**Research Informed Consent /**

**HIPAA Authorization**

**(*As applicable, add or replace with***

**Research Assent/Parental Permission /**

**HIPAA Authorization)**

**IRB #**

|  |
| --- |
| **Study Name:** |
| **Full Title:** |
| **Study Doctor/Lead Researcher*[Select appropriate one]*:** |
| **Site(s)**: |
| **Study Phone Number**: |
| *(Required for studies that are greater than minimal risk)* **24-Hour Phone Number**: ***[Insert number]*** (Hospital Operator) |
|  |
| **Funded by**: |

**Note to researchers:** This template includes all required and some additional elements of informed consent and HIPAA authorization relevant to non-exempt human subjects research, as required by federal regulations. These requirements and readability guidance can be found on the [HRPP website on geisinger.org](https://www.geisinger.org/-/media/OneGeisinger/pdfs/ghs/research/guidance-informed-consent-hipaa-auth-01-21-2019.pdf?sc_lang=en&hash=854BE8891ABE9327045CB91DCFD20F0A).

It is strongly recommended research teams start with this *Geisinger informed consent/assent/parental permission/HIPAA authorization* template to draft consent forms, rather than starting with consent forms from previously approved research studies to ensure that all current institutional template language is included.

PLEASE NOTE: CONSENT FORMS SHOULD BE WRITTEN IN LAYPERSON’S TERMS. PLEASE AVOID USE OF MEDICAL TERMINOLOGY AND EXPLAIN ANY TERMS THAT MAY BE UNFAMILIAR TO INDIVIDUALS OUTSIDE OF HEALTHCARE, ACADEMIC SETTINGS, OR YOUR FIELD.

**DELETE ALL INSTRUCTIONAL BLUE TEXT PRIOR TO SUBMISSION TO THE IRB.** **Review, delete, edit, and reformat all bracketed text as necessary. Delete or modify (as appropriate) all text that does not apply to your research.**

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

***Study Summary: The consent must begin with a concise and focused presentation of key information that participants need to make a decision, and which explains why a potential subject might or might not want to participate. Consider including non-text elements like pictures or icons to describe your study.***

**Study Summary**

We are asking you to join this study because you have [insert the condition/illness]. We are doing this study to (*if applicable* - see how an investigational drug/device/procedure/intervention ***[Select appropriate one]*** affects people with [insert the condition/illness]).

***If applicable, explain what investigational products they will receive, for example:*** If you join this study you will be given either an investigational drug **or** placebo. This is decided by chance. You do not get to choose.

You don’t have to join this study (*if applicable* - to get treatment for your illness/condition ***[Select appropriate one]***. You have other choices.)

This study might or might not help you. There are risks related to the study.

You will be in the study for about [insert number] days/weeks/months/years ***[Select appropriate one]***. You will have [insert applicable research activities - e.g., clinic visits, phone calls, surveys, tests, procedures] as part of the study. ***Address any invasive procedures, high visit frequency, lengthy visits, collection of sensitive info, if study would prohibit other treatments, or any other important information.***

For this study, we share information about you [***if Applicable***: and your samples] with [insert “study sponsor and its partners”] or [name(s) other entities who will receive participant data] ***[select appropriate one]***.

**The rest of this form will describe the study in more detail.**

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

You do not have to be in this study. If you join this study, you can stop at any time by contacting the study team listed in the box above. Your decision will not affect your status as a/an [patient, employee, student, etc.] ***[Select appropriate one]***. Your usual care or access to care at Geisinger will not change if you say no. You will not lose any benefits to which you are otherwise entitled if you decide not to join the study or if you decide to stop taking part after you join.

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

**What should I do?**

Your participation in this research is voluntary, and you should only join the study if you completely understand what the study requires and what the risks of participation are.

* 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?**

***Provide the purpose and description of the study.***

We want to learn more about [insert the condition/illness]. ***Include information on the investigational drug/device, whether it is FDA approved, cleared or experimental and why the study is being done.***

**Who will be in the study?**

About [insert number] people will join this study at Geisinger. ***If applicable***: About [insert number] will join this study worldwide/in the US ***[Select appropriate one]***.

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

You will be in the research study for about [insert duration].

***If applicable (required for FDA-regulated research):***

The study doctor could decide to take you off this research study without your consent if:

* The doctor believes it is in your best interest
* You do not follow the study directions
* ***If applicable, add other reasons***
* For any other reason

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

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

You may be asked to sign an authorization form for the release of medical Records. This form allows the study staff to obtain your medical records, if you receive care at a hospital outside of Geisinger during the study.

