

Behavioral Research (Patient) Informed Consent

Title of Study: DISCO: A Patient Intervention to Reduce the Financial Burden of Cancer

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Funding Source: American Cancer Society

Key Information about this Study

1. This project is research, and participation is voluntary.
2. The purpose of the study is to learn about ways to improve how patients and oncologists discuss cancer treatment costs.
3. Little risk is associated with this study.
4. No direct benefits exist for participating.
5. The alternative to this study is not to participate.

Purpose

You are being asked to participate in this research study of the financial costs of cancer because you are planning to meet with an oncologist (cancer specialist) to discuss possible cancer treatment. The purpose of the study is to learn about ways to improve how patients and oncologists discuss cancer treatment costs. This study is being conducted at Wayne State University/Karmanos Cancer Institute. The estimated number of study participants to be enrolled is 240.

Please read this form and ask any questions you may have before agreeing to be in the study.

Study Procedures

If you agree to take part in this research study, we will ask you to complete a brief survey over the phone or in the clinic before your next scheduled appointment with your oncologist. Completing the survey takes about 20 minutes and you will be assisted by a research assistant, if needed. If you decide to complete the survey in the clinic before seeing your oncologist, we will ask you to arrive 30 minutes early before your scheduled appointment. The survey asks questions about you such as your age, employment and marital status and your thoughts and feelings about your health and healthcare. At the end of the survey, you will be randomized (i.e. assigned by chance, like a coin toss) into one of three groups. Neither you nor the research assistant can decide which group you will get.

You will be in the study for up to one year. During the year, we will ask you to complete four additional surveys by phone or through a link sent by email. The surveys will take about 10 minutes. The surveys will take place 1 month, 3 months, 6 months, and 12 months after the video-recorded interaction.

If you are assigned to **Group 1**, we will video record an upcoming appointment. Your oncologist has agreed to be video recorded. Immediately after the recording, we will ask you to complete another

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brief survey that takes about 10 minutes. The questions will ask about how the meeting went. Your meeting with the oncologist will not be delayed or changed in any way because of this study.

If you are assigned to **Group 2**, at your scheduled appointment, we will show you an iPad with an “app” while you wait to see your oncologist. We will demonstrate how the app works, and you will then have time to use the app and explore its features. The app includes a short video and asks questions about your financial concerns. The app will give you a list of questions you may want to ask your oncologist during your appointment. Using the app takes about 15 minutes so we will ask you to arrive 15 minutes early before your scheduled appointment. You will then meet with your oncologist. Your meeting with your oncologist will be video recorded. Your oncologist has agreed to be video recorded. Immediately after meeting your oncologist, you will complete another brief survey, which will take about 10 minutes. The questions will ask about how the meeting went and what you thought of the app. Your meeting with the oncologist will not be delayed or changed in any way because of this study.

If you are assigned to **Group 3**, at your scheduled appointment, we will show you an iPad with an “app” while you wait to see your oncologist. We will demonstrate how the app works, and you will then have time to use the app and explore its features. The app includes a short video and asks questions about your financial concerns. The app will give you a list of questions you may want to ask your oncologist during your appointment. Using the app takes about 15 minutes so we will ask you to arrive 15 minutes early before your scheduled appointment. You will then meet with your oncologist. Your meeting with your oncologist will be video recorded. Your oncologist has agreed to be video recorded. Immediately after meeting your oncologist, you will complete another brief survey, which will take about 10 minutes. The questions will ask about how the meeting went and what you thought of the app. Your meeting with the oncologist will not be delayed or changed in any way because of this study. Two months after the video-recorded appointment, we will send you a reminder of the information that was presented on the app.

Benefits

As a participant in this research study, we expect no direct benefit for you. However, information from this study may benefit other people now or in the future.

Risks

Some people may feel uncomfortable answering some of the questions in the surveys, but you can skip any questions you prefer not to answer. Also, some people might be uncomfortable with the video or audio recording, but you can stop the recording at any time.

Study Costs

Participation in this study will be of no cost to you.

Compensation

For your time and contribution, if you agree to participate in this research study, you will be compensated up to \$150 in the form of gift cards at the following times:

- \$20 after completing a video recording and associated pre- and post-surveys
- \$20 after completing a *potential* second video recording
- \$20 after completing your 1-month follow up survey
- \$20 after completing your 3-month follow up survey

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- \$20 after completing your 6-month follow up survey
- \$50 after completing your 12-month follow up survey

Confidentiality

We will keep all study information about you completely confidential. We will assign you a code number and not use your name. Your survey answers and recordings will be maintained in a locked cabinet or password-protected computer at Wayne State University. Only authorized research staff will have access to this information. When the results of the research are published or presented, no information will be included that would reveal your identity. If photographs, videos, or audiotape recordings of you will be used for research or educational purposes, your identity will be protected or disguised. Only study personnel will have access to the recordings. Five years after the study is completed, all the video- and audio-recordings and identifiable information about you will be destroyed (unless you give signed permission to keep the recordings longer).

