CONSENT FOR PHYSICIANS/STAFF

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 focus group concerning your practice's participation in the Colorectal Cancer Screening intervention, about attitudes and behaviors about colorectal cancer screening, and about management of normal and abnormal screening tests. This focus group is being conducted to assess the baseline measures and impact of a study designed to increase colorectal cancer screening and tracking, conducted by Dr. Brian Stello. You are invited to participate in this focus group because your practice agreed to take part in the intervention of this study.

In order to decide whether or not you will participate in this focus group, you need to understand enough about its risks and benefits to make an informed judgement. This process is known as informed consent. A discussion with study personnel will go over all aspects of the research: its purposes, the intervention, the purpose of this focus group, any risks due to participation in this focus group and possible benefits. Once you understand the participation 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 the 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. The purpose of this focus group is to assess the conducted intervention, attitudes and behaviors about colorectal cancer screening, and management of normal and abnormal screening tests.

DURATION: Your participation in this focus group will last about 30 minutes.

PROCEDURES: You have been told that during the course of this focus group, you will be asked to allow a researcher to ask questions assessing the intervention, attitudes and behaviors about screening, and management of normal and abnormal screening tests. 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 focus group because your practice agreed to participation in this intervention.

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

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

NEW FINDINGS: We will tell you of any new information that may affect your willingness to participate in this focus group.

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, beyond your attendance, for participating in this study.

PAYMENT FOR PARTICIPATION: You will receive no compensation for your participation.

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. Specifically, your decision to refuse or withdraw participation will not incur any penalty or loss of benefits through your employment. You also understand that the investigator has the right to withdraw you from the focus group 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 focus group participant, 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:_____