***If participants will be asked to undergo research imaging or testing procedures that are not performed, read or resulted through standard processes, please include language informing the participant about the research testing and/or result reporting. Example language is provided below.***

***Example language for research MRI [modify as appropriate]:***The MRI scan is being done to answer research questions, not to examine you for medical reasons.  The research scan may not show problems that may be picked up by a clinical MRI scan. We will tell you and your doctor if the research test shows an abnormality that requires follow-up. These results could cause you to worry or undergo additional testing if a problem were suspected, but not actually found.

***If applicable, include if research includes HIV testing):***

Your blood sample will be tested at [insert 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 your identity and the positive test result to the local health department. This is required by state law.
* You can /cannot ***[Select appropriate one]*** continue in this study.

***If applicable:***

Staff working for the sponsor could be present during your procedure at Geisinger.

***If applicable:***

If you leave the study early for any reason, we may ask you to come in for end-of-study tests for your safety. ***[describe what is required]***

***If applicable:***

***Explain what would happen if a patient chooses not to complete all study activities, for example contact by phone every year or collect data from the medical record, or come for a final study visit, or how to discontinue medication, etc.***

***Use 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.

***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, whether authorization can be revoked and if any findings will not be shared with the participant.***

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.

***For studies involving genetic testing, see the Guide to Informed Consent Genetic Testing Language. The guide language may be customized as needed. Please use, or provide your own language, for all applicable situations.***

**Will my data [*if applicable:*** and samples] **be used for future research?** ***Please note: Broad data sharing within and outside of Geisinger should be the default option. Many funders and journals require data sharing or use of data for future projects. Include 1 of the 3 following statements***:

Your information ***[if applicable:*** and samples] will not be stored or shared for future research purposes.

**OR**

Your information ***[if applicable:*** and samples] will be stored and shared for future research. Your data and samples will be stripped of identifiers so it cannot be used to identify you. You will not be asked to provide consent when your information [if applicable: and samples] are shared for future research.

**OR**

Your information ***[if applicable:*** and samples] will be stored and shared for future research purposes. Your information [***if applicable:*** and samples] include your ***[****list identifiers****]***. Researchers may receive information that could identify you. This future use will require review and approval by an Institutional Review Board (IRB).

***If future research will occur:***

***Add a general description of the types of research that may be conducted with the data/ specimens. State whether participants can opt out of future research, if consent will be requested for any future research or if any results will be shared with the participant.***

***PLEASE NOTE: IF participants’ data/ specimens will be de-identified before any future use, participants must be informed that they could be used for future research studies and/or shared with other investigators for future research studies without additional informed consent.***

We will/will not ***[Select appropriate one]*** give you any results from these studies.

We may share your information ***[if applicable:*** and samples] with:

***Revise as applicable*** academic and medical institutions, other researchers, drug and device companies, biotechnology companies and others.

You will likely not directly benefit from future research with your information ***if applicable:*** and samples. What is learned may help develop new scientific knowledge [***insert as applicable***: help others by improving our understanding of health and disease, improving health care, making safer or more effective medical therapies].

**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 and potential benefits to participants and/or society.***

**What are the risks?**

**Use Section A or B based on whether or not this study includes physical risks:**

**Section A – Use when this study does NOT include any physical 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.

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

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

***If applicable, include any risks associated with receiving test results or incidental findings (e.g. psychological risks, impacts on insurability, employability, family plans, family relationships, and costs of additional medical care and testing).***

**Section B – Use when this study DOES include physical risks:**

There are risks related to your illness/condition ***[Select appropriate one]*** and routine care. This form will not list those risks. We will only list the added risks of being in this study.

### ***If applicable, include any risks associated with receiving test results or incidental findings (e.g. psychological risks, impacts on insurability, employability, family plans, family relationships, and costs of additional medical care and testing).***

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

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

***If applicable:* What are the risks for a pregnancy?**

This study might involve risks to you or your unborn child if you are pregnant or become pregnant. This could include risks that are unforeseen.

***[Insert sponsor language. Revise as needed to improve readability and lower reading level.]***

**What if I am harmed? *If applicable (required for studies with physical risks):***

***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 us right away.

Call: [insert name and phone number].

The study sponsor [insert sponsor name] 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 beneficiary I.D. 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: [insert 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.

**What are the costs? *If applicable: Remove this section for studies that are not associated with clinical visits, tests or procedures.***

**Use Section A or B based on the study Billing Determination.**

**Use Section C if this study is collecting data about a participant’s routine care, and there are no clinical visits, tests or procedures done only for research purposes (because the individual is participating in the study).**

**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 receive whether or not you take part 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 done at no cost to you or your insurance.