All information collected about you during this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code number. Information that identifies you personally will not be released without your written permission. However, the study sponsor, the Institutional Review Board (IRB) at Wayne State University, or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.] may review your records.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Voluntary Participation/Withdrawal

Taking part in this study is voluntary. You have the right to choose not to take part in this study. You are free to only answer questions that you want to answer. If you decide to take part in the study, you can later change your mind and withdraw. Your decisions will not change any present or future relationship with Wayne State University or its affiliates, or other services you are entitled to receive.

We may stop your participation in this study without your consent. We will make the decision and let you know if it is not possible for you to continue. The decision that is made is to protect your health and safety, or because you did not follow the instructions to take part in the study.

Questions

If you have any questions about this study now or in the future, you may contact Dr. Hamel or one of her research team members at the following phone number 313-576-9627. If you have questions or concerns about your rights as a research participant, the Chair of the Institutional Review Board can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call the Wayne State Research Subject Advocate at (313) 577-1628 to discuss problems, obtain information, or offer input.

Participation in Future Studies

We may want to contact you in the future to ask if you are interested in being in other studies about patient-doctor communication. If you do not want to be in future studies, you can say no. **Please provide a checkmark here if you give permission to be contact for future studies.**

_____ I give my permission to be contacted for future studies on patient-doctor communication.

Consent to Participate in a Research Study

To voluntarily agree to take part in this study, please sign on the line below. If you choose to take part in this study, you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all your questions answered. You will be given a copy of this consent form.

Signature of participant

Date

Printed name of participant

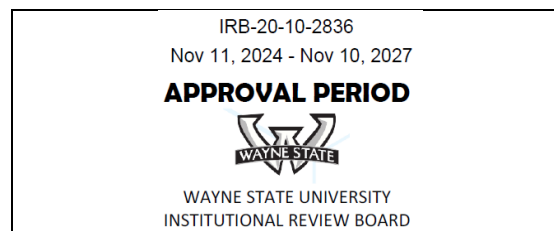
Time

Signature of person obtaining consent

Date

Printed name of person obtaining consent

Time



Permissions for Future Use of the Audio/Video Recordings

You have agreed to be audio/video recorded as part of this research. We would also like to ask your permission to use the recordings for future research and educational purposes. You may decline to have your recording used in any other way and still be in the study.

Please put your initial below if this is acceptable to you.

___ I agree to allow the recordings to be used for **future research**. The researchers will only be allowed to use the recordings if they are specifically authorized by Dr. Hamel and Wayne State University. They will receive special training in the protection of research participants' privacy.

___ I agree to allow the recordings to be used for **educational purposes**. This may involve students, doctors, community members, and researchers who are interested in learning about patient-doctor communication to view/hear the recording.

___ I give permission for the video recordings to be stored for future research after completion of the study.

HIPAA Authorization

A federal regulation, known as the “Health Insurance Portability and Accountability Act (HIPAA)” gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission (authorization) is required for the use and sharing of any protected health information collected as part of this research study. If you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.

The principal investigator (PI) and her research team will use your medical records and information created or collected as part of this research study. Your PHI is important for the PI and her research team in order to collect information about you during the study, to be able to contact you if needed, and to provide treatments to you during the study, if required. The PI may send out your study related health information to the sponsor or other entities involved in this study.

Your medical records, which may contain information that directly identifies you, may be reviewed by representatives from groups identified below. The purpose of these reviews is to assure the study is being conducted properly, that data is being obtained correctly or for other uses authorized by law. These reviews occur at the study site or in the PI’s research office and can take place anytime during the study or after the study has ended.

The PHI that will be “USED” for this research includes the following: name, address (street address, city, state and zip code), e-mail address, elements of dates, telephone numbers, medical record number, and any unique identifying numbers or characteristics or code.

The PHI that will be “DISCLOSED” or shared with others for this research includes the following: name, address (street address, city, state and zip code), e-mail address, elements of dates, telephone numbers, medical record number, and any unique identifying numbers or characteristics or code.

Your study information may be **used** or **shared** with the following people or groups:

- The PI, co-investigators, and key personnel of WSU associated with the research project
- WSU’s Institutional Review Boards (IRB)
- Authorized members of WSU’s workforce who may need to access your information in the performance of their duties.
- Federal agencies with appropriate regulatory oversight (e.g., FDA, OHRP, OCR, etc.) may review your records.

Once your information has been released according to this Authorization, it could be released again and may no longer be protected by the HIPAA regulations.

This Authorization does not expire. The research team may need to correct it or provide missing information about you even after the study has ended, and your medical records may be needed to assist in this process.

- During your participation in this study you will have access to your medical record and any study information that is part of that record. The PI is not required to release research information that is not part of your medical record.

You may withdraw (take back) your permission for the **use** and **disclosure** of your PHI for this research at anytime, by **writing** to the PI at the address on the first page of this form. Even if you withdraw your permission, the PI for the research project may still use your PHI that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission for use of your PHI, you will also be withdrawn from the research project. Withdrawing your authorization **will not** affect the health care that will be provided by the Detroit Medical Center and/or the WSU School of Medicine Practice Plans.

Authorization to use and disclose PHI

- ❖ By signing this document, you are authorizing the PI to **use** and **disclose** PHI collected about you for the research purposes as described above.

Signature of participant

Date

Printed name of participant

IRB-20-10-2836
Nov 11, 2024

APPROVED



WAYNE STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD