Consent to Participate in Research

Title of Research Study: *ImmunOncoTool*

Principal Investigator: Dr. *Betina Yanez, PhD.*

Supported By: This research is supported by the American Cancer Society, the Melanoma Research Association, and Bristol-Myers Squibb.

Disclosure: If your doctor is also the person responsible for this research study, please note that he/she is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

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 better understand the experiences of patients who have received care at the Robert H. Lurie Comprehensive Cancer Center. More specifically, we are interested in learning about patient's concerns and needs throughout their experience with immunotherapy treatment.

You will be asked to complete an in-person interview, and another interview similar to the first about 12 weeks from now. During that time you will be participating in a 5-month long study where you will either use an online health tool or not. We expect that you will be in this research study for about 5 months.

The primary risk of participation is discomfort due to the sensitive nature of questions we may ask. You are able to withdraw your consent at any point in time if you feel uncomfortable. 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 are a patient with cancer and you are currently receiving immunotherapy treatment.

How many people will be in this study?

We expect about 80 people will participate 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"?

- If you agree to participate in this research, a member of our research team will schedule a time for an orientation appointment for remote orientation procedures or in person orientation procedures.
- Remote orientation procedures can be used if you have no upcoming appointments that will bring you to the Northwestern campus or if you prefer this option.
- In person orientation procedures can be done with you while you are receiving your immunotherapy treatment, at a reserved room on the Northwestern campus, or at our research space at 625 North Michigan Avenue, 21st Floor. Location, date, and time of orientation procedures are set up to accommodate you.
- Before your orientation, you will be randomly placed into one of two groups using REDCap randomization. The group you will be assigned to will be chosen by chance, like flipping a coin. You will have an equal chance of being assigned to any given group. Depending on which group you are assigned to, you will receive one of two programs: Group 1 or Group 2.
- Depending on the group that you are put into, you may receive more information on the program and tools that you will have access to after the meeting. This orientation will take about 30 minutes.
- We are also requesting HIPAA authorization from you in order to obtain medical and treatment-related information from your medical records (e.g., stage of diagnosis, cancer treatments and dates of treatment, medical co-morbidities, healthcare utilization) so that we can track your medical events over the course of the study.
- 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. Once we have receipt of your consent, staff can continue with orientation procedures.
- During orientation, research staff will administer to both groups a demographics form, the FACT-G8 (functional assessment of cancer therapy-general) a health-related quality of life (HRQoL) measure, and the Health Questionnaire, a immune-related adverse event (irAE) measure. Note that the questionnaires distributed to the different condition groups are identical.
- Coronavirus disease 2019 (COVID-19) is expected to have an impact on the health-related quality of life (HRQoL) of cancer patients and survivors. Due to our patient population, we will be implementing the COVID-19: IMPACT OF THE PANDEMIC AND HRQOL IN CANCER PATIENTS AND SURVIVORS questionnaire at T1 or our participants' earliest convenience. This questionnaire measures COVID-19 Specific Distress (Emotional and Physical Reactions) and Health Care Disruptions and Concerns (Concerns About Medical Care). Note that participants in both condition groups will receive this questionnaire.
- Certain Health Questionnaire responses will cause research team members to reach out to participants to urge them to seek medical care.
- Text messages and/or emails will be sent to you from a secure Northwestern Outlook account or REDCap during the your participation in the study. These texts/emails can contain links to study assessments, can be reminders for completion of study assessments, or can be reminders of upcoming T1/T2/T3 appointments.
  Other than the main timepoints of the study (T1, T2, and T3), the Group 1 participants and the Group 2 participants will follow different procedures.

GROUP 1

- Group 1 participants will be completing health questionnaires at orientation/T1, at week 12 of their participation/T2, and at week 20 of their participation/T3.

- At the T2, participants will also have a debriefing interview and complete a healthcare utilization form with the help of research staff. These Health Questionnaires take about 10 minutes each to complete.
- Group 1 participants will complete the main timepoints of the study and complete a weekly health questionnaire for the first 12 weeks of their participation.
- For the last 8 weeks of the 5-month period, the Group 1 participants will complete the Health Questionnaire on a biweekly basis.
- The Health Questionnaire responses generated from the group 1 participants will be reported to their clinical team throughout the study.

