MSK **Verbal Consent Form for Part 2**

Feasibility Study of the Head and Neck Survivorship Tool: Assessment and Recommendations
(HN-STAR)

DIRECTIONS FOR CONSENTING PROFESSIONAL:

PLEASE NOTE- YOU CAN ATTEMPT CONTACTING THE POTENTIAL PARTICIPANT 3 TIMES ONLY.

Hello! May I speak with _____ (Potential Participant's Name)?

If not available: DO NOT leave your name or number to call back. *Just say that you will call back another time and ask for a good time to reach them.*

If you reach voicemail: You may leave your name or number to call back if the potential participant has listed in the medical record that it is okay to leave messages, or if calling a personal cell phone. Please refer to Appendix P: Recruitment Voicemail Script.

If available:

My name is <*consenting professional*> and I am calling from Memorial Sloan Kettering. I am contacting you in regard to our study about an online tool being used in our cancer survivorship clinic. You are being asked to take part in this study because you have completed treatment for head and neck cancer and you are scheduled for an upcoming appointment or due for an appointment at the survivorship clinic. You should have recently received a letter about this study.

Would now be a good time to speak with you regarding this study? Our conversation will take about '10' minutes.

If no: When would be a better time for me to call? _____
If yes: continue with the call

A research study is completely voluntary and includes only people who choose to take part. Please take your time to make your decision about taking part. If at any time you have questions, please feel free to ask me for further explanation.

During our discussion we will cover information about the research study. Once you understand the study, its risks, and its benefits, and we have discussed your questions, you will be asked if you want to take part.

Do you have any questions so far?

Would you like to hear about our Study?

- **If NO:**

  We would appreciate if you could take a moment to provide a brief reason why you are not interested. Can you please provide the reason why you decline to learn more or participate in

this study? _____
Thank you for taking your time. Goodbye.

- **YES- Continue with next section, but first:**
  Did you receive the letter we sent that describes our research study?

If no: Would you like me to send you another letter so that you can read more about the study after we speak?

If yes: Good. We will also review that information during this conversation.

Today's date is _____ **(MM/DD/YYYY)**. My name is _____ and I am verbally consenting you to participate in the study, Feasibility Study of the Head and Neck Survivorship Tool: Assessment and Recommendations (HN-STAR).

Can you please state your full name? _____
(Please ask them to spell)

Study Information:
DIRECTIONS FOR WRITING SCRIPT SECTION: Briefly describe below the specific study and the participant's potential role. This must include, but not limited to what we are trying to learn more about, how many participants will take part and duration, what will happen to participant (before, during, after) (refer to hard copy of consent's images/calendars, if previously mailed), and that they can stop or be stopped at any time:

We are committed to improving the care of cancer survivors. Researchers at Memorial Sloan Kettering and Hartford Healthcare have developed a tool called HN-STAR that we hope will improve care for head and neck cancer survivors. HN-STAR includes an online questionnaire called the Survivor Self-Assessment, so that patients can report the health issues that are important to them. The Survivor Self-Assessment will help us understand what we should discuss at your upcoming visit. It will also help us create a Survivorship Care Plan for you to take home and share with your family, friends, and other doctors.

This study is being done to understand how survivors of head and neck cancer think we can make HN-STAR (the Survivor Self-Assessment, the survivorship clinic experience, and the Survivorship Care Plan the best it can be. In Part 1 of the study, we have already gotten feedback from 10 survivors of head and neck cancer, who told us how we can make HN-STAR easier to read and understand, and we have made some changes based on their opinions. Now for Part 2 of the study, we are asking you for your opinions. Once we have your input and input from other survivors, we can make final changes to HN-STAR, so that we can test this tool in a larger study with many survivors in many hospitals. The larger study will tell us whether using HN-STAR improves the care of head and neck cancer survivors.
Once we have your input and input from other survivors, we can make changes to HN-STAR, so that we can test this tool in a larger study. The larger study will tell us whether using HN-STAR improves the care of head and neck cancer survivors.

There is only one study group. A total of 55 head and neck cancer survivors (40 from Memorial Sloan Kettering and 15 from Hartford HealthCare) will take part in this study to see whether the Survivor Self-Assessment and Survivorship Care Plan can be used conveniently in the cancer

survivorship clinic. We need your input to make the Survivor Self-Assessment, the Survivorship Care Plan, and the surveys easy to understand and use.

If you decide to participate in the research study, you will be asked to complete the Survivor Self-Assessment and answer a few questions about it online before your visit – either at home or in the clinic waiting room.

When you have your upcoming routine visit with the nurse practitioner, she will have access to your Survivor Self-Assessment responses, and she will discuss your responses with you during your visit.

Right after your visit, you will receive a printed Survivorship Care Plan that summarizes your prior cancer history and your clinic visit. You will then be asked to complete an online survey about the Survivorship Care Plan and your clinic visit.

In 6 months, we will call you to answer a few brief questions about the Survivorship Care Plan.

As a thank-you for your time and participation, you will be compensated with a $50 gift card to CVS, which you will receive after your clinic visit.

