**Research Consent /Authorization Form/**

**Parental Permission/Assent**

**IRB #**

|  |
| --- |
| Study Name: |
| **Full Title:** |
| [Study Doctor/Lead Researcher]: |
| Site(s): |
| **Study Phone Number**: |
| **Funded by**: |

In this consent form, “you” always refers to the person taking part in the research study. If you are a parent or guardian, “you” refers to the person taking part in the research study.

# 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.

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.

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.

# Why is this study being done?

We are asking you to join this study because you have \*\*\*. We want to learn more about \*\*\*. Provide a description of the study.

# Who will be in the study?

About \*\*\* people will join at Geisinger or AtlantiCare [select appropriate one]. If applicable: 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 \*\*\*.

# What will I be asked to do?

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

**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.

# If Applicable: What are the costs?

Remove this section for studies that are not associated with visits, tests or procedures.

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

* Add bulleted list of items (ex. nasal swabs, urine collection)

OR

For this study, we will collect information about you and your medical care. You or your insurance company will be charged for the costs of your medical care.

# 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 applicable: 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 no physical risks expected with this study. There is a risk that your information could be seen by someone other than the study staff. However, we will take steps to protect your information.

Add other risks as applicable: for example, anxiety related to sensitive questions.

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You or your insurance will be charged for the diagnosis and treatment of any injury that results from your routine care.

# 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.

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

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. 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.

Write to: [Enter name of study, internal zip code and address]

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.

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>)

# 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 Section**

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Research Participant’s Printed Name

**Signature Page: Adult Participants**

**(Remove if not applicable for the study)**

**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 Signature Date

**Consenter**

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

**Signature Page: Participants 15 to 17 years of age**

**(Remove if not applicable for the study)**

**Participants 15 to 17 years old:**

**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 Signature Date

**Parents/Guardians:**

**I give permission for my child** **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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Print Name of Parent

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Signature of Parent/Guardian Date

**Consenter:**

I confirm that the research study was thoroughly discussed with this minor participant and parent/guardian. We reviewed the consent form. I answered all questions and discussed all concerns. The participant appeared to be engaged and indicated that he/she understands what the research study involves. The parents/guardians of this participant were invited to participate in all discussion of this research study. Both the participant and parent/guardian appeared to have understood the information.

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Person Obtaining Consent Signature Date

**Signature Page: Participants less than 15 years of age**

**(Remove if not applicable for the study)**

**Parents/Guardians:**

**I give permission for my child** **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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Print Name of Parent/Guardian

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Signature of Parent/Guardian Date

**Consenter:**

For children 7 years of age and older, I confirm that this research study was discussed with the minor participant using language and concepts appropriate to this child’s developmental ability. The participant was encouraged to ask questions and voice concerns. The parent/guardian of this child were invited to participate in this engaged discussion.

The participant **agrees** to participate.

The participant **does not agree** to participate.

The participant is less than 7 years of age or

does not have the capacity to assent.

A waiver of assent must be requested for those under 7 years of age.

The research study was thoroughly discussed with the parent/guardian. We reviewed the consent form and I answered all questions discussed all concerns. The parent/guardian appeared to have understood the information.

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Person Obtaining Consent Signature Date