**Research Consent /Authorization Form**

**IRB #**

|  |
| --- |
| **Study Name:** |
| **Full Title:** |
| **[Study Doctor/Lead Researcher]**: |
| **Site(s)**: |
| **Study Phone Number**: |
| **24-Hour Phone Number**: 570-271-6211 (Hospital Operator) |
|  |
| **Funded by**: |

**We are asking you to be in a health research study.**

You do not have to be in this study. Your access to care at Geisinger or AtlantiCare [select appropriate one] will not change if you say no. If you join this study, you can stop at any time.

This form tells you about the study and how your health information will be used.

**What Should I do?**

* Read this form or have it read to you.
* Make sure we explain the study to you.
* Make sure we explain what is done for research and what is done as part of your routine care.
* Ask questions.
* Take time to think about this, and talk to your family and friends.

**Why is this study being done?**

We are asking you to join this study because you have \*\*\*. We want to learn more about \*\*\*. Include information on the investigational drug/device, whether it is FDA approved or experimental and why the study is being done.

**Who will be in the study?**

About \*\*\* people will join at Geisinger or AtlantiCare [select appropriate one]. About \*\*\* will join this study [worldwide/in the US].

**How long will I be in the study?**

You will be in the research study for about \*\*\*.

The study doctor could decide to take you off this research study if:

* The doctor believes it is in your best interest
* You do not follow the study direction
* For any other reason

**What will I be asked to do?**

Add general statements. Use table/schedule of events for specific visit information.

If applicable:

Your blood sample will be tested at [lab] for HIV (the virus that causes AIDS). The results will be shared with you, the sponsor and study staff. You do not have to agree to this testing. However, if you refuse you will not be able to take part in this study.

If you are found to have HIV:

* You will be referred for medical care.
* We will report the positive test result to the local health department. This is required by PA law.
* You [can /cannot] continue in this study.

**If applicable: What will happen to my [blood, urine, tissue]?**

Include how much is collected, where samples will be stored, for how long, whether identifiers are removed and whether authorization can be revoked. State whether clinically relevant research results will be disclosed, under what conditions.

State whether specimens can be used for future research studies or shared with other investigators for future research studies. State whether subjects will be provided details about these studies and if additional informed consent would be required for this use. If identifiable samples are shared describe the type of institutions or researchers. If applicable: state whether the research will/ may include whole genome sequencing.

If you allow your [identify samples: blood, urine, tissue, etc.] to be kept for research, you can change your mind at any time. Please tell us in writing. Your [samples] will be destroyed unless they can no longer be traced to you.

Only for studies or sub-studies with genetic components: The Genetic Information Nondiscrimination Act of 2008 (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This protection does not apply to life insurance, disability insurance, or long-term care insurance.

Only for AtlantiCare (New Jersey) studies or sub-studies with genetic components: The Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. In addition, the New Jersey Genetic Privacy Act protects against discrimination by companies that provide life insurance, annuity and disability insurance coverage. This protection does not apply to long-term care insurance.

**What about Pregnancy?**

DO NOT use for Geisinger Holy Spirit studies:

The study drug/device may cause risks to an unborn child.  For this reason, you cannot join this study if you are:

* pregnant,
* nursing a child or
* planning to become pregnant during the study.

To join this study, you must have a negative pregnancy test and agree to use birth control during the study. Your study doctor will talk to you about suitable birth control.

During the study, if you think you may be pregnant, tell the study team right away.  If you are pregnant, you will be removed from the study. You will be asked to sign a consent form to allow information about the pregnancy, delivery and health of the child to be collected.

Only for Geisinger Holy Spirit studies:

Women who are pregnant or nursing a child may not participate in this study. You must confirm that, to the best of your knowledge, you are not now pregnant and that you do not intend to become pregnant during the study. If you are of child bearing potential, the trial doctor will discuss adequate birth control measures with you. If you suspect that you have become pregnant during the study, you must notify the trial doctor immediately and you will be withdrawn from the study without your consent.

