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

# PROTOCOL FACE PAGE FOR MSK NON THERAPEUTIC PROTOCOL

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**Please Note: A Consenting Professional must have completed the mandatory Human Subjects Education and Certification Program.**

| OneMSK Sites |
|---|
| Manhattan |

| MSK Alliance Clinical Trials Sites | PI's Name | Site's Role |
|---|---|---|
| Hartford Healthcare | Andrew Salner, MD | Data Collection |

| Participating Institutions – If multicenter study coordinated by MSK: | PI's Name | Site's Role |
|---|---|---|
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Table of Contents

## 1.0 PROTOCOL SUMMARY AND/OR SCHEMA

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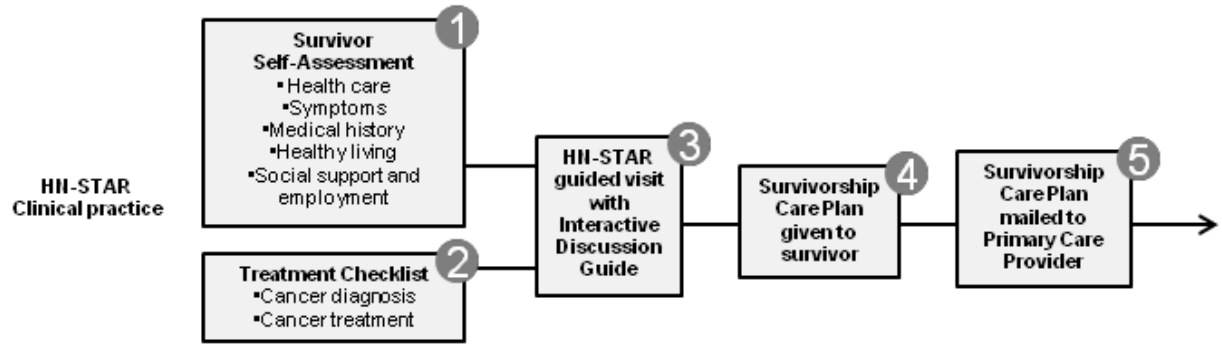
|---|---|
| Title | Feasibility Study of the Head and Neck Survivorship Tool: Assessment and Recommendations (HN-STAR) |
| Objective | Assess the feasibility of implementing HN-STAR in clinical practice to prepare for a future evaluation trial. |
| Study Aims | 1. Determine the usability and feasibility of HN-STAR.<br>2. Assess preliminary metrics of HN-STAR use in preparation for a multi-site randomized controlled trial. |
| Patient Population | Patients who have completed treatment for head and neck cancer at least one year prior and are eligible, scheduled, or due for a routine follow-up at a survivorship clinic at MSK or Hartford Healthcare (HH). |
| Treatment Plan | None |
| Intervention | Patients visiting a head and neck cancer survivorship clinic and their nurse practitioner will use HN-STAR"s web-based interfaces to provide patient information that will first create a discussion guide for the clinic visit and then create a survivorship care plan for the patient and the primary care provider. |
| Study Design | Aim 1: Part 1. Component Pilot Testing: Patients at MSK and their nurse practitioner will complete usability testing for all parts of the HN-STAR process.<br>Aim 1: Part 2. After incorporating changes to HN-STAR resulting from feedback in Aim 1: Part 1, patients visiting the MSK or HH head and neck cancer survivorship clinic will use HN-STAR for a routine clinic visit. Patients and their primary care providers will provide feasibility feedback. |
| Assessment | Usability outcomes will come from patient surveys and interviews, and a nurse practitioner interview in Aim 1: Part 1. In Aim 1: Part 2, patients and their primary care providers will complete online surveys regarding feasibility. Nurse practioners will be interviewed at the end of Aim 1: Part 2. Health outcomes and data regarding health care actions will be collected from HN-STAR and the clinic note will be collected to assess feasibility of collecting these metrics in a future trial. |

Survivors of head and neck cancer have a complex set of ongoing health needs. People who have completed treatment for head and neck cancer commonly experience severe long-term toxicities, late-occurring symptoms, and significant risks of second primary malignancy and comorbid illnesses. With multiple simultaneous health issues, health care providers often fail to comprehensively address the needs of these complex cancer survivors.

