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# CONSENT TO TAKE PART IN A RESEARCH

# STUDY Phase 2

**Title of Study:** Enhancing Self Care Among Oral Cancer Survivors: The Empowered Survivor Trial

**Principal Investigator:** Sharon Manne, PhD

**STUDY SUMMARY:** This consent form is part of an informed consent process for a research study. It will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to evaluate and gather feedback from participants on 2 online interventions for cancer survivors. The 1st intervention is called Empowered Survivor. Empowered Survivor was developed by the study team. The 2nd intervention is called Springboard Beyond Cancer. Springboard Beyond Cancer was developed by National Cancer Institute and American Cancer Society.

If you take part in this study, you will be asked to:

- Complete 3 surveys.
- View and give feedback on 1 of the 2 interventions.

After you complete the 1st survey, you will be randomly assigned to view Empowered Survivor or Springboard Beyond Cancer. You will be asked to complete surveys at 2 months and 6 months after you complete the 1st survey.

Your time in the study will take about 6-7 months. Each survey will take you about 30 minutes to complete. Viewing the Empowered Survivor or Springboard Beyond Cancer interventions could take approximately 2 hours. We may contact you by phone for a short, optional debriefing interview to clarify the responses you gave in your evaluation, to ask you questions about why you did or did not complete the website, and to gather any suggestions for changes to the website.

**Possible harms or burdens** of taking part in the study may be:

- Feeling upset by a survey question.
- Feeling upset by looking at information about cancer in the interventions.

Possible benefits of taking part may be:

- Learning information about managing any symptoms you have.
- Learning more about cancer survivorship.

**An alternative to taking part in the research study** Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study. It will tell you what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them. You should expect to be given answers you completely understand.

After your questions have been answered and you wish to take part in the research study, you will be asked to acknowledge this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by acknowledging this consent form.

**Who is conducting this study?**
Dr. Sharon Manne is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Sharon Manne may be reached at 732-235-6759. Her mailing address is

Sharon Manne, PhD
Rutgers Cancer Institute of New Jersey
195 Little Albany Street
New Brunswick, NJ 08901

You will be able to download a copy of the electronic consent form to keep.

**Sponsor of the Study**: National Institutes of Health (NIH)/ National Cancer Institute (NCI)

**Why is this study being done?**
The purpose of this study is to evaluate and gather feedback from participants on 2 online interventions for cancer survivors. The 1st intervention is called Empowered Survivor. Empowered Survivor was developed by the study team. The 2nd intervention is called Springboard Beyond Cancer. Springboard Beyond Cancer was developed by National Cancer Institute and American Cancer Society.

**Who may take part in this study and who may not?**
**People who meet the following may take part in this study:**

1) Age 18 years to 89 years;
2) Diagnosed with a first primary oral or oropharyngeal cancer within the past 3 years;
3) Has internet access;
4) Reads English, and;
5) Has sufficient vision to read a survey and complete an online intervention.

- Children are not included because the incidence of these cancers in children is rare.

**Why have I been asked to take part in this study?**
You have been invited to take part in this study because you have been diagnosed with oral or oropharyngeal cancer.

**How long will the study take and how many subjects will take part?**
We expect your participation in the study to last approximately 6-7 months because we it will take time to collect the 6–month follow-up surveys. We expect to recruit participants over the course of about 2.5 years.

You will be one of approximately 600-675 participants in this study. Study staff may contact you via email, mail, phone call or text message to discuss the study.