* 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 receive whether or not you are 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.

**Section C - Use when the study is only collecting data about a participant’s routine care. No clinical care is done for research purposes only.**

For this study, we will collect information about you and your routine care (the care you would receive whether or not you are in this study). You or your insurance company will be charged for the costs of your routine care.

**Will I be paid?**

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

***Add if paid by check****:* Your check will arrive about 8 weeks after your study visit. 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.

If your total payments are $600 or more in a calendar year, Geisinger, [insert sponsor] or [other] ***[select appropriate one]*** will send you a 1099 form for your taxes. This is reportable income.

You will not be entitled to any of the financial benefits resulting from this study or from the use of your samples or data.

**How will my information be** **used?**

**Your information will be collected and used by Geisinger study staff.**

Geisingerstudy staff will view and collect information about you during this study. The information collected about you for the study will include: ***Only include the bullets that are applicable to your study.***

* Information from your medical record. This may include data from non-Geisinger providers.
* Dates related to you, your care and this study.
* List any identifiable data (Name, address, social security number, etc.)
* If applicable, device model and serial number.
* If you will be collecting information related to substance use disorder (drug/alcohol use or addiction treatment), describe here.
* If you will be collecting information related to behavioral or mental health, describe here.
* If you will be collecting information related to HIV (including Hepatitis and/or HIV test results), describe here.
* If you will be collecting information about illegal behaviors, describe here.
* If you will be collecting information about sexual attitudes, describe here.

Some study information will be placed in your medical record. Information in your medical record can be seen by both Geisinger and non-Geisinger providers that care for you. ***Describe any sensitive information that may be added to the medical record.***

Some study information will be kept in a research record at Geisinger***.*** 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. ***[Select appropriate one]*** Any information placed in your medical record will be a permanent part of your medical record.

***If applicable – Insert this section if sharing data outside of Geisinger:***

**How will my information be** **shared?**

**Your information will be shared outside of Geisinger for this study.**

Information about you will be shared with [insert “study sponsor and its partners”] or [name of other entities who will receive participant data] ***[select appropriate one].*** They may keep and use the following information without end for the research purposes described in this form: ***Only include the bullets that are applicable to your study. Add a second list if several entities are receiving data, and the entities will receive different sets of participant data.***

* Information from your medical record. This may include data from non-Geisinger providers.
* Dates related to you, your care and this study.
* List any identifiable data (name, address, social security number, etc.)
* If applicable, device model and serial number.
* If you will be sharing information related to substance use disorder (drug/alcohol use or addiction treatment), describe here.
* If you will be sharing information related to behavioral or mental health, describe here.
* If you will be sharing information related to HIV (including hepatitis and/or HIV test results), describe here.
* If you will be sharing information about illegal behaviors, describe here.
* If you will be sharing information about sexual attitudes, describe here.

**How will my information be** **protected?**

**We will take steps to protect your information.**

We will do our best to make sure that this doesn’t happen. However, we cannot guarantee total privacy. ***Add a description of the steps to be 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, some federal privacy laws might not apply.

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

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

***OR***

***Add the following*** [***Certificate of Confidentiality (COC)***](https://grants.nih.gov/policy/humansubjects/coc.htm) ***language for any NIH-funded research (or research that is not NIH-funded but the researcher obtained or intends to obtain a COC from NIH) that collects or uses identifiable, sensitive information related to a participant. For additional information about COCs, please refer to*** [***Certificates of Confidentiality (CoC) | grants.nih.gov***](https://grants.nih.gov/policy/humansubjects/coc.htm)***:***

**This study has a Certificate of Confidentiality (COC).**

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the [insert the name of the institution that issued the Certificate, such as the NIH or CDC]. This means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law in the United States.

There are some limits to this protection, including:

* If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
* If it is used for other scientific research in a way that is allowed by the federal regulations that protect research participants;
* The FDA and other government agencies who audit the research.

Information about you can be released when you say it is okay. For example:

* You may give us permission to release information to insurers, medical providers or any other persons not connected with the research.
* You and your family can share information about your part in this research, if you wish.