This study evaluates the use of a new, secure, web-based tool in the head and neck cancer survivorship clinic at MSK and adult survivorship clinic at HH. The Head and Neck Survivorship Tool: Assessment and Recommendations (HN-STAR) uses electronically collected data from patients and nurse practitioners (NPs) to create a discussion guide for

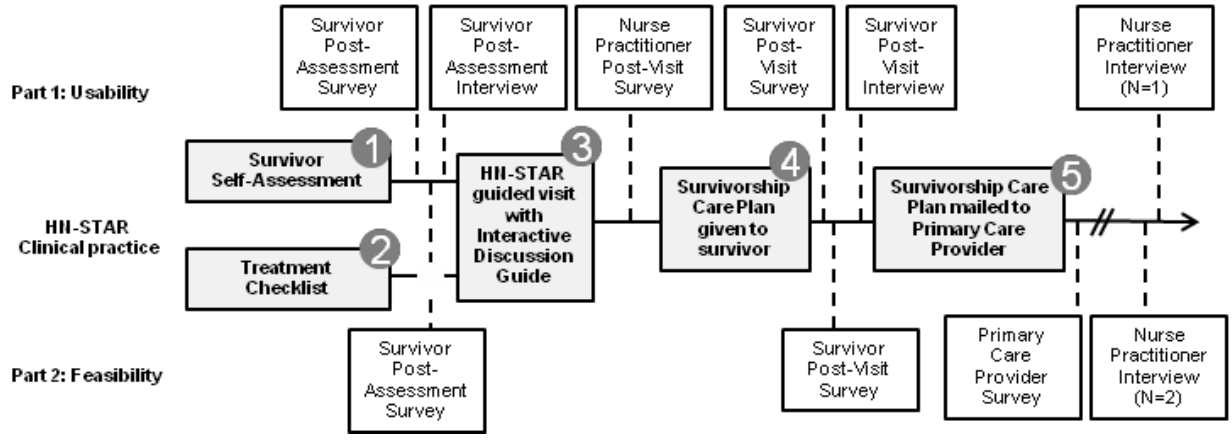
a routine clinic visit and a survivorship care plan. Figure 1 shows how HN-STAR integrates patient-reported outcomes from the Survivor Self-Assessment (1) and medical record data from the Treatment Checklist (2) to create an Interactive Discussion Guide (3) that the NP can use to structure the clinic visit. Lastly, HN-STAR creates a survivorship care plan based on the clinic visit, and it is given to the survivor (4) and the primary care provider (5).

***Figure 1: Study Summary***




**This study evaluates the usability and feasibility of HN-STAR from the perspective of key stakeholders, so that we can study its effectiveness in a future multi-center trial.** We will enroll 55 head and neck cancer survivors who are seen in an NP-led survivorship clinic and implement HN-STAR for their routine survivorship visits. The study will take place in two parts. In Aim 1: Part 1, we will assess usability and feasibility outcomes of HN-STAR from the perspective of key stakeholders, and in Aim 1: Part 2 we will assess the planned outcomes intended for the larger trial. We will collect usability and feasibility data from online surveys of survivors and their providers. In Aim 2, we will collect preliminary data on relevant health actions to inform the feasibility of collecting these data in a future trial.

***Figure 2. Study Schema***



## 2.0 OBJECTIVES AND SCIENTIFIC AIMS

Aim 1. Determine the **usability and feasibility** of HN-STAR.

We will evaluate the components of HN-STAR in two parts. In Aim 1: Part 1, survivors at MSK (N=10) and their nurse practitioner (N=1) will provide in-depth feedback on the usability of HN-STAR.

After refining HN-STAR, Aim 1: Part 2 will elicit feedback from survivors at MSK (N=30) and Hartford HealthCare (N=15) and the survivors" primary care providers (N=45) regarding feasibility of HN-STAR in clinical practice. The nurse practitioners (N=2) will provide in-depth feedback on the usability of HN-STAR.

Aim 2. Assess **preliminary metrics** of HN-STAR use in preparation for a multi-site randomized controlled trial.

Using data from survivors in Aim 1: Part 2 (N=45), we will abstract data on health care actions from both the medical record and HN-STAR. Such data include receipt of appropriate oncologic surveillance, identification and management of symptoms, and appropriate preventive health services, as indicated by referrals, prescriptions, and recommendations in both clinic notes and the HN-STAR Survivor Self-Assessment. This Aim will determine the feasibility of data collection, establish baseline health status measures, and contribute to power calculations for the future trial.

