Geisinger

Consent to Participate in Research

You are being invited to participate in a research study.

Before you agree, the investigator must explain a number of things to you. These things include:

- The purpose of the study
- How many people will be enrolled in the study and how long the study will last
- The tests, procedures or treatments that will be done
- Which tests, procedures or treatments are experimental
- Any risks from the study. There may be risks from a study drug or device, or from a study test or procedure
- If the study will benefit you in any way
- How you will be told if there is new information about the study that could affect your decision to continue with the study
- Other options you have rather than participating in the study
- What to do if you are injured or hurt during the study
- Whether there are any costs to you for participating
- Whether you will be paid anything for participating
- Reasons the investigator may stop your participation in the study
- Who can see or use information about you from the study
- How your information and privacy will be protected

Your participation in this research study is voluntary. If you decide not to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

You may contact _____ phone number_____ any time you have questions about the research.

You may contact _____ phone number_____ if you have questions about your rights as a research subject or what to do if you are injured.

You will be asked to sign this form to show that

- The research study and the information above have been discussed with you
- You agree to participate in this study

You will receive a copy of this signed form and the summary of the study that will be discussed with you.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be signed by the participant who is 18 years of age or older.

WITNESS

By signing below you confirm that the study has been fully explained to the potential subject in a language they understand and all their questions have been answered.

_____	_____	_____
WITNESS (SIGNATURE)	WITNESS (PRINT)	DATE

NOTE: Study team member obtaining consent must sign long version of consent form.

If short form will be used in a study where children are enrolled, insert the following signature section(s) (where applicable) translated into the language of the short form.

Parental/Guardian Permission

By signing below you confirm you have the legal authority to sign for this child.

_____	_____	_____
PARENT/GUARDIAN (SIGNATURE)	PARENT/GUARDIAN (PRINT NAME)	DATE

Second parent/guardian signature section to be added if there is risk but

no benefit to the participant.

_____	_____	_____
PARENT/GUARDIAN (SIGNATURE)	PARENT/GUARDIAN (PRINT NAME)	DATE

NOTE: Study team member obtaining permission must sign long version of consent form.

Assent from Child

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed for any child aged 7 to <18.

NOTE: Study team member obtaining assent must sign long version of consent form.

WITNESS

By signing below you confirm that the study has been fully explained to the parent/ guardian and the child (less than 18 years of age) in a language they understand and have answered all their questions.

_____	_____	_____
WITNESS (SIGNATURE)	WITNESS (PRINT)	DATE

Surrogate Consent (Giving approval for another adult to be in the study)
To be used in the event the adult participant is unable to give informed consent for participation in this study. This section may only be used if IRB has approved surrogate consent.

Surrogate Consent

_____/_____ _____
PERSON GIVING CONSENT FOR PARTICIPANT DATE
(Signature/ Printed)

RELATIONSHIP TO PARTICIPANT:
_____

NOTES: Study team member obtaining consent must sign long version of consent form.
If the study is approved by the full board, the attending physician must sign the long version of the consent form.

WITNESS
By signing below you confirm that the study has been fully explained to the surrogate in a language they understand and have answered all their questions.

_____ _____ _____
WITNESS WITNESS DATE
(SIGNATURE) (PRINT)

Consent of the Participant to Continue to Be in the Study
Your legal representative gave his/her permission for you to be in this research study. This is because you were not able to make your own decision due to your illness. Your condition is now better. You are being asked to decide whether to continue to be in this study. The decision is up to you. Before you sign this form, please ask questions about any part of this study that is not clear to you. When you sign below, you are saying you understand the information we gave you about the study and in this form.
If you sign this form it means that you agree to continue being in the study.

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

NOTE: Study team member obtaining consent must sign long version of consent form.

WITNESS

By signing below you confirm that the study has been fully explained to the subject in a language they understand and have answered all their questions.

_____	_____	_____
WITNESS (SIGNATURE)	WITNESS (PRINT)	DATE