**Facilitators and Barriers to Cancer Screening: Stakeholder Perspectives on Implementation**

**NCT04683744**

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**INDIANA UNIVERSITY STUDY INFORMATION SHEET FOR RESEARCH**

**Facilitators and Barriers to Cancer Screening: Stakeholder Perspectives on Implementation (IRB# 2012926551)**

For patients

You are being asked to participate in a research study. The study is being conducted by Peter H. Schwartz, MD, PhD, Indiana University School of Medicine and Center for Bioethics. It is funded by the Patient-Centered Outcomes Research Institute (PCORI) (CDR-2018C3-14715).

**Why is this study being done?**
The purpose of this study is to learn about what effects people's decisions to engage in cancer screening and preventive healthcare during the COVID-19 pandemic.

**What will happen during the study?**
You will talk with a member of the study team at a time convenient for you. During the interview, we will ask you questions about your thoughts about getting preventive healthcare during the COVID-19 pandemic, including your perception of risk, barriers to getting healthcare, and information needed for decision making. We will also ask you questions to collect basic information about you such as gender, educational level, employment status and marital status.

We estimate the interview will take about 45 minutes.

The interview can be conducted by phone or videoconferencing platform such as Zoom or WebEx. The conversation will be recorded and all identifying information will be removed.

**Taking part in this study is voluntary.**
You may choose not to take part or may leave the study at any time. Your decision whether or not to participate in this study will not affect your current or future relations with IU Health or Eskenazi Health.

If you decide to participate in this study, you can change your mind and decide to leave the study at any time. If you decide to withdraw, you can let the study team know by calling 317-278-3254 or email: iucbdas@iupui.edu.

**What are the risks and benefits of taking part in this study?**
The risks of participating in this research are loss of confidentiality. Efforts will be made to keep all information collected for this study confidential. Study information will be stored securely in compliance with Indiana University Department of Medicine policies.

The benefits to participation in the study that are reasonable to expect are that you may feel good helping in a research study; however, we can't guarantee that you will personally benefit from participating. Others may benefit in the future from the information we find in this study.

**Will I be paid for participation?**
You will receive a $100 gift card for completing the interview.

**How will my information be protected?**
Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study and databases in which results may be stored. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, Patient-Centered

Outcomes Research Institute and any state or federal agencies who may need to access your medical and/or research records (as allowed by law).

**Will my information be used for research in the future?**
Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

**Who should I call with questions or problems?**
For questions about the study, contact the principal investigator, Peter Schwartz, MD, PhD at 317-278-4034 or phschwar@iu.edu. After business hours, please call his pager at 317-310-7732.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

**INDIANA UNIVERSITY STUDY INFORMATION SHEET FOR RESEARCH**

**Facilitators and Barriers to Cancer Screening: Stakeholder Perspectives on Implementation (IRB# 2012926551)**

For Healthcare system leadership, providers, and staff

You are being asked to participate in a research study. The study is being conducted by Peter H. Schwartz, MD, PhD, Indiana University School of Medicine and Center for Bioethics. It is funded by the Patient-Centered Outcomes Research Institute (PCORI) (CDR-2018C3-14715).

**Why is this study being done?**
The purpose of this study is to identify facilitators and barriers to implementing patient decision aids, provider notifications, and cancer risk assessments in primary care. Our research team is currently conducting another study testing whether providing patients and their providers with personalized messages about advanced colorectal neoplasm risk results in increased colorectal cancer screening and higher decision quality. The patients view a decision aid and the providers are sent a notification through the EHR. We are interested in learning how primary care practices and healthcare systems could use the results from that study to increase colorectal cancer screening and decision quality. We are also interested in identifying the facilitators and barriers of other cancer screening initiatives especially during the COVID-19 pandemic.

**What will happen during the study?**
You will be asked to meet with a member of the study team every 3-4 months for the next 2 years at a time convenient for you. During the meetings, we will ask you questions about your thoughts about implementing decision aids, provider notifications, and cancer risk assessments in your health center or healthcare system. These questions may be specific to colorectal cancer screening or more generally about other cancer screenings. We may also ask you questions about cancer screening initiatives your health center or healthcare system engaged in during the COVID-19 pandemic.

You can meet individually with the study team member, or if there are other participating providers or staff from your healthcare system who agree, you can meet as a group.

We anticipate that the length of the meetings will vary especially if they are conducted individually or in a group; however, we estimate the meetings will take no longer than an hour.

The meetings can be conducted by phone, videoconferencing platform, or in-person according to your preference and COVID-19 pandemic restriction guidelines. The meetings may be recorded and all identifying information will be removed.

**Taking part in this study is voluntary.**
You may choose not to take part or may leave the study at any time. Your decision whether or not to participate in this study will not affect your current or future relations with IU Health or Eskenazi Health.

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. If you decide to withdraw, you can let the study team know by calling 317-278-3254 or email: iucbdas@iupui.edu.

**What are the risks and benefits of taking part in this study?**
The risks of participating in this research are loss of confidentiality. Efforts will be made to keep all information collected for this study confidential. Study information will be stored securely in compliance with Indiana University Department of Medicine policies.

The benefits to participation in the study that are reasonable to expect are that you may learn about ways to improve cancer screening uptake by using patient decision aids, provider notifications, and cancer risk assessment tools. You may also learn about facilitators and challenges to your healthcare system's cancer screening initiatives. Others may benefit in the future from the information we find in this study.

**Will I be paid for participation?**
You will receive a $100 gift card for attending each meeting.

**How will my information be protected?**
Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study and databases in which results may be stored. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, Patient-Centered Outcomes Research Institute and any state or federal agencies who may need to access your medical and/or research records (as allowed by law).

**Will my information be used for research in the future?**
Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

**Who should I call with questions or problems?**
For questions about the study, contact the principal investigator, Peter Schwartz, MD, PhD at 317-278-4034 or phschwar@iu.edu. After business hours, please call his pager at 317-310-7732.

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