## 3.0 BACKGROUND AND RATIONALE

After cancer treatment is complete, cancer survivors need a new approach to their ongoing care. *Comprehensive survivorship care* involves routine surveillance for recurrence and new cancers, detection and management of chronic and late-developing toxicity (together called late effects), and management of comorbid conditions. For some survivors, the risks of recurrence and late effects are low, and a primary care provider can effectively oversee comprehensive survivorship care with minimal involvement of oncology providers. Other groups of cancer survivors, however, have more complex needs and require continued follow-up with their oncology providers.[1]

Head and neck cancer patients are one such group of complex cancer survivors who confront numerous and serious health challenges beyond the risk of local recurrence. Advances in treatment, specifically concurrent radiation and chemotherapy, have improved survival in head and neck cancer but have also led to an increase in chronic and late-developing toxicity.[2-7] Some common late effects include hearing loss, dry mouth, decreased taste, neck fibrosis, and lymphedema in the neck and face.[8-11] More debilitating late effects include destruction of the jaw, inability to speak, difficulty swallowing, and difficulty opening the mouth.[12-16] Up to half of head and neck cancer survivors are diagnosed with psychological distress.[17-19]

Because many head and neck cancers arise in the setting of chronic tobacco or alcohol exposure, these patients also often have other tobacco-related comorbid illnesses, such as other cancers, pulmonary disease, and cardiovascular disease and can have multiple non-cancer health care providers.[20-26]

Recently, there has been a dramatic rise in the incidence of head and neck cancer due to human papillomavirus (HPV).[27,28] Patients with HPV-related disease differ in that they have excellent 3-year tumor control rates, are on average younger at diagnosis, and have lower rates of comorbid illnesses.[29,30] As a result, HPV-positive survivors are likely to live years or decades beyond diagnosis. Longer survival translates to more years at risk for late-developing serious toxicities of treatment, such as radiation-related carotid artery stenosis and second malignancies – both of which develop many years after primary treatment.[25,31,32] Taken together, then, head and neck cancer survivors are a heterogeneous population with the potential to develop multiple, serious health issues.

With such complex needs, comprehensive survivorship care may be difficult to deliver. The central focus of survivorship care in head and neck cancer is early identification of recurrent and second head and neck cancers.[1] Although surveillance by oncology providers also includes the identification and management of late effects, there is no central clearinghouse for guidelines or standards in head and neck cancer, suggesting that methods for addressing late effects are likely *ad hoc*. Beyond oncologic surveillance, coordinated primary care is necessary to improve survival. Primary care should include aggressive management of comorbid illnesses, risk modification (e.g. tobacco-cessation), completion of recommended cancer screening, vaccination, and receipt of general preventive care.[21,33] Unfortunately, in one study, only half of head and neck cancer survivors reported even seeing a primary care provider.[34]

Addressing multiple medical issues simultaneously, and identifying which provider is responsible for management, can complicate a cancer survivor"s ongoing care. In its landmark report, From *Cancer Patient to Cancer Survivor: Lost in Transition*, the Institute of Medicine (IOM) recommended the use of survivorship care plans to facilitate coordination of survivorship care between oncology and primary care providers.[35] A survivorship care plan is a document given to the patient by oncology providers at the end of treatment that includes 1) a treatment summary and 2) a plan of care describing late effects and recommendations for interventions and self-management.[35] The survivorship care plan, which is shared with the primary care provider, includes explicit plans for who is responsible for each aspect of care. Survivorship experts have widely endorsed the use of survivorship care plans, and multiple professional societies have encouraged their use.[36-43] In their 2012 accreditation standards, the Commission on Cancer called for the implementation of a "process to disseminate a comprehensive care summary and follow-up plan" to all patients who have completed cancer treatment.[44] However, the development and consistent implementation of survivorship care plans in clinical practice have been challenging.[45-51] The major barriers to the use of survivorship care plans are the time and personnel required to create them and the difficulty reviewing their content during routine visits.[45-49,51] These barriers may be particularly problematic for complex cancer survivors, like head and neck cancer survivors, who may have multi-modality treatment histories, have treatment-based surveillance recommendations, experience numerous persistent toxicities, be at risk for late effects, require management of comorbidities, and need modification of multiple risk factors – all of which should to be noted in survivorship care plans.

