in this study.* For a complete Description of benefits please refer to the Detailed Consent.

**WHAT ARE THE REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?**

*State the* ***most important*** *reasons {risks} a person may NOT want to participate in this study.* For a complete Description of risks please refer to the Detailed Consent.

**DO YOU HAVE TO TAKE PART IN THIS STUDY?**

You do not have to take part in this research. It is your choice whether or not you want to take part. You can agree to take part and later change your mind. If you choose not to take part or choose to stop taking part at any time, there will be no penalty to you or loss of benefits to which you are otherwise entitled.

*Add the following for student volunteers and/or employees:* As a student/employee, if you decide not to take part in this study, your choice will have no effect on your academic status or class grade(s) or employment status.

**WHAT IF YOU HAVE QUESTIONS OR CONCERNS?**

The person in charge of this study is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ {Principal Investigator, PI}. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: {PI contact information}.

This research is being overseen by an Institutional Review Board (“IRB”). You may talk to them at 202-994-2715 or via email at [ohrirb@gwu.edu](file:///C%3A%5CUsers%5Crescxr%5CAppData%5CLocal%5CTemp%5Cohrirb%40gwu.edu) if:

1. You have questions, concerns, or complaints that are not being answered by the research team or if you wish to talk to someone independent of the research team.
2. You have questions about your rights as a research subject.

## Detailed Consent Form:

## Why am I being invited to take part in a research study?

We invite you to take part in a research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. [Fill in the circumstance or condition that makes subjects eligible for the research].

## Who can I talk to if I have questions?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at [Insert contact information for the research team]

This research is being overseen by an Institutional Review Board (“IRB”). You may talk to them at 202-994-2715 or via email at [ohrirb@gwu.edu](file:///C%3A%5CUsers%5Crescxr%5CAppData%5CLocal%5CTemp%5Cohrirb%40gwu.edu) if:

1. You have questions, concerns, or complaints that are not being answered by the research team or if you wish to talk to someone independent of the research team.
2. You have questions about your rights as a research subject.

## Why is this research being done?

[Tell the subject the purpose of the research. Explain the background of the research problem. Explain any potential benefits to others. Describe any procedures that are important to the research that will be performed regardless of whether the subject takes part in the research.]

## How long will I be in the study?

We expect that you will be in this research study for \_\_\_\_\_\_\_\_ [hours/days/months/weeks/years, until a certain event].

## How many people will take part in this research study?

We expect about \_\_\_\_\_ people will take part in the entire study.

## What happens if I agree to be in this research?

[Tell the subject what to expect using lay language and simple terms. Whenever appropriate include the following items:]

* A time-line description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits
* All visits and telephone or written follow-up
* The length and duration of visits and procedures
* With whom will the subject interact
* Where the research will be done
* When the research will be done
* List experimental procedures and therapies and identify them as such
* How often procedures will be performed
* What is being performed as part of the research study
* What is being performed as part of standard care
* What procedures are part of regular care that will be done even if the subject does not take part in the research
* When applicable indicate that the subject will be contacted for future research.

## What other choices do I have besides taking part in the research?

[Include if there are alternatives other than participating. Otherwise delete]. Instead of being in this research study, your choices may include: [List alternatives procedures. For student subject pools describe alternatives for course credit. For clinical trials describe the options that you would normally offer patient. If applicable, include supportive care as an option].

## What happens if I agree to be in research, but later change my mind?

[Include for research involving students or employees. Otherwise delete] If you are a student or employee at George Washington University/George Washington University Hospital or the MFA, your academic standing/employment status will not be affected in any way should you choose not to take part or to withdraw at any time.

[Include for all research] You may refuse to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you would otherwise be entitled.

If you decide to leave the research, please contact the research team so that they can [Describe the procedures for orderly termination by the subject, if any].

## Is there any way being in this study could be bad for me?

*[Please note that all research study has some risk.]*

 [Describe each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk. The risks may be presented in a table form]

* [Physical risks
* Psychological risks
* Privacy or confidentiality risks
* Legal risks
* Social risks
* Economic risks]

[Include for research that involves only minimal risks, otherwise delete]. The risks and discomforts associated with participation in this study are not expected to be greater than those ordinarily encountered in daily life or during the performance or routine physical or psychological examinations or tests.

**What happens if I believe I am injured because I took part in this study?**

You should promptly notify the research team in the event of any injury as a result of being in the study.

[Include if compensation for research related injury is not available. Otherwise delete and insert language detailing compensation and medical treatment available.] If you believe that you have been injured from taking part in this study, you should seek medical treatment from GWU Hospital and/or the GWU MFA or through your physician or treatment center of choice. Care for such injuries will be billed in the ordinary manner to you or your insurance company.

You will not receive any financial payments from GWU, GWU Hospital and/or the GWU MFA for any injuries or illnesses. You do not waive any liability rights for personal injury by signing this form.

