Study Title: Video Intervention to Address Pre-Test Patient Education for Tumor Genomic Testing

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The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title: Video Intervention to Address Pre-Test Patient Education for Tumor Genomic Testing

Principal Investigator: Daniel Stover M.D.

Sponsors: National Institutes of Health, Healthy State Alliance

IRB Protocol Number: 2021C0209

Introduction:

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study
The following is a short summary to help you decide whether or not to be a part of this study.

A set of videos have been created for patients to watch when their doctors order tumor genomic testing as part of their cancer treatment. The goal of this study is to measure the effectiveness of these videos at relaying information about genomic testing to patients and to see how they feel about tumor genomic testing. Participation in this study will occur over two office visits. Today would be the first of those visits and we would ask you to take a survey, watch a brief video, then take a second survey. Your time commitment today would be 30-minutes. On the office visit that your doctor discusses the results of your own tumor genomic testing, we would ask you to take one last survey, requiring 15-minutes of your time. You will be rewarded with a $10.00 gift card to Amazon.com or Target for each survey completed. There are no direct benefits for you associated with participation in this study, only the benefit to society in the overall improvement of communication regarding tumor genomic testing.

Why is this study being done?

This study is being performed to determine if an informative video can improve patients' experiences with tumor genomic testing.

How many people will take part in this study?

200 people will complete this study.

What will happen if I take part in this study?

You will be asked to take a total of 3 electronic surveys and view a brief video. You will also permit study team members to review your medical records.

How long will I be in the study?

To participate in this study, you will take a 15 minute survey, watch a 3-minute video and then retake the survey. This initial investment in time is expected to take approximately 30-minutes. On a later date, after your tumor genomic test results come back, you will be asked to retake the survey, requiring approximately an additional 15 minutes. In total, active participation in this study will last less than 1 hour. Your medical records may be reviewed by study personnel for five years following receipt of your tumor genomic testing to determine how the testing impacted your treatment.

Can I stop being in the study?

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.

What risks, side effects or discomforts can I expect from being in the study?

There are no perceived physical or health risks related to participation in this study. However, there is a risk that topics that may arise from the questionnaires or video viewing could cause an emotional response in participants but this is not beyond what is expected in everyday life as it pertains to tumor genomic testing.

What benefits can I expect from being in the study?

While participation in this study offers no direct benefit to your health, it may improve your understanding of tumor genomic testing. Society may benefit through improvements to cancer care based on results of the study.

What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

What are the costs of taking part in this study?

There is no cost to you to participate in this study.

Will I be paid for taking part in this study?

You will receive a $10.00 gift card to Amazon or Target for each survey that you complete. Today's participation would include two surveys, $20.00 in gift cards, and there is one follow-up survey after your test results are reported to you, another $10.00. You can receive a total of $30.00 in gift cards.

By law, payments to participants are considered taxable income.

What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

What are my rights if I take part in this study?

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 subject 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.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

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

No

Will my study-related information be kept confidential?

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;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors

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.

We will work to make sure that no one sees your survey responses without approval. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you.

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.

HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

Past and present medical records

Research Records;

Records about phone calls made as part of this research;

Records about study visits;

Information that includes personal identifiers such as; your name, or a number associated with you as an individual.

Information gathered for this research about:

Physical exams
Lab/X-rays, and other test results
Questionnaires

II. Who may use and give out information about you?

Researchers and Study Staff

III. Who might get this information?

The Sponsor of this research. "Sponsor" means any persons or companies that are: working for or with the Sponsor; or are owned by the Sponsor.

The Sponsors for this study are the National Cancer Institute and Healthy State Alliance.

Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;

Others: Study Collaborators

Daniel Stover, M.D.

Leigha Senter-Jamieson, M.S., L.C.G

Amanda Toland, Ph. D.

Carolyn Presley, M.D.

Shelly Hovick, Ph. D.

Wei Lai, Ph. D.

Deloris Veney, MACPR

Additional authorized Ohio State University staff that become involved with the study.

IV. Your information may be given to:

The U.S. Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
Governmental agencies in other countries;
Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

To do the research;
To study the results; and
To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers: Daniel Stover 512 Biomedical Research Tower 460 W 12th Avenue Columbus, OH 43210. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related information. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it is given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

Contacts and Questions:

- For study questions, concerns, or complaints, to withdraw consent and HIPAA authorization, or if you feel you have been harmed as a result of study participation, you may contact: Dr. Daniel Stover at Daniel.Stover@osumc.edu or (614) 293-8000.
- For questions related to your privacy rights under HIPAA or related to this research authorization, please contact: HIPPA Privacy Officer, Suite E2140, 600 Ackerman Road, Columbus, OH 43201 or by telephone (614) 293-4477.
- 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: Office of Responsible Research Practices at 1-800-678-6251.
- If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact: Dr. Daniel Stover at Daniel.Stover@osumc.edu or (614) 293-8000.
- If you are suffering psychological distress such as an emotional response as a result of participating in this study, please contact: Dr. Daniel Stover at Daniel.Stover@osumc.edu or (614) 293-8000.

Providing Consent:

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 combined consent and HIPAA research authorization form.

Please click the button below to proceed and participate in this study.
If you do not wish to participate, please close out your browser window.

YES, I WOULD like to participate in this research study.
* must provide value

- ◯ I am consenting to participate for myself
- ◯ I am consenting to participation on behalf of someone else

Please type participant's first name
* must provide value

Please type participant's last name
* must provide value

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.
* must provide value

Research staff member's signature
* must provide value

Please tap the "now" button to record current date and time.
* must provide value

M-D-Y H:M:S

Next Page >>