Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: Implementing a Patient-Centered Intervention to Reduce Cancer Patients' Financial Toxicity

Principal Investigator: Mary Politi, PhD at 314-747-1967

Research Team Contact: Christine Marx, MA, at 314-362-9656

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

Key Information

This is a research study conducted by Mary Politi, PhD to learn about cancer patients and survivors' experiences with healthcare costs. We are interested in learning about how cancer patients and their care team discuss care costs and financial resources. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to join, or why you might not want to join. You may choose to join or not.

If you agree and sign this consent, you will be volunteering to join the research study. As a voluntary participant, you will be asked to spend about 10 minutes completing a survey. You can complete the survey over the phone or via email at home. The main risk if you join the study is that confidential information about you may be accidentally disclosed.

We don't expect this study to benefit you directly, but it will help us understand how to support cancer patients and survivors as they manage care costs. By volunteering you may help someone else in the future. There is no cost to you and you will be paid with a $10 Walgreen gift card for being a volunteer participant. All of this information will be explained and is listed in more detail in this consent document. The research team must give you a copy of this signed consent document.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to join in this research study because you have been diagnosed with lung, colorectal, or gynecologic cancer in the past.

The purpose of this research study is to help cancer patients talk about cancer care costs and use health insurance and other resources to help with some of these costs.

WHAT WILL HAPPEN DURING THIS STUDY?

If you choose to complete in-person:

1. After your next oncology appointment, research staff will schedule a time to meet with you at our office or in the community.
2. At the appointment, research staff will provide a paper or electronic copy of the survey for you to complete.

We would also like to record the following data from your electronic medical record: insurance status, distress score, and other health conditions.

If at any point in the study you no longer wish to participate, you can exit out of the survey. You can send us an email or give us a phone call to let us know you no longer wish to participate. You will not be penalized or lose any benefits for which you otherwise qualify.

If you do not tell us you no longer wish to participate in the study or need more time to think about your participation, we will follow-up with you with a phone call and/or email in two weeks. We will reach out three times before removing you from the study.

Will you save my research information to use in future research studies?

Your private information will NOT be used for future research studies or shared with other researchers for their studies, even if we remove identifiers.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 215 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for 10 minutes.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because it may help us understand how to better support cancer patients and survivors as they manage care costs.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will receive a $10 Walgreens gift card to thank you for your time.

You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a gift card will be mailed to you. It will take approximately 2 weeks for the gift card to be delivered. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

WHO IS FUNDING THIS STUDY?

The National Cancer Institute is funding this research study. This means that the Washington University is receiving payments from National Cancer Institute to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from National Cancer Institute for conducting this study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- National Cancer Institute
- University representatives to complete University responsibilities
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly

identify you.

To help protect your confidentiality, we will use an ID code to identify your surveys instead of your name. We will destroy the link between the code number and your name after the study is over. All data will be stored electronically under password protection in a secured server. Study-related computers will be under firewall protection and will maintain automated virus update mechanisms. Timely notification regarding relevant patches will be provided. Hard copies of data collection forms will be stored in locked cabinets in locked areas to which only authorized personnel will have access. In addition, all study staff annually sign a confidentiality statement attesting to their understanding of, and willingness to abide by, written policies on research ethics and confidentiality. Access to the data entry website will be password protected and restricted to personnel trained to use the system.

The Siteman Cancer Center at Washington University School of Medicine and Barnes-Jewish Hospital is supported by funding from the National Cancer Institute (NCI). To meet NCI requirements, identifiable information about you relating to your participation in this study (including your social security number) will be stored in a secure database at the Siteman Cancer Center. This database and also your health care records may be reviewed by Siteman Cancer Center personnel. All information will be securely and confidentially maintained.

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.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to

you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

CAN WE CONTACT YOU BY EMAIL?

We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- Links to surveys
- Information about an appointment time, if we make one

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test

message to ensure we have the correct email address.

- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your health information via email?

_____ Yes _____ No
Initials Initials

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study.

If at any point in the study you no longer wish to participate, you can exit out of the survey. You can send us an email or give us a phone call to let us know you no longer wish to participate. You will not be penalized or lose any benefits for which you otherwise qualify.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Christine Marx, MA, at 314-362-9656. If you feel that you have been harmed in any way by your participation in this study, please contact Mary Politi, PhD at 314-747-1967.

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.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: N/A.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)