We developed a web-based, algorithm-driven platform called the **Head and Neck Survivorship Tool: Assessment and Recommendations (HN-STAR)** to address the most salient issues in providing comprehensive survivorship care to head and neck cancer survivors. First, HN-STAR ensures the identification of all late effects by collecting symptom data directly from patients. It then synthesizes patient-reported outcomes, treatment data, and current evidence about survivorship care into a tailored Interactive Discussion Guide. The oncology provider uses the Interactive Discussion Guide in a routine oncology follow-up visit to address all elements of

comprehensive survivorship care. Finally, HN-STAR automatically creates the Survivorship Care Plan based on the clinic visit, which minimizes burden for oncology providers. This Survivorship Care Plan is updated at each visit to incorporate symptom changes, modified management plans, and more current evidence regarding survivorship care.

**The goal of our proposal is to evaluate the feasibility of HN-STAR in the setting of survivorship clinics, in preparation for a future multi-site randomized controlled trial.** The future trial will randomize clinics at multiple centers to use HN-STAR or usual care, and the primary outcomes will be changes in 1) the number of late effects identified and 2) the number of late effects managed in clinic. We will also investigate adherence to recommended care and any changes in health outcomes. The *current protocol* is a necessary feasibility study to inform preliminary outcomes, design, and sample size for the future trial.

## 4.1 OVERVIEW OF STUDY DESIGN/INTERVENTION

### 4.2 Design

This is a pilot study of HN-STAR for routine follow-up visits in two survivorship clinics – the Head and Neck Survivorship Clinic at MSK and the Survivorship Clinic of the Gray Cancer Center.

Patient Survivorship Program at HH. Each clinic is led by a single NP, Ms. Janet McKiernan at MSK (co-Investigator) and an NP at HH, Ms. Deborah Walker, who is a co-investigator on the HH study team. Each hospital has determined patient eligibility for the clinic. The head and neck survivors seen in each clinic have completed treatment for head and neck cancer at least one year prior and have no evidence of disease. In standard care, the NP provides oncologic follow-up, creates and delivers a survivorship care plan, addresses healthy behaviors, and ensures that the survivor has a primary care provider who will manage general preventive care.

For this pilot study, we will incorporate HN-STAR into a routine NP-led survivorship visit, in order to assess feasibility of HN-STAR in clinical practice. For a single routine visit, each patient will report his or her medical history, preventive care, and symptoms online, and this information (as well as other medical history information) will populate an Interactive Discussion Guide for the NP to use in the clinic visit. In Aim 1: Part 2 of the study, each patient and his or her primary care provider (PCP) will receive the automatically generated Survivorship Care Plan. This study will use surveys at multiple time points during this process to elicit usability and feasibility data from patients, NPs, and PCPs regarding the use of this system (Aim 1).

This study also includes non-survey outcomes assessments. HN-STAR will automatically collect patient reports about symptoms, preventive care, and medical history. Other oncology-related outcomes (such as referrals, medications, and other treatment decisions) will appear in the clinic note for each visit. Both data sources will be used to establish baseline measures and inform feasibility of collecting data for a future trial (Aim 2). In addition, as part of Aim 2, the oncology-related metrics from the clinic visit will enable us to gain preliminary insight into changes after HN-STAR, using a pretest-posttest design.

Data collection will take place in two parts. Aim 1: Part 1 will enroll 10 patients at MSK to participate in component pilot testing and usability testing of HN-STAR and the associated surveys. We will also elicit feedback from the NP. After incorporating any changes to HN-STAR or the surveys based on findings from Aim 1: Part 1, Aim 1: Part 2 will enroll 30 additional patients

from MSK and 15 from HH to provide feedback on usability. We will also survey each patient"s PCP in Aim 1: Part 2. We will also elicit feedback from the NPs.

## 4.3 Intervention

We have created HN-STAR in consultation with the Web Survey Core Facility (Web Core) at MSK, which develops web-based platforms that integrate data from online patient self-assessments and MSK records.[52] HN-STAR has four components, described below.

