CONSENT FOR PATIENTS

TITLE OF STUDY: Health Care Systems for Increasing and Tracking Colorectal Cancer Screening Tests

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RESEARCH STUDY: You have been invited to participate in a research study being conducted by Dr. Brian Stello. This study is designed to increase colorectal cancer screening and tracking.

In order to decide whether or not you will participate in this study you need to understand enough about its risks and benefits to make an informed judgement. This process is known as informed consent. This consent form gives you detailed information about the research study that a member of the research team will discuss with you. This discussion goes over all aspects of this research: its purposes, the procedures that will be performed, any risks of the procedures, and possible benefits. Once you understand the study and all of your questions are answered, and you wish to participate, you, along with the investigator and a witness, will be asked to sign this informed consent and you will receive a copy of it to keep as a record.

PURPOSE: The purpose of this research study is to explore whether the creation of a centralized process of identifying and inviting eligible patients to participate in recommended colorectal cancer screening increases screening rates above that seen in the usual care delivered by local primary care practices.

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DURATION: Your participation in this focus group will last about 2 hours.

PROCEDURES: You have been told that during the course of this focus group, you will be asked to allow a researcher to ask about your attitudes and beliefs regarding colorectal cancer screening. This focus group may be audio-taped and transcribed. All audio tapes and transcriptions will remain confidential.

SUBJECTS: You have been invited to participate in this study because you are eligible for colorectal cancer screening based upon the recommended guidelines.

RISKS: There are no foreseen risks to you for your participation in this study. Everything you say will be kept confidential.

BENEFITS: There may be no direct benefits to you for your participation in this study. Information from this study may allow your practice to improve the delivery of care colorectal cancer screening.

NEW FINDINGS: During the course of this study, you will be told about any new information that may affect your willingness to remain in the study.

CONFIDENTIALITY: If you do participate, all information collected in this focus group will be kept strictly confidential. All information may be inspected by the Lehigh Valley Hospital and Health Network Institutional Review Board, and the researchers at the Lehigh Valley Hospital Department of Family Medicine. Only de-identified information will be provided to researchers at CNAC, researchers at Thomas Jefferson University and federal agencies to which we report this study's results. If any publications result from this research, results will be written in a way that will protect your identity. All information will be kept in a locked cabinet for ten years after the completion of the study and access will be limited to the above-mentioned groups.

FINANCIAL COSTS TO THE SUBJECT: There will be no cost to you for participating in this study.

PAYMENT FOR PARTICIPATION: You will receive a $10 gift card for participation in this focus group.

INJURY/DISCLAIMER: Although there are no foreseen risks to you for your participation in this study, if you do sustain an injury directly related to participation in this study, the following information is important for you to know. Medical therapy will be arranged for you by LVHHN for any physical injuries sustained as a direct consequence of your participation in this research. Your health insurance carrier or other third party payor will be billed for the cost of this medical therapy. All claims shall be made to the researcher who will arrange for review in accordance with LVHHN policy. No other compensation is available. The LVHHN and the Federal Government do not have any program to provide compensation to you if you experience a problem by participating in this study.

RIGHT TO REFUSE OR WITHDRAW: You understand that your participation is voluntary and you may refuse to participate, or may discontinue your participation at any

time. You also understand that the investigator has the right to withdraw you from the study at any time.

INDIVIDUAL TO CONTACT: If you have any questions pertaining to your participation in this particular research study, you can contact Dr. Brian Stello (principal investigator of this study) by calling 610-969-2572. If you have any questions about your rights as a research subject, you can contact the IRB Director, LVH, 17th and Chew Streets, Allentown, PA 18105, (610) 969-2525.

You will receive a copy of this consent form if you agree to participate in this research study.

You have read this entire form and you understand it completely. All of your questions regarding this form or this study have been answered to your complete satisfaction. You agree to participate in this research study.

Title of Protocol: Health Care Systems for Increasing and Tracking Colorectal Cancer Screening Tests
Principal Investigator: Brian Stello, M.D.

YES_____NO_____

SIGNATURE_____

SIGNATURE OF SUBJECT

Subject:
Name:_____Signature:_____Date:_____

Witness:
Name:_____Signature:_____Date:_____

SIGNATURE OF INVESTIGATOR

Investigator:

Name:_____ Signature:_____ Date: _____

Witness:
Name:_____Signature:_____Date:_____