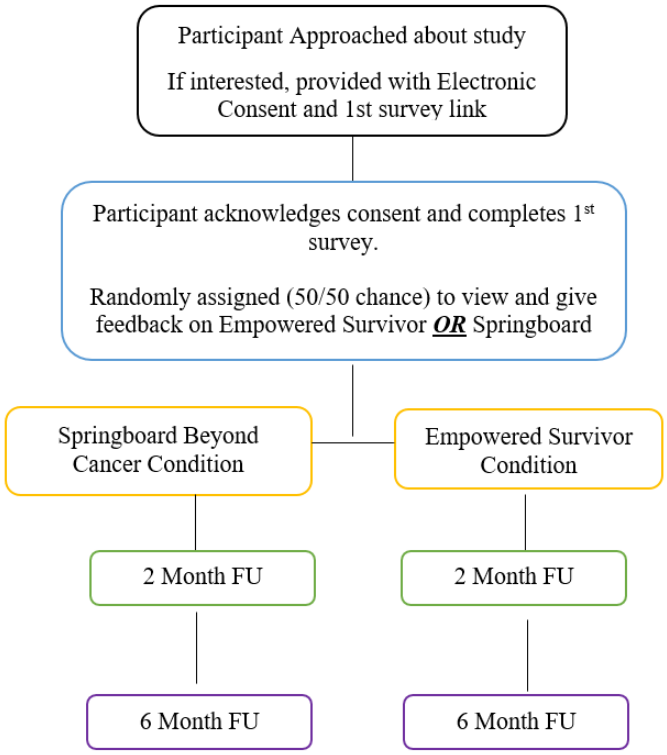
**What will I be asked to do if I take part in this study?**
If you take part in this study, you will be asked to:

- Complete 3 surveys.
- View and give feedback on either Empowered Survivor intervention or Springboard Beyond Cancer intervention.
- Participate in a short, optional debriefing interview phone call.

After you complete the 1st survey, you will be randomly assigned, or assigned by 50/50 chance, to view Empowered Survivor or Springboard Beyond Cancer. You will be asked to give feedback on things you liked or did not like about the intervention you viewed. Study staff may send up to 4 email/text message reminders encouraging you to complete the intervention you have been randomized to view.

You will then be asked to complete surveys at 2 months and 6 months after you completed the 1st survey. The study team will send you an email with a link to each survey. All of the surveys should take around 30 minutes to complete.

We may contact you by phone for a short debriefing interview to clarify responses you gave in your evaluation, to ask you questions about why you did or did not complete the website, and to gather any suggestions for changes to the website. This telephone debriefing interview is completely optional, and you can let the study team members know if you are interested in taking part or not when they contact you about it. The phone call will take approximately 20 minutes. The debriefing interview will take place after Survey 2 (2-month follow-up) and before Survey 3 (6-month follow-up). We are including a chart below of the steps you would be asked to take part in.




**What are the risks of harm or**

**discomforts I might experience if I take part in this study?**
It is not expected that you will experience any risks or discomforts from taking part in this study. However, potential risks are 1) breach of confidentiality and 2) emotional distress that might come with being asked questions or reading information related to your cancer diagnosis.

As with all research that collects protected health information, there is a risk of breach of confidentiality. Although this is a risk that is unlikely, there is a data security plan in place to minimize such a risk.

The risk of emotional distress is occasional and if you feel uncomfortable with a question, you can skip the question or withdraw from the study altogether.

If you feel any distress during participation, please let the study team know. An investigator who is trained in psychology and works with cancer patients can give you information about sources of professional help.

**Are there any benefits to me if I choose to take part in this study?**
The benefits of taking part in this study may be

- Learning information about managing any symptoms you have.
- Learning more about cancer survivorship.

However, it is possible that you may not receive any direct benefit from taking part in this study.

**What are my alternatives if I do not want to take part in this study?**

There are no alternatives available. Your alternative is not to take part in this study.

**How will I know if new information is learned that may affect whether I am willing to stay in the study?**

During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

**Will I receive the results of the research?**

In general, we will not give you any individual results from the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

A summary of the study results is available to you on ClinicalTrials.gov.

**Will there be any cost to me to take Part in this study?**

There will be no cost to you to take part in this study.

