CONSENT FOR ELIGIBILITY TESTING FOR A CLINICAL STUDY

STUDY TITLE:

SPONSOR:

INSTITUTION:

PRINCIPAL INVESTIGATOR:

CO-INVESTIGATOR:

DISCLOSURES:

INTRODUCTION

You are being invited to have testing to determine if you are eligible to be in a research study called [STUDY NAME]. It is your choice whether or not to have this testing. Before you decide, you should learn about the testing. You also may want to learn about the study to see if you are interested in it. This may help you decide whether to have the testing to find out if you qualify for the study. The process of making these choices is called informed consent.

This consent form only provides information about the testing you need to have before joining the study. It describes the purpose, procedure, and possible benefits and risks of the testing. This form will also explain how your medical information will be used and who may see it. If you agree to the testing, you will need to sign this form. We will give you a copy of it for your records.

Information about the study is in another consent form. You may want to read that form to learn about the study. You do not need to sign that form at this time.

PURPOSE

We want to find patients that qualify for the [NAME] Study, sponsored by [SPONSOR]. [STUDY] is a study of… The purpose of the study is… The study doctor thinks that you may qualify for this study. We are asking you to have [TEST] to be sure. The [TEST] allows us to…

PROCEDURE AND DURATION

[TEST] is… It takes about [TIME] to complete.

We will use the test results to… If [DESCRIBE ELIGIBILITY REQUIREMENT], you will qualify for [STUDY].

If applicable We will share the results of your [TEST] with the [CORE LAB]. The [CORE LAB] will verify your [TEST] results.

POSSIBLE RISKS OR DISCOMFORTS

[RISKS OF TEST]

BENEFITS

You likely will not receive any personal benefit from the testing. You would benefit only if the [TEST] echo helps to diagnose an otherwise unknown problem.

COSTS / PAYMENT TO YOU
You will not have to pay for the [TEST]. We [will/will not] pay you to have the [TEST]. **Payment info if applicable**

ALTERNATIVES
The testing is for research purposes only. The alternative is to not have the testing, which means you will be able to join the study.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this testing is voluntary. This means it is your choice whether to have the [TEST]. You may refuse to have the [TEST], or you may stop it at any time. You will not lose benefits or suffer any penalty if you do. You also will not jeopardize the medical care you receive from your doctor.

CONFIDENTIALITY
As applicable If you consent to the [TEST], you are allowing [CORE LAB] to review the [TEST] results. We will remove your name and use only a study identifier when we send a copy of the results to [CORE LAB]. The results of this [TEST] will be noted in your medical record, and kept confidential, as required by law.

SUBJECT'S RIGHTS OR CONCERNS
The Human Research Protection Program (HRPP) provides oversight of all research activities involving human subjects at Lancaster General Health. If you have any questions about your rights as a research participant, or if you have complaints or concerns, you may send an e-mail to the HRPP (SM- HRPP@lghealth.org). You also may call the Chair of the Institutional Review Board at Lancaster General Hospital at 717-544-5091.

QUESTIONS
You may contact [PI] at 717-544-8300 if you have any questions about the testing or the study. You also may call [him/her] if you feel you were injured from the testing, or if you have concerns or complaints about it.

HIPAA AUTHORIZATION:
To conduct clinical research studies, we need to use and disclose patients' health information in certain ways. The Federal law known as the Health Insurance Portability and Accountability Act ("HIPAA") requires that we get you to authorize the ways we use and disclose your health information.

Your [TEST] results will be used and disclosed for research purposes. This means that your [TEST] results will be seen by the researchers. They will be shared with [SPONSOR] and [CORE LAB], after removing your personal identifiers. [SPONSOR] and [CORE LAB] will only use your results as described in this form. Also, your test results could be seen by representatives of government organizations, review boards, or other persons required to monitor the conduct of research. However, you will not be identified in any publication about the study.

You do not have to sign this Authorization. However, if you do not sign, you will not be able to have the [TEST] or join the study. This authorization does not expire. However, you may change your mind and revoke it at any time. To do so, you must write to [PI], MD, at Research Institute, Lancaster General Health, 131 E Frederick St, Lancaster, PA 17602. This will not change the use

of information we already have, but it will end your research participation and any further collection of information about you.

STATEMENT OF CONSENT:

I have read the above information, or have had it read to me. I understand the purpose of the testing and the possible benefits and risks. I have had the chance to ask questions, and all of my questions have been answered to my satisfaction. I freely give my informed consent to take part in the testing.

SIGNATURES

_____	_____	_____
Patient name (printed)	Signature	Date
_____	_____	_____
Name of person obtaining consent (printed)	Signature	Date