**4.2.1** First, the HN-STAR **Survivor Self-Assessment** elicits the presence and burden of toxicities using relevant items from the National Cancer Institute"s Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE).[53] (Survivor Self-Assessment, Appendix A) For symptoms that are specific to head and neck cancer but not included in existing PRO-CTCAE measures, we have created items using the same format and symptom attributes as existing items. In addition, the Survivor Self-Assessment includes items regarding medical history and preventive health. Items from validated screening instruments are used to screen for alcohol misuse, tobacco use, physical activity, sexual function, and depression, as shown in Table 1.[54-58] For other health behaviors, *ad hoc* assessments are based upon guidelines and institutional consensus at MSK.[59-66] For Aim 1: Part 1, participants will fill out the Survivor Self-Assessment online in a designated room in the clinic as part of the usability testing. For Aim 1: Part 2, patients fill out the Survivor Self-Assessment online before the visit, either at home or in the clinic waiting room.

| ***Table 1.*Standardized Items in Survivor Self-Assessment H&N** | **Source** |
|---|---|
| Symptom: memory, insomnia, fatigue, tiredness, or lack of energy, numbness or tingling in your hands or feet, shortness of breath, cough, ringing in your ears, dry mouth, voice changes, nosebleeds, mouth or throat sores, pain (general), difficulty swallowing, dizziness | PRO-CTCAE[53] |
| Symptom: difficulty hearing, neck or shoulder stiffness, neck pain, jaw pain, pain in your mouth, pain in your throat, frequency of pain (general), difficulty with opening your mouth, bad breath, bleeding from your mouth | Based on PRO-CTCAE |
| Symptom: Sexual function | EORTC QLQ – H&N35[67] |
| Symptom: Depression | PHQ-2[55] |
| Physical Activity: Frequency | Godin Leisure-Time Exercise Questionnaire[56] |
| Physical Activity: Average exercise time | Current MSK Survivorship Patient Assessment<br>(Based on the Godin Leisure-Time Exercise Questionnaire) |
| Smoking Status: At least 100 cigarettes in entire life | National Health Interview Survey[68] |
| Smoking Status: Years as a smoker | Lung Cancer Screening Decision Tool[69] |
| Smoking Status: Current smoking | Current MSK Survivorship Patient Assessment<br>(Based on the National Health Interview Survey) |
| Cigarettes per day | Current MSK Survivorship Patient Assessment |
| Alcohol use | The CAGE questionnaire[54] |

**4.2.2** The **Treatment Checklist** (Appendix B) collects claims data about the head and neck cancer diagnosis and treatment, which will then be translated into lay language. This will be done differently at the two participating sites. At MSK, HN-STAR generates an Automated Treatment Checklist, which presents an organized list of diagnosis, staging and treatment received at MSK using claims data from billing codes in the MSK record. The NP is prompted to verify the accuracy of the presented list and make necessary corrections. At HH, where claims data will not be automatically ported to HN-STAR, there is a Manual Treatment Checklist, in which all possible diagnosis and treatment options are presented as an organized checklist. The NP must manually complete the Manual Treatment Checklist by referring to the patients‟ medical records. At either institution, once a patient has agreed to participate in the study, prior to the participant‟s survivorship clinic visit, the NP will verify or complete the checklist. The checklist will result in the generation of a lay language treatment summary that will appear in the Survivorship Care Plan (described below in section 4.2.4). The NPs at both sites will be trained on how to use the Treatment Checklist.

**4.2.3** The **Interactive Discussion Guide** (Appendix M) integrates data from the Survivor Self-Assessment, data from the Treatment Checklist, and data regarding evidence-based survivorship care. Three algorithms will then use these data to generate the Interactive Discussion Guide that the NP can use during the routine visit.

1. *Treatment algorithms* use Current Procedural Terminology (CPT) codes and National Comprehensive Cancer Network (NCCN) guidelines to generate personalized surveillance recommendations (e.g., annual thyroid studies for survivors who received radiation to neck).[1]

*2. Symptom algorithms* use PRO-CTCAE responses to identify toxicities of treatment and other relevant issues to address. In the Interactive Discussion Guide, seen only by the NP, these symptoms populate an evidence-based list of common diagnosis to consider evaluation and management options. We have developed these recommendations based on existing evidence when available and institutional consensus within MSK and approval from HH otherwise. We will refine these guidelines as new evidence emerges.[38,70-81]

*3. Prevention algorithms* use patient responses and demographic information to generate a list of personalized prevention recommendations, based on guidelines from the United States Preventive Service Task Force and the NCCN survivorship guidelines.[1,59-66,82-85] Using the Interactive Discussion Guide, the NP will discuss ongoing care and select management plans with the survivor. Selected symptom management plans are entered into HN-STAR and populate the Survivorship Care Plan (described below).