**What are the costs?**

Use Section A or B based on the study Billing Determination:

Section A – Use when all items are paid by the sponsor:

All visits, tests and procedures listed under “What will I be asked to do?” are done for the study only. They will be done at no cost to you or your insurance company.

You or your insurance company will be charged for the costs of your routine care (the care you would have received if you were not in this study).

Section B – Use when some items are sponsor-paid, and others are routine care. A color/letter-coded schedule of events or other easily displayed cost information is recommended. However, a bulleted list can be used. Use only the sections below that are applicable.

If applicable:

The items below are done for the study only and will be done at no cost to you or your insurance.

* Add bulleted list of items that apply if not using color/letter-coded graph

If applicable:

The items below are done as part of your routine care but will be paid for by the study sponsor.

* Add bulleted list of items that apply if not using color/letter-coded graph

All other tests/and procedures listed in this form are considered routine care (the care you would have received if you were not in this study). The tests and procedures ordered as part of your routine care could be different. Any items done as part of your routine care will be billed to you or your insurance.

**Will I be paid?**

Add subject payment/reimbursement information here. This is taxable income and reportable to the IRS.

If paid by check: Your check will arrive in the mail up to 8 weeks after your study visit. In order to issue you a check, you will be asked to complete a W-9 Form. This will include your name, address and Social Security Number. This form will be given to the Geisinger or AtlantiCare [select appropriate one] Research Finance and Accounts Payable Departments. If your total payments are $600 or more in a calendar year, a 1099 form will be sent to you.

If this study leads to a marketed product, this product will be the property of the [sponsor]. You will not be entitled to any of the [sponsor]’s financial benefits resulting from this product, the study, or from the use of your samples.

**Can being in this study help me?**

This study might or might not help you. We hope that what is learned from this study will help others in the future. Add any known benefits.

**What are the risks?**

There are risks related to your (illness/condition) and routine care. This form will not list those risks. We will only list the added risks of being in this study.

Insert Risks Diagrams, pictographs or color coding can be used. Provide probability of harm.

There might be effects that we do not know about yet.

**What if I am harmed?**

Use Section A or B based on the study Billing Determination/contract:

Section A: For use for industry sponsored trials.

If you are ill or injured due to this study, call your study doctor right away.

Call: [name and phone number].

[Sponsor] will pay for the diagnosis and treatment of your illness or injury if it is caused by a study drug, device or test that is not part of your standard care. However, there is no money set aside to pay you for discomfort, disability, missed work, etc.

If you are injured, we will share information about you with the sponsor or its partners.  This information includes:

* Your name
* Date of birth
* Social Security number
* Medicare claim number (if you have one)
* Description and date of the injury

The sponsor will use that information to check to see if you have Medicare.  If you do have Medicare, the injury payments will have to be reported to the Centers for Medicare & Medicaid Services. This is a government agency. The sponsor or its partners will report this information. Your information will not be used for any other purpose.

Section B: For NIH studies or cooperative group studies.

If you are ill or injured due to this study, call your study doctor right away.

Call: [name and phone number].

Medical treatment is available but will be provided at the usual charge. You or your insurance company will be charged for the medical care and/or hospitalization for your injury or illness. There is no money set aside to pay you for discomfort, disability, missed work, etc.

Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study.

**How will Geisinger or AtlantiCare [select appropriate one]** **use and share my information?**

The Geisinger or AtlantiCare [select appropriate one] study staff will view and collect information that is in your medical record. We will collect information about you during this study. Some of this information will be kept in a research record at Geisinger or AtlantiCare [select appropriate one]. These records will be kept [for at least \*\*\* and then destroyed. / indefinitely./ for at least \*\*\* and then information identifying you will be removed. The deidentified records will be kept indefinitely.] Any information placed in your medical record will be a permanent part of your medical record.

Your primary care doctor or specialist [may/will] receive information about your participation in this study.

We will share your information with the study sponsor and its partners.

If applicable: Staff working for [sponsor] could be present during your procedure at Geisinger or AtlantiCare [select appropriate one].

