Document Coversheet

Study Title: Accelerating Colorectal Cancer Screening Through Implementation Science in Appalachia (ACCSIS)

Institution/Site:	University of Kentucky
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The Ohio State University Consent to Participate in Research

Study Title:	**Accelerating Colorectal Cancer Screening through Implementation Science (ACCSIS) in Appalachia – Education Session**
Researcher:	**Electra D. Paskett, PhD/Mark Dignan, PhD**
Sponsor:	**National Cancer Institute**

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate.

Your participation is voluntary.

Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form.

Purpose: You are being asked to participate in this education session because rates of colorectal cancer are higher and rates of colorectal cancer screening are lower in some parts of Ohio/Kentucky. Your community health center / local community asked for updated information about colorectal cancer and colorectal cancer screening in your state and in your local community, as well as ways to increase colorectal cancer screening and follow-up for local residents.

The goal of this education session is to increase colorectal cancer and screening knowledge, change attitudes toward screening, and increase confidence and skills in recommending colorectal cancer screening and follow-up to age-eligible patients.

Procedures/Tasks: If you agree to take part in this project, you will attend two educational sessions over the next 6 months. You will be asked to fill out a short questionnaire before the start of each session that will ask you questions about yourself (age, race, job status, etc.), as well as questions about colorectal cancer and colorectal cancer screening knowledge and attitudes. You will also be asked to fill out a similar questionnaire at the end of the education session. There will be a session leader who presents the information and leads any discussion that follows. The sessions will be recorded using a digital voice recorder.

Duration: The first education session will last approximately 1 hour. A second education session will take place in about 6 months and will also last about 1 hour.

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

Risks and Benefits: We believe there are no known risks associated with participating in the education session; however, a possible hassle may be the time it takes to complete the pre-post tests and take part in the session.

You may not directly benefit from taking part in today's session; however, we hope that your participation in the education session will help you feel more confident in recommending colorectal cancer screening and successfully navigate needed follow-up for patients in your clinic.

Confidentiality: What is said in the education sessions will be kept confidential. If you want to have the recorder turned off at any time, tell the session leader, and he/she will do so. Every effort will be made to keep any information shared strictly confidential.

Any information which could identify you will be kept on a secured database separate from the project data. All paper files with identifiable information will be stored under lock and key at all times. All computer files with the audiotapes (which contain no names or identifiable information about the individuals in the session) will be stored under lock and key at all times. All computer systems will be password-protected against intrusion. All network-based communications of confidential information will be encrypted. All datasets used for analytic purposes will not contain name, addresses, or any other personally identifiable information. All education session records and audiotapes will be destroyed three years after the close of the study.

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor, if any, or agency (including the Food and Drug Administration for FDA-regulated research) supporting the study.

The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

Study information that has health implications may be placed in your medical record where authorized employees may see the information. Further, authorized requests for your records (medical record release for continuity of care) may result in research-related information being released.

Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

You may also visit the NIH website at https://humansubjects.nih.gov/coc/faqs to learn more.

Will my de-identified information be used or shared for future research?

No.

Incentives: There are no costs for you taking part in this education session, and you will not be paid for taking part in the session.

Participant Rights:

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

Contacts and Questions:

For questions, concerns, or complaints about the study, or you feel you have been harmed as a result of study participation, you may contact Dr. Electra Paskett at 614-293-7713.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 800-678-6251.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of participant	**Signature of participant**
	AM/PM
	Date and time
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
	AM/PM
Relationship to the participant	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time