None of the patients will see the Interactive Discussion Guide, which is intended only for the NP to use during the clinic visit. An example of content of Interactive Discussion Guide is shown below in Figure 3. The NP at each site will be trained on how to use the Interactive Discussion Guide.

***Figure 3. Excerpt of Interactive Discussion Guide for Insomnia***

***SYMPTOM: INSOMNIA***
*Frequency:* Occasional *Severity:* Moderate *Interference with usual activities:* Very Much

**Common diagnoses to consider** (Check any diagnoses or ongoing work-up below.)
□ *Medications*
□ *Anxiety/Depression*
□ *Sleep Apnea*
□ *Insomnia*
□ *Pain*
□ *Other* _____
□ *Work-up is ongoing.*

**Focused Evaluation**
History
- Onset, duration, change over time, alleviating/aggravating factors
- Nature of the sleep problem – sleeping at night, daytime sleepiness
- Assess for sleep apnea
- Medication and alcohol use review
- Sleep hygiene – total sleep time, sleep latency, daytime napping, circadian rhythm, sleep environment

Physical exam
- Assess for increased neck size or obesity indicating possible causes of sleep apnea

**Recommendations for evaluation and management** (Check all that apply.)
□ Referral to primary care provider
□ Sleep log
□ Sleep hygiene review (routine of bed time and awakening, light exposure, avoiding naps, and only being in bed to sleep)
□ Consider discontinuing or reducing use of steroids, opioids, anti-depressants.
□ Physical activity (moderate aerobic exercise for 2.5 hours a week and strength training 2-3 days a week)
□ Referral to psychology (MSK)
□ Referral to psychology (outside)
□ Referral to integrative medicine (MSK)
□ Prescription for sleep aide
□ Patient education material on sleep
□ Video on sleep
□ Not discussed because chronic and previously addressed
□ Other (Note names of providers or other details not described above)
_____

**4.2.4** Finally, the **Survivorship Care Plan** will present a treatment summary and plan of care. HN-STAR generates a Survivorship Care Plan after each visit (See template in Appendix C). The treatment summary contains a plain-language cancer history. The plan of care contains personalized recommendations for cancer surveillance, management of late effects, and preventive care. It also reports a list of non-cancer conditions reported by the patient. Each recommendation includes a schedule and clear delineation of who is responsible. The plan of care also contains generic survivorship information, with a description of signs and symptoms to report to the oncology provider, contact information for the oncology provider, and recommendations to visit a primary care provider.

**4.2.5 Clinical flow using HN-STAR**

1. *Before the survivorship visit:* At MSK, the institutional database of CPT codes will automatically populate the Automated Treatment Checklist in HN-STAR, and the NP will verify its accuracy. At HH, the NP will complete the Manual Treatment Checklist. At both sites, the Treatment Checklist will inform treatment-based recommendations in the Interactive Discussion Guide and generate a plain-language treatment summary for the Survivorship Care Plan.

2. *Before the survivorship visit,* survivors will complete the online Survivor Self-Assessment. Using the Survivor Self-Assessment and Treatment Checklist data, HN-STAR will create the Interactive Discussion Guide for the clinic visit that presents 1) an oncologic surveillance schedule, 2) a list of severity-based symptom management options, and 3) personalized preventive care and screening recommendations.

3. *During the visit,* the NP will use the Interactive Discussion Guide to facilitate conversation. Specifically, the NP and survivor will discuss ongoing care, select plans for symptom management, and identify who is responsible for each action (NP, survivor, or primary care provider).

4. *At the end of the visit*, the Treatment Checklist will be combined with the selected plan of care from the visit in the Survivorship Care Plan. At the end of the visit, the Survivorship Care Plan will be given to the survivor and discussed with the survivor.For Aim 1: Part 2, after the visit, the Survivorship Care Plan will be sent to each survivor‟s primary care provider.