By signing this form, you are giving Geisinger or AtlantiCare [select appropriate one] permission to use and share your health information. It can be shared indefinitely for purposes of this study. If you change your mind, tell us in writing to stop using and sharing your information. Write to: [Enter name of study, internal zip code and address] Information already collected will still be used. We will only use and share new information if it is needed to protect your safety or follow with the law.

If protocol requires collecting information about participant’s death: If you pass away while talking part in this trial, the study staff may get in touch with your emergency contacts for additional information.

**How will others use and share my information?**

The information shared with [sponsor] and its partners will include: Only include the bullets that are applicable to your study. Add a second list if another group will receive a different set of patient information.

* Initials
* Date of Birth
* Study ID number
* Medical history (including dates)
* Information about the medical care you receive during the study (including dates)
* Device model and serial number
* Images from your study procedures (your name and medical record number will be removed)
* If you will be sharing information related to drug and alcohol use, illegal behaviors, sexual attitudes, describe here
* If you will be sharing information related to mental health, describe here.
* HIV test results

The information sent to the [sponsor] and its partners may be kept and used without end.

If applicable: A group of experts, who do not work for the sponsor, will review the progress and safety of this research study.

Your research and medical record could be reviewed for quality and to make sure rules are followed. This review could be done by: Only include the bullets that are applicable to your study.

* Geisinger Institutional Review Board
* Geisinger or AtlantiCare [select appropriate one] staff
* The Food and Drug Administration (FDA),
* Department of Health and Human Services (DHHS)
* Office for Human Research Protections (OHRP)
* [sponsor] and its partners
* Government agencies in other countries

If information from this research study is included in an article published in a medical journal or presented at a medical or scientific meeting, it will be done in a way that does not identify you.

If applicable, for data sharing: Information from this study might be used for other, future research projects. Those projects can focus on any topic and might be unrelated to the goals of this study. Information we share with researchers at Geisinger or AtlantiCare [select appropriate one], research institutions or companies around the world, will not identify you directly.

**How is my information protected?**

We will take steps to protect your information. Add a description of the steps taken. Some laws that protect your information only apply to hospitals, doctors’ offices, and other healthcare providers. When your information is shared outside of Geisinger or AtlantiCare [select appropriate one], some federal privacy laws might not apply.

We will share your information with a court of law or the government, in the unlikely event this is required.

OR

Certificate of Confidentiality required language (see sponsor’s language or <https://grants.nih.gov/grants/policy/coc/suggested-language.htm>)

**Do I have other choices?**

You do not have to be in this study. You have other choices. You could choose:

* Usual care for your illness or condition
* No treatment
* To be in a different study

Your study doctor will talk to you about your choices.

During the study, we will tell you if there is new information or changes to the study that could affect you, your health or your desire to stay in the study.

A description of this clinical trial will be available on [www.clinicaltrials.gov](https://spresearch/PEResearchInformedConsent/Shared%20Documents/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.

**What if I have questions or problems?**

Call: [name and phone number], if you:

* Have questions, concerns or complaints about the study
* Feel you have had a study-related injury

Call the Geisinger Institutional Review Board (IRB) at:

844-542-3299 or 570-271-8663 (Danville, PA)

or 609-449-4395 (Atlantic City, NJ) [Only add for AtlantiCare studies]

* If you have questions about your rights as a research participant.
* If you have questions, concerns or complaints about the research.

**Signature**

**I agree to take part in this research study and allow my health information to be used for this research. My questions have been answered. I will get a signed copy of this form.**

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Research Participant’s Printed Name

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Research Participant’s Signature Date

I confirm that the research study was thoroughly explained to the participant. I reviewed the consent form and answered all questions. The participant appeared to have understood the information.

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Person Obtaining Consent Signature Date

Not required if discussion is documented in EPIC:

I confirm that the study (drug/device), risks, benefits and alternatives were discussed. All questions were answered. I believe the participant is able to make an informed choice to join the study.

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Study Physician Date