GROUP 2

- Group 2 participants will be completing health questionnaires at orientation/T1, at week 12 of their participation/T2, and at week 20 of their participation/T3.
- At the T2, participants will also have a debriefing interview and complete a healthcare utilization form with the help of research staff.
- The Health Questionnaire responses generated from the group 2 participants will not be reported to their clinical team until the end of the study.

CONCLUSION

- 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, this will not affect your ability to participate in the current study if you wish to do so.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include providing information to healthcare providers to improve care for patients undergoing cancer immunotherapy treatment in the future.

Although it is possible that you will benefit from sharing your cancer experience, we cannot guarantee a direct benefit.

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.

ImmunOncoTool was created solely for the purposes of research and it is not intended to replace your clinical care or management with your healthcare provider. If there is a medical emergency, please call your healthcare provider's office directly or call 911 to report to the nearest emergency room. We do not forsee that the use of the website will cause distress, it's meant to increase self-efficacy in communication and coping with emotions, as well as increase knowledge about cancer. It contains information from legitimate sources, and it has been vetted by multiple clinical psychologists and doctors at Northwestern University.

In an emergency, or if you have an urgent medical or mental health issue, call 911. If you have less pressing questions regarding the website you can contact us, but note that it could take us up to 72 hours to respond.

While any information in the website is protected, there is some possibility that the use of the website in public could cause loss of confidentiality since those around you could see what you are inputting or looking at within it. Also, there is a risk if you try to access the website on your smartphone or tablet while walking or driving since it could involve injury or accidents. Therefore, you are not permitted to use the website while walking or driving.

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 decide to leave the research no more information will be collected from you. If you decide to leave the research, contact the investigator so that the investigator can 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.

Study information, such as baseline and follow-up assessments and clinical information from the electronic health record, will be documented in REDCap, a secure data capture service in cooperation with Northwestern Medicine that includes a secure connection. Terms of service may be viewed at https://confluence.nubic.northwestern.edu/display/RUCP/REDCap+Security.

Additional study information, such as your symptom updates and program usage (e.g., number of log-ins, interaction with the program), will be collected through the website that was developed by Bright Outcomes on a server hosted at Connectria Inc. All program data will be encrypted and transferred to password-protected Northwestern servers. Besides the email required for log-in, no other private health information will be collected or stored within the website. If you do not have an email address, or do not wish to use your personal email, we will create a temporary email address using pseudonyms which will be deleted at the end of the study. The following is a complete list of information that the website will collect:

- Email address
- Username information
- Login events
- Responses to activities on the website and when your responses were submitted
- Page view events (what page you viewed on the website and when it was viewed).

Terms of service may be viewed at https://oncotool.brightoutcome.com/#/terms-conditions

Any study records that can identify you, such as this informed consent, will be kept confidential. They will be stored separately from your interview under lock and key. Any information collected will be accessible only to the research staff on this study for purposes of analysis.

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 (eg. Previous cancer diagnosis)
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study 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,
- The American Cancer Society, the Melanoma Research Association, and Bristol-Meyers Squibb 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.
Unless you revoke your consent, 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
625 N. Michigan Ave., Suite 21-013
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.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

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. Recordings will be used only for data analysis and will not be seen by any persons outside of the study team. 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 if they judge that it is in your best interest to do so.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

Compensation

Participants will be compensated $75 after completing their orientation and baseline assessments (T1). Participants will be compensated $50 after completing the last main timepoint of the study (T3). If a participant does not complete all time points of the study, they will only be compensated for their T1. Participants who complete all time points of the study will be entered into a raffle for a $250 gift card. There will be two gift cards given out for the raffle.

Financial compensation can be presented via cash, a pre-loaded, physical gift card, or a pre-loaded, electronic gift card.

Furthermore, in the event that you require transportation, we would reimburse up to $7.00 for your travel expenses (e.g. cost of bus or train to Northwestern), or provide you with a ticket for parking at a designated lot by our office.

Because the goal of this study is to improve a patient monitoring system, it is possible that your health care provider will give us feedback about their experience with the new process that we are developing.

Who can I talk to?

If you have questions, concerns, or complaints talk to the research team by calling Dr. Betina Yanez at 312-503-5341 or Karina Reyes at 312-503-5422.

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 marking 'Yes' or 'No' for each activity.

1. 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.

   - o Yes
   - o No

Consent to Participate in Research

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