Cooper University Hospital

INFORMED CONSENT AND HIPAA AUTHORIZATION
TO PERMIT THE USE AND DISCLOSURE
OF PROTECTED HEALTH INFORMATION (PHI)
FOR RESEARCH PURPOSES

TITLE OF STUDY: A pre-consultation compassion video to reduce anxiety among patients referred to a cancer center.

PRINCIPAL INVESTIGATOR: Brian W. Roberts, MD, MSc

DEPARTMENT(S): Department of Emergency Medicine, Department of Medicine, Department of Medicine - Hematology/Oncology

PHONE NUMBER(S): 856-342-2352

SPONSOR: Cooper Health System

What does the research study involve?
You are being invited to take part in a research study. This form is part of an informed consent process. It will give you information to help you decide if you want to volunteer for this research study. Volunteer means you choose to take part. You do not have to take part in this study to receive treatment at Cooper Hospital. The study doctor or his staff will discuss with you what is involved in this research study. If you decide to take part, you and the study doctor or a member of the study team will sign this consent form. You will receive a copy of this consent form to keep. If you have questions at any time during the research study, you should feel free to call any of the doctors listed above and ask your questions until you receive answers that satisfy you.

What is the purpose of this research study?
Patients coming to a cancer center for the first time may have a lot of anxiety. You are being asked to participate in this study because you are here for your first appointment at MD Anderson at Cooper. The purpose of this study is to see if patients who are coming to the cancer center for the first time are anxious.

If you decide to take part in this study, you will be asked to complete a survey. The survey asks questions about anxiety and depression that you may be feeling. Prior to your visit today you were sent a link to view one of two videos. Both videos are very similar. Which video you were sent was determined at random (like flipping a coin). Both videos go over your care here at MD Anderson at Cooper.

The survey also asks questions about your thoughts of the video you were sent. It is ok if you did not watch the video. You can skip the questions about the video if you did not watch it. This survey is not part of routine care. We expect it will take about 5-10 minutes to complete the survey. Being part of this study will in no way affect the care you receive for your medical needs.

We will record the following information that would be collected from you anyway as part of usual care (i.e. the measurements are not being done for research):

- We will record information about your past medical history, demographics, and details of you visit today.

What risks are there?
This study will not change the care you receive. We do not anticipate any medical risks from being in this study. You do not need to answer any questions you feel uncomfortable with.

There is a risk of a loss of confidentiality of your information recorded for research. We will record information on password protected forms, which are stored on a secure server. This will reduce the risk of loss of your information. A study number will be used on these forms. We will not use your name. The only link between your data and your name will be kept on a password protected computer server here at Cooper. Once the data collection for all subjects is complete, data that could identify you will be deleted. At the completion of this study the data collected will be shared publically so other researchers may analyze the data. However, this shared data will not contain any identifying information. It will not be able to be linked back to you (NO individual will be personally identified).

What benefits are there?
You may have a direct benefit because the survey asks questions about anxiety and depression. This may uncover symptoms that may not be found at this time if you were not in the study. If these symptoms are uncovered, it is possible that they are having a negative impact on your life. Your cancer doctor should know about them. The results of this survey will be shared with your cancer doctor.

Also, the results of this study may help future patients with cancer.

What are your alternatives (other choices) if you do not take part in this study?
Your alternative is to choose not to be a part of this study. You will receive standard care for your condition whether or not you participate in this study.

When can your participation be terminated by the investigator?
The investigator may terminate your participation in the study if you are not able to complete the required survey.

Are there any other costs?
There are no costs to you for participating in this study.

Will you be paid for participation?
You will not be paid for participating in this study.

What will happen if you withdraw?
Tell the investigator if you want to withdraw from the study. If you withdraw from the study, you will continue to have access to health care at the Cooper Health System.

Will you be told about new information that might affect your decision to take part in this research?
During the study, you will be told if any new information is learned that could affect your willingness to stay in the study.

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Will your information be kept confidential?