**Will I be paid to take part in this study?**

You will receive up to $150.00 for completing the study surveys according to the following schedule:

- $50.00 Amazon electronic gift card for completing the **first** survey
- $50.00 Amazon electronic gift card for completing the **second** survey
- $50.00 Amazon electronic gift card for completing the **third** survey

You will receive up to $100.00 for viewing the Empowered Survivor Intervention, if you are randomized to this study arm, according to the following schedule:

- $20.00 Amazon electronic gift card for completing **Module 1**
- $20.00 Amazon electronic gift card for completing **Module 2**
- $20.00 Amazon electronic gift card for completing **Module 3**
- $20.00 Amazon electronic gift card for completing **Module 4**
- $20.00 Amazon electronic gift card for completing **Module 5**

You may also receive additional compensation if you are eligible for a one-time entry lottery. A 'winner' will be randomly selected to receive a $20 Amazon electronic gift card. This is for the Empowered Survivor Intervention study arm and lottery eligibility is based on intervention completion. Eligible participants will be notified of lottery guidelines via email/text.

We will send you all of the electronic gift cards to you via email. We will not provide any compensation for participating in the voluntary debriefing interview.

**How will information about me be kept private or confidential?**
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

You will be assigned a unique study ID number. All records that contain your name, telephone number, email address or other information that could identify you are kept separate from the survey forms and medical record information. Rutgers Cancer Institute of New Jersey uses username/password security measures to restrict access to only those study team members who are authorized. Data collected through the Internet (DatStat Illume) will be stored on password protected servers.

We will know your IP address when you respond to the Internet survey. The researchers will see your individual survey responses and the results. These downloaded data will be labeled with participant numbers only. All data on servers are password-protected and limited to authorized research personnel.

We believe that these procedures will be effective in protecting against and minimizing potential risks.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require, such as laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.

The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**What will happen to my information or biospecimens collected for this research after the study is over?**

- The information collected about you for this research will not be used by or distributed to investigators for other research.

**What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?**

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to: Sharon Manne, PhD
Rutgers Cancer Institute of New Jersey
195 Little Albany Street
New Brunswick, NJ 08901

**Who can I contact if I have questions?**

If you have questions about taking part in this study or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Sharon Manne, Population Sciences department, 732-235-6759.

If you have questions about your rights as a research subject, you can contact the Rutgers IRB Director at: New Brunswick/Piscataway HealthSci IRB 335 George St., Liberty Plaza Ste. 3100, New Brunswick, NJ 08901, (732)235-9806, or write us at 65 Bergen St., Suite 507, Newark, NJ 07107.

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# PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

**What Is The Purpose Of The Research And How Will My Information Be Used?**

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

**What Information About Me Will Be Used?**

- Radiology records or images (MRI, CT, PET scans)
- Medical history or treatment

- Laboratory/diagnostic tests or imaging
- Pathology reports, specimen(s) or slide(s)
- Operative reports (about a surgery)

**Who May Use, Share or Receive My Information?**
The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University Investigators Involved In The Study
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Non-Rutgers investigators on the study team: (The New Jersey State Cancer Registry and its staff, The Cancer Registry of Greater California (CRGC) and its staff). The Utah cancer Registr and its staff (UCR), The Iowa Cancer Registry (ICR) and its staff
- ITX corporation
- Members of the Data Safety and Monitoring Board

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

**Will I Be Able To Review My Research Record While The Research Is Ongoing?**
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

**Do I Have To Give My Permission?**
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

**If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?**
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision:
Sharon Manne, PhD
Rutgers Cancer Institute of New Jersey
195 Little Albany Street
New Brunswick, NJ 08901

**How Long Will My Permission Last?**
Your permission for the use and sharing of your health information will last until the end of the study. The Rutgers Cancer Institute of New Jersey study team will destroy your identifiable information after study completion.

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If you wish take part in the research, follow the directions below:

Please acknowledge that you have read through this consent form and agree to participate in this study by clicking yes below which will take you to the survey.

If you do not wish to participate, click no and this form will close.

- **Yes.** I acknowledge that I am 18 years of age or older and have read and understand the information. I agree to take part in the research, with the knowledge that I am free to withdraw my participation in the research without penalty. [By agreeing to participate you will be prompted to the baseline survey]

- **No.** I do not wish to take part in the research.