***(If applicable) Add the following paragraph if funding is expected to end before all data is collected at Geisinger. It is preferable to submit a request for a COC from NIH. If you do not obtain a new COC, add the following language:*** The Certificate expires when the [insert NIH or CDC] funding for this study ends. Currently this is [insert date]. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

**How might my information be** **reviewed for quality?**

Your research and ***[if applicable:*** and medical] record could be reviewed for quality and to make sure research rules are followed. This review could be done by:

* Geisinger Institutional Review Board
* Geisinger staff

***Only include the following bullets that apply to the study:***

* The Food and Drug Administration (FDA) *[applicable if FDA-regulated study]*
* Department of Health and Human Services (DHHS) *[applicable if federally supported]*
* Office for Human Research Protections (OHRP) *[applicable if federally supported]*
* [insert collaborators] or [study sponsor and its partners]
* Government agencies in other countries *[applicable if global study]*

**Do I have other choices? *[If applicable – Insert this section if there are other appropriate procedures or courses of treatment that might be appropriate for participants:]***

You do not have to be in this study. You have other choices. You could choose: ***Only include the bullets and add other alternatives that are applicable to your study.***

* 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.

**Investigator relationship with study sponsor *[If applicable - insert if there is a Conflict of Interest Management Plan for any investigator]***

Please note: [Insert name of investigator(s) to whom this applies] is/are personally paid by [Insert Sponsor Name] for **[*describe relationship i.e.*** consulting, teaching and training other physicians around the country]. Please ask the study doctor or staff if you want more information about this.

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

Call: [insert 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)

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

***Add if applicable (required for FDA-regulated studies):*** 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.

**Signature**

By signing this form, you are giving Geisinger permission to use and share your health information. It can be shared indefinitely for purposes of this study and for future research as explained in this form. If you change your mind, tell us in writing to stop 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 you do not sign this form, you cannot join this study.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***The pages that follow are SIGNATURE PAGES FOR PARTICIPANTS, PARENTS/GUARDIANS, LARs, PERSONS OBTAINING CONSENTS AND STUDY PHYSICIANS (required when the research includes investigational drugs or devices). Select and only include the Signature Page(s) applicable to your study population. Remove all others.***

* ***Adult Research Participant***
* ***Legally Authorized Representative (LAR)***
* ***Parental Permission & Participants 15 to 17 years of age***
* ***Parental Permission & Participants less than 15 years of age***

**Signature Page: Adult Research Participant**

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

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

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

Research Participant’s Printed Name

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

Research Participant’s Signature Date

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**Person Obtaining Consent**

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.

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

Person Obtaining Consent Printed Name

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

Person Obtaining Consent Signature Date

***If Applicable – required for IND/IDE studies, but not required if consenting discussion is documented in EPIC by the physician:***

I confirm that the study drug/device ***[Select appropriate one]***, 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.

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

Study Physician Date

**Signature Page: Legally Authorized Representative**

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

For use when a adult participant is incapable of providing informed consent. The form **must** be signed by the Legally Authorized Representative (LAR).

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

**Printed Name of Research Participant**

**Assent (if adult participant is able to indicate agreement to participate):**

I agree to take part in this research study.

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

Assent Signature of Research Participant

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The following, in descending order of legal authority, can serve as the participant’s LAR. The study participant cannot be enrolled in the study if there is more than one LAR in the highest category, the LARs disagree and there is no majority.

Check the appropriate box for the LAR providing consent for research purposes.

**For Pennsylvania:**

A court appointed guardian. The document should be provided or verified in EPIC.

A Health Care Durable Power of Attorney. The document should be provided or verified in EPIC.

Spouse, unless one of you has filed for divorce

Adult child

Parent

Adult sibling

Adult grandchild

Close friend

**Legally Authorized Representative**

As the Legally Authorized Representative (LAR), I allow the research participant to take part in this research study.

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

Printed Name of LAR

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

LAR Signature Date

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**Witness (not involved with the research study or the study doctor) –RECOMMENDED, BUT NOT REQUIRED IN PENNSYLVANIA – *Remove if not requiring witness to the consent process in this study.***

I confirm that I witnessed the consent process and that the information in the consent form and any other written information was explained to the LAR.

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

Printed Name of Witness

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

Witness Signature Date

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_**

**Person Obtaining Consent**

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.

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

Person Obtaining Consent Printed Name

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

Person Obtaining Consent Signature Date

***If Applicable – required for IND/IDE studies, but not required if consenting discussion is documented in EPIC by the physician:***

I confirm that the study drug/device ***[Select appropriate one]***, 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

**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

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**Person Obtaining Consent**

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 Printed Name

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

Person Obtaining Consent Signature Date

***If Applicable – required for IND/IDE studies, but not required if consenting discussion is documented in EPIC by the physician:***

I confirm that the study drug/device ***[Select appropriate one]***, 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

**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

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**Person Obtaining Consent**

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

***If Applicable – required for IND/IDE studies, but not required if consenting discussion is documented in EPIC by the physician:***

I confirm that the study drug/device ***[Select appropriate one]***, 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