

Consent to Participate in Research

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Title of Research Study: Feasibility of OncoTool to Improve Self-Management and Adherence to Oral Anticancer Medications

Principal Investigator: Betina Yanez, Ph.D.

Supported By: This research is supported by the National Cancer Institute.

Key Information about this research study:

The following is a short summary of this study to help you decide whether to be a part of this study. Information that is more detailed is listed later on in this form.

The purpose of this study is to develop a web-based tool to improve the wellbeing of cancer survivors who have been prescribed an oral cancer medication. You will be asked task-based usability questions about this tool in an in-person interview, and complete three questionnaires online over the next three weeks. We expect that you will be in this research study for about three weeks. The primary risk of participation is discomfort due to the sensitive nature of questions we may ask. The main benefit is potentially benefiting from sharing your cancer experience.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you have been diagnosed with cancer that your doctor has prescribed oral cancer medication for.

How many people will be in this study?

We expect about 10 people here will be in this research study.

What should I know about participating in a research study?

- Someone will explain the research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

What happens if I say, “Yes, I want to be in this research”?

- You will be asked several questions about your opinion on the materials we’ve developed for a website for patients undergoing oral cancer medication for their cancer. The questions will focus on how helpful and user friendly the topics and design of the website are. As part of the interview, we will ask you to complete a questionnaire on demographic information. We will also ask you to complete tasks or scenarios on this website so we can see how easy it is to find information in the website and how easy it is to use.
- It will take approximately 60 minutes to complete the in-person interview and it will be conducted at the Department of Medical Social Sciences at Northwestern University by a member of our research team.
- The researcher will be observing and taking notes during this interview.
- The interview for this study will be audio and video recorded so we can remember and refer to what you said, and see how you interact with the Oncotool interface. Audio and video

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recording is required for participation. If you do not want to be audio or video recorded, then it is not possible for you to be in this study. Your name will not be included in the audio and video recording, and it will be destroyed at the end of the study to protect any other identifying information that it may contain.

- Additionally, if you consent to being part of our study, the information you've already given us during the eligibility screening questionnaire we completed over the phone will be retained as part of the study records.
- We will also ask you if we can use some of the information in your medical records as part of the study. This information will be used to better understand the information collected during your interview. Granting us permission to use this information from your medical records is required for participation.
- At the end of this informed consent, we will ask you if you would like to be contacted to learn about similar future studies designed by Dr. Betina Yanez. You are free to decline to being contacted to learn about future studies, and this will not affect your ability to participate in the current study if you wish to do so.
- After you complete the in person interview, you will be asked to monitor your health through an online health questionnaire weekly for a duration of 3 weeks. The health questionnaire will take approximately 15 to 20 minutes for you to complete. Your responses will be recorded in a secure Northwestern database known as REDCap. You will receive a link to the survey through a secure study email and, for your convenience, study staff can send you text message reminders for you to complete these questionnaires online

At the end of the three weeks, you will have a 5 minute phone call with a study team member where you will give us your opinion on the length and content of the questionnaires. Your responses will help us improve our cancer care questionnaire in the future.

Will being in this study help me in any way?

We cannot promise any direct benefits to you or others from your taking part in this research. However, possible benefits to yourself include sharing your cancer experience. The information gained from this study may benefit society by providing information to healthcare providers to develop a program to better assist cancer patients to manage symptoms from oral cancer medication and to improve their quality of life after cancer treatment.

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Is there any way being in this study could be bad for me?

Your participation does not involve any risks other than what you would encounter in daily life. Some of the questions we ask might make you feel some discomfort. If you are uncomfortable, you are free to decline or to skip any questions. If the investigator feels you are experiencing a lot of distress, we will provide you with a referral for psychological support.

What happens if I do not want to be in this research?

Participation in research is voluntary. You can decide to participate or not to participate.

You can withdraw from this study at any time. Choosing not to be in this study will not negatively affect your right to any present or future medical treatment.

What happens if I say “Yes”, but I change my mind later?

You can leave the research at any time and it will not be held against you.

If you withdraw from the study, no more information will be collected from you. If you indicate you wish to withdraw, the investigator will ask if the information already collected from you can be used.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

The online survey is being hosted by Redcap and involves a secure connection. Terms of service, addressing confidentiality, may be viewed at <https://projectredcap.org/partners/termsofuse/>.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Cancer Institute which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

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HIPAA Authorization:

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Information in a medical record (such as cancer diagnosis and treatment information)
- Results of physical examinations (staging, diagnostic results)
- Medical history (e.g., previous cancer diagnosis)
- Lab tests, or certain health information indicating or relating to a particular condition as well as diaries and questionnaires
- Records about medication or drugs

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy.

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,

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- The National Cancer Institute, who is sponsoring the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Unless you revoke your permission to access information from your medical records, it will expire at the end of the study.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Dr. Betina Yanez
Northwestern University, Feinberg School of Medicine
Medical Social Sciences
633 N. Saint Clair Street, Suite 19-071
Chicago, Illinois 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

Data Sharing: De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Can I be removed from the research without giving my OK?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include no longer meeting inclusion and exclusion criteria, and unsuitability as participant.

What else do I need to know?

Compensation: If you agree to take part in this research study, we will pay you \$60 for your time and effort. **You will be paid \$20 in cash after your in-person interview**, and after your final phone call at the end of the study you will be mailed a \$40 pre-paid gift card. **There is a fee associated with the gift card if it is not used at all within 6 months of issuance, and you will be notified of that date when you receive the card.**

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Who can I talk to?

If you have questions, concerns, or complaints, or think the research has affected you in some way, talk to the research team at Northwestern University.

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree I disagree

_____ _____ The researcher may contact me in the future to see whether I am interested in participating in other research studies by the principal investigator of this study.

Signature for Adult 18 or older

Your signature documents your permission to take part in this research.

Signature of participant

Date

Printed name of participant

Signature of person obtaining consent

Date

Printed name of person obtaining consent