After your visit, we will send your Survivorship Care Plan to your primary care provider. We will ask him or her questions about whether the Survivorship Care Plan is helpful.

You will get medical treatment if you are injured as a result of taking part in the study.
If you think you have been injured as a result of taking part in this research study, you must tell your study doctor or the person in charge of this research study as soon as possible. The name and phone number of the person in charge of this research are listed on this consent form.

We will offer you treatment for research injuries as a result of your taking part in this study. You and/or your health plan will be charged for this treatment. Medical services will be offered at the usual charge. You will be responsible for any costs not covered by your health plan/insurance
If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

Do you have any questions about this study and our discussion so far?

Would you like to hear more so you can decide whether to take part?

- **NO:**
  We would appreciate if you could take a moment to provide a brief reason why you are not interested. Can you please provide the reason why you decline to learn more or participate in this study? _____
  Thank you for taking your time. Goodbye.

- **YES- Continue with next section.**

DIRECTIONS FOR WRITING SCRIPT SECTION: Briefly describe the Risks, Benefits, Alternatives, and Rights of potential participant; see following suggestion:

Taking part in this study is completely your choice; you can decide to stop your participation at any time. If you decide to stop participating, you will still receive your routine survivorship care. There are no expected side effects or risks from being in the study. If you feel uncomfortable or anxious discussing any of the information involved with participating in this study, you may stop participating in the study at any time.

Risks for this study are minimal, and we will aim to protect participants from risk. Participants will complete the consent form and respond to the study surveys and interviews. The information presented to survivors about their symptoms may cause psychological distress. We have taken steps to minimize the risk of distress attributable to study participation. All study personnel will be trained and supervised to implement study procedures. All assessments will be conducted by research staff skilled in interviewing participants in a sensible manner with the utmost respect for human subjects' issues. In the unlikely event of psychological distress observed or expressed by participants, appropriate referrals will be made. Participants will be treated with respect and sensitivity.

There are no direct benefits in taking part in this study. However, the responses from the Survivor Self Assessment that you complete will be given to your nurse practitioner for your visit, which may help you talk about your symptoms and medical history. Also, you will receive a Survivorship Care Plan summarizing your cancer history and outlining your plan for ongoing care, which you may find helpful. The information gained from this study will be used to help other cancer survivors in the future.

Please remember the choice to take part in this study or not is yours and should be based on what I have explained to you. We will notify you in the future about new information or changes in the study that may affect your health or your willingness to continue in the study.

Do you have any questions about this study and our discussion so far?
DIRECTIONS FOR WRITING SCRIPT SECTION: Briefly describe Potential Costs/Injury and Privacy aspects of the study; see following suggestion:

There are no additional financial costs to you for taking part in this study other than the expected cost of your regularly scheduled clinic visit.

It is the responsibility of the research staff at Memorial Hospital to make sure that your records are managed to protect your privacy. We cannot use any of your health information for research unless you tell us that we can. If information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. Access to your medical information (e.g. entire medical/research record and NYS requirement for disclosure of HIV-related information) will be limited to those individuals involved with this study, our Institutional Review Board/Privacy Board whom reviewed this new study to make sure that your rights and welfare are protected, staff of the hospital's clinical research teams, our Data Safety Monitoring Board, and the Quality Assurance Committee. In addition and if necessary, the National Cancer Institute, National Institutes of Health, U.S. Food and Drug Administration, other agencies responsible for oversight and the sponsor of this study, National Cacner Institute, would have access. Your protected health information may also be used for your research treatment, to collect payment for care you receive while on the study (when applicable), and to run the business operations of the hospital. Some of the people or organizations I mentioned may not be subject to privacy laws. This means they could share your information again.

Please remember if you agree to take part in this study, it means you are giving us permission to share your protected health information. We can only share it with the people/organizations I just described. If you withdraw from the study at any time we cannot use or share anymore of your research data. If we have already used or shared your information, it cannot be taken back.

A description of this clinical trial may be available on http://www.ClinicalTrials.gov. 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.

Do you have any questions about this study or your participation?

You can talk to your study doctor about any questions or concerns you have about this study. Contact the study doctor, Shrujal Baxi at 646-888-4236 or baxis@mskcc.org and/or the study research assistant at 646-888-8206.

For a non-physician whom you may call for more information about the consent process, research patients' rights, or research related injury is Jorge Capote, RN, Patient Representative, telephone number: (212) 639-8254.

Are you ready to decide whether or not to participate?

By verbally agreeing to take part in this study, you acknowledge that you understand and accept all of the information provided to you. Do you voluntarily agree to participate in this study? (Participants should state YES or NO) _____.

AFTER INTERVIEW, STATE PARTICIPANT'S NAME, DATE, AND INTERVIEWER'S NAME ON THE FORM.

_____ _____
PARTICIPANT NAME AND MRN DATE: MM/DD/YYYY

_____
SIGNATURE OF THE CONSENTING INDIVIDUAL

_____
NAME (PRINT) OF THE CONSENTING INDIVIDUAL