## Will being in this study help me in any way?

[Include if there are no benefits to participation. Otherwise delete]. You will not receive any benefits from participating in this research.

[Include if there are benefits to participation. Otherwise delete]. We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Then describe the potential benefits of participation. First describe any direct benefits to the subject, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit].

 [Include for research involving prisoners] Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

## Can I be removed from the research without my permission?

[Delete this section if not applicable].

[Include for research where this is a possibility. Otherwise delete]. The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include [describe reasons why the subject may be withdrawn, if appropriate].

[Include for research where this is a possibility. Otherwise delete]. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

## What happens to my information collected for the research?

To the extent allowed by law, we limit your personal information to people who have to review it. We cannot promise complete secrecy. The IRB and other representatives of this organization may inspect and copy your information. Others include [Add to this list other organizations that may have access to the subject’s records such as the Food and Drug Administration, when the research if FDA-regulated, the Department of Health and Human Services, when the research is conducted or funded by DHHS, the sponsor, contract research organization, sponsor’s agent and other collaborating institutions].

[Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities]. The privilege of confidentiality does not extend to information about sexual or physical abuse of a child. If any member of the research team has or is given such information, he or she is required to report it to the appropriate authority or agency, such as child protective services, a law enforcement agency, or your State’s toll-free child abuse reporting hotline. The obligation to report includes past and current alleged or reasonably suspected abuse as well as past or current known abuse. Examples of such abuse include physically harming your child or having inappropriate sexual contact with your child.

[Include if requesting a Certificate of Confidentiality. Otherwise delete]. To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, *[except as explained below]*. *[Use the following language as applicable]* The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information. *[Language such as the following should be included if researcher intend to make voluntary disclosure about information obtained in the research such as child abuse, or intent to hurt self or others.]* The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of *[list what will be reported, such as child abuse and neglect, or harm to self or others]*.

*[If data or specimens will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the date or specimens will be retained].*

*[If your research requires HIPAA Authorization, please insert HIPAA authorization language here. Please see the biomedical consent template for HIPAA language].*

[Include for research involving prisoners. Otherwise delete]. If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

## Are there any costs for participating in this research?

*[Include any costs that may be incurred due to the research].*

## Will I be paid for my participation in this research?

[Include if subjects will be paid. Otherwise delete]. If you agree to take part in this research study, we will pay you \_\_\_\_\_\_\_\_ [indicate amount] for your time and effort. [Indicate if the amount is pro-rated for research visit completion].

[Include if subjects will be paid. Otherwise delete.] Your name and social security number will be reported to the appropriate George Washington University (or GW Medical Faculty Associate) employees for purposes of making and recording the payment. You are responsible for paying income taxes on any payments provided by the study. If you receive $600 or more from the University (or the GW Medical Faculty Associate), GW must report the amount you receive to the Internal Revenue Service (IRS) on the form 1099-Misc. This form tells the IRS that payment was made to you, but it does not say that you were paid for taking part in this research study. You should talk to your tax advisor regarding the proper use of this form 1099-Misc.

**WILL WE contact YOU WITH INFORMATION ABOUT PARTICIPATING IN future studies?**

*(If you are planning to contact these research subjects in the future regarding their potential participation in additional research studies, their permission to do so is recommended. If you do* ***NOT*** *plan to contact these research subjects regarding participation in additional studies, DELETE this section.)*

The research staff would like to contact you with information about participating in future studies. If so, it will be limited to *{specify frequency}* times per year.

Do you give your permission for the investigator or staff to contact you regarding your willingness to participate in future research studies?  **Yes**  **No Initials\_\_\_\_\_\_\_\_\_**

## What else do I need to know?

[Include for sponsored research. Otherwise delete]. This research is being funded by [Insert name of sponsor].

 [Include for research involving prisoners where there may be a need for follow-up examination or care after the end of participation. Otherwise delete]. If you are released from jail before you finish this research study, you should take steps to get insurance or Medicaid coverage. Regular office visits and standard treatment will be billed to you or your health insurance. You may continue in the research study after your release from prison. If you move out of the area, we will help you make arrangements to be followed by a physician.

 *[When applicable indicate when and how the subject will be informed of the results of the research].*

 [Omit the signature page if there is no written documentation of consent].[

Include if investigators have a conflict of interest, and tailor to specific conflict. Otherwise delete.] An individual responsible for the conduct of this research study has a financial interest in this research study.

Signature Block for Adult

By signing below, you agree that the above information has been explained to you and you have had the opportunity to ask questions. You understand that you may ask questions about any aspect of this research during the course of the study and in the future. Your signature documents your permission to take part in this research.

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

Printed name of subject

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

Signature of subject Date

 *[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects].*

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

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

Signature of witness to consent process Date