The privacy regulations of a law passed by Congress became effective on April 14, 2003. The law is called the Health Insurance Portability and Accountability Act, HIPAA for short. The law gives subjects in research studies certain rights about their protected health information. Protected health information (PHI) is information about a person's physical or mental health that can be identified with or linked to that particular person. If you sign this form you are giving the investigators, their staff, and certain other people described in this form your permission to use your protected health information for this research study.

The information collected about you for this study is called "protected health information" (PHI). It includes: demographic information (e.g., your name, medical record), medical history, and your answers to the study survey.

All of this information is being collected because you are participating in this research study.

Information about you will also be collected from your medical records that are located in Cooper University Hospital's electronic medical records. The information that is collected will be used to decide if you qualify to participate in this research, to follow your treatment, and will be analyzed to answer the research questions.

To help maintain the confidentiality of your study records, you will be assigned a subject number. All of your study related-information will have only your subject number. Identifying information, like your name and medical record number, will be linked to your subject number but will be kept separate from your study-related information. Your study documents will be stored on a secure password-protected computer server. The information from this study may be published in scientific journals or presented at scientific meetings but you will not be personally identified in these publications and presentations.

By signing this form, you are allowing the following people or groups to have access to the information described above (your PHI).

The research team, which includes the investigators listed on this form and other personnel involved in this specific study need to analyze the data.

Cooper's Institutional Review Board (IRB), a committee that reviews, approves, and monitors research involving human subjects may look at your study records.

All of these people and entities are obligated to protect your PHI.

You have the right to limit the use and sharing of your PHI, and you have the right to see your research study records and know who else is seeing them. You will not be allowed to see your health information that is created or collected during the course of the research. After the research is finished, however, you may see this information.

You are authorizing us to use and disclose your PHI until the end of the research study. You may revoke this authorization to use and share your PHI at any time by contacting the principal investigator, in writing, at the address on the front of this form. If you decide not to authorize the investigator to use and disclose your PHI or you revoke this authorization, you will no longer be

able to participate in this research study, and the use or sharing of future PHI will be stopped. However, the PHI that has already been collected may still be used.

Whom can you contact if you have a question?
If you have any questions about this research, you can contact the principal investigator at the number on the first page.

You should call the Chief Medical Officer or his representative at (856-342-3071) (a) if you have any questions about your rights as a research subject or your rights related to the research use of your PHI, (b) if you believe that you have not been told about all the risks, benefits, and alternative treatments, (c) if you believe that you are being forced to stay in this study when you do not want to, or (d) you have any complaints about the research.

You should also contact that person if you believe that you have not been adequately informed as to the risks, benefits, or alternative procedures of this research study, or that you are being pressured to participate in the study against your wishes.

If you have any questions about the research or your rights as a subject or any complaints about the research, you may also contact the Institutional Review Board (IRB) of the Cooper Health System. The IRB is responsible for protection of subjects participating in this research project. The address of the IRB is E&R Building, 401 Haddon Ave., Room 288, Camden, NJ 08103. The phone number is 856 757-7832.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. At the conclusion of the study, the web site may include a summary of the results. However, this web site will not include information that can identify you. You can reach this web site at any time.

CONSENT STATEMENT

Your participation and your decision to allow the use of your PHI are entirely voluntary. You do not have to participate or let us use your PHI. If you decide not to participate or not to let us use your PHI or you decide to stop participating or to stop letting us use your PHI, it will not affect your treatment at Cooper University Hospital. Your doctors will continue to treat you the way they always have.

All of the above has been explained to me. All of my questions have been answered. I can ask questions that I have about the research or about the use and disclosure of my PHI at any time. My questions will be answered by one of the investigators listed on the first page of this form.

By signing this form I agree to participate in this study and I agree to the use and disclosure of my PHI for the purposes described above. A copy of this form will be given to me.

Signature Block for Adult Subjects

Printed Name of Subject : _____

Signature: _____ Date:_____ Time: _____

I have discussed the study described above with the subject.

Printed Name of Person Obtaining Consent: _____

Signature: _____ Date:_____ Time: _____

Winn C, *et al. BMJ Open* 2021; 11:e048201. doi: 10.1136/bmjopen-2020-048201