## 5.0 CRITERIA FOR SUBJECT ELIGIBILITY

### 5.1 Subject Inclusion Criteria

**Aim 1: Part 1**

Patients must:

- Have completed treatment for head and neck cancer at least 1 year prior to survivorship visit and have no evidence of disease
- Be able to provide informed consent
- Be able to speak and read English
- Be at least 18 years old

**Aim 1: Part 2**

Patients must:

- Have completed treatment for head and neck cancer at least 1 year prior to survivorship visit and have no evidence of disease
- Have a primary care provider
- Be able to provide informed consent
- Be able to speak and read English
- Be at least 18 years old

### 5.2 Subject Exclusion Criteria

Subject exclusion criteria for patients recruited to Aim 1: Parts 1 and 2 is the same.

- Patients or providers who cannot speak or read English
- Patients with cognitive, visual, or motor impairment such that they cannot complete the Survivor Self-Assessment as assessed by the research team.

## 6.0 RECRUITMENT PLAN

**Recruitment Plan (with Limited waiver of Authorization)**

Potential research subjects will be identified by a member of the patient"s treatment team, the protocol investigator, or research team at Memorial Sloan Kettering Cancer Center (MSKCC).

The principal investigator may also screen the medical records of patients with whom they do not have a treatment relationship for the limited purpose of identifying patients who would be eligible to enroll in the study and to record appropriate contact information in order to approach these patients regarding the possibility of enrolling in the study.

During the initial conversation between the investigator/research staff and the patient, the patient may be asked to provide certain health information that is necessary to the recruitment and enrollment process. The investigator/research staff may also review portions of their medical records at MSKCC in order to further assess eligibility. They will use the information provided by the patient and/or medical record to confirm that the patient is eligible and to contact the patient regarding study enrollment. If the patient turns out to be ineligible for the research study, the research staff will destroy all information collected on the patient during the initial conversation and medical records review, except for any information that must be maintained for screening log purposes.

In most cases, the initial contact with the prospective subject will be conducted either by the treatment team, investigator or the research staff working in consultation with the treatment team. The recruitment process outlined presents no more than minimal risk to the privacy of the patients who are screened and minimal PHI will be maintained as part of a screening log. For these reasons, we seek a (partial) limited waiver of authorization for the purposes of (1) reviewing medical records to identify potential research subjects and obtain information relevant to the enrollment process; (2) conversing with patients regarding possible enrollment; (3) handling of PHI contained within those records and provided by the potential subjects; and (4) maintaining information in a screening log of patients approached (if applicable).

This limited waiver applies only to MSK. HH will obtain a limited waiver of authorization for their site.

Aim 1: Part 1: Component pilot testing

*Head and neck cancer survivors.* Aim 1: Part 1 will be completed at MSK. We will recruit 10 patients (meeting eligibility criteria described in Section 5.0, above) to participate in end-user testing with a Research Study Assistant (RSA) before and after an HN-STAR-guided routine clinic visit. Patients scheduled to be seen at the Head and Neck Cancer Survivorship Clinic at MSK will be screened for eligibility Two weeks before each patient"s scheduled survivorship clinic visit, eligible head and neck cancer survivors will be invited by mail to participate in the HN-STAR study. A consenting professional will follow-up with a phone call. At least three attempts will be made to reach the patient by phone. When the consenting professional reaches the patient by phone, she will describe the study and invite interested and eligible patients to participate. During the phone call, the consenting professional will follow a standard consent script that describes the study and confirms eligibility. Interested and eligible participants will be asked to provide consent. Participants who are not interested in participating will not be contacted again. As part of the verbal consenting process, reasons for non-participation may be asked in order to identify whether the study recruitment strategy is adequate. Patients will be consented over the phone before arriving to the clinic for their visit.

Because we want to sample a range of responses representing a diverse group of survivors, we will enrich for minorities in this group by enrolling no more than 7 white non-Hispanic patients. After enrolling 7 white non-Hispanic patients, if we have not yet enrolled 10 total patients, we will only invite non-white or Hispanic patients to participate until 10 patients enroll. With over 20 new survivors seen in the Head and Neck Cancer Survivorship Clinic at MSK clinic each month, this will not hinder enrollment.

Patients who participate in Aim 1: Part 1 of the study, will receive $100 to provide thanks for their time and effort and a voucher to cover their parking fee, for those participants who drive.

*NP.* We will be asking the MSK NP to provide feedback (via survey and interview) about her experience using HN-STAR. Through the consent process, participants will understand that their NP will be surveyed and interviewed about HN-STAR as part of the study. The NP responsible for head and neck cancer survivors will be asked to provide written consent to participate.

Aim 1: Part 2: Feasibility in clinical practice

There is a designated RSