Study Title: Implementing multilevel colon cancer screening interventions to reduce rural cancer disparities

Date: 11/25/2020

NCT#: NCT04651504

We invite you to participate in a research study being conducted by investigators from Washington University in St. Louis. You are being asked to participate in this research study because you are a primary care provider or staff member in central or southern Illinois that is involved with the cancer screening process. The purpose of this study is to learn about the current processes used to support and monitor colorectal cancer screening, and assess the use of an intervention toolkit for colorectal cancer screening and follow-up on screening rates at participating clinics. NIH is funding this research study.

If you agree to participate, a study member will conduct an audio-recorded interview with open-ended questions lasting 10-45 minutes. You will be in a private room individually or with other providers or staff at your clinic. You will be asked about current processes used to support and monitor colorectal cancer screening from initiation to results and through documentation after a diagnostic colonoscopy. You will be asked to discuss your clinic's capacity and interest in applying evidence-based intervention strategies and your roles and goals pertaining to colorectal cancer screening, and/or your clinic's use of the study intervention toolkit. You are free to skip any question you prefer not to answer. Approximately 54 people will take part in this study at Washington University. We may contact you at a later time to ask if you are interested in completing a second interview as part of this same study. You are free to decline participating in a second interview.

One aspect of this study involves making audio of you. This is done so that the coordinator doesn't miss any important information and if we have questions, we can refer back to them. Access to these recordings is limited to research team members only. They will be destroyed 7 years after the study ends.

Identifiers may be removed from your private information and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

There are no known risks from being in this study, and you will not benefit personally. However, we hope that others may benefit in the future from what we learn as a result of this study. You will not have any costs for being in this research study and you will not be paid.

To help protect your confidentiality, electronic data will be on a password-protected laptop and audio-recordings and hard-copy (paper) data will be inaccessible to those not on the study team during transfer to the locked office suite in a locked file cabinet. All study data will be labeled only with a unique study ID. Only the study team will have access to the audio-recordings and these will be transcribed with names removed (put into written form) before being shared with those outside the study team. However, federal regulatory agencies and Washington University, including the Washington University Institutional Review Board (a committee that reviews and approves research studies) and the Human Research Protection Office may inspect and copy records pertaining to this research. If we write a report about this study we will do so in such a way that you cannot be identified.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from

the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Your participation in this study is completely voluntary. You may choose not to take part at all. If you decide to participate in the study you may stop participating at any time. Any data that was collected as part of this study will remain as part of the study records and cannot be removed. If you decide not to take part in the study or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

If you do not wish to participate in this study or want to end your participation in the study, let the research member know you do not wish to participate before or during the interview. You will not be penalized or lose any benefits for which you otherwise qualify.

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Julia Maki 314-286-2835**.** If you feel you have been harmed from being in the study, please contact**:** Dr. Aimee James at 314-454-8300. If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445 or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

Thank you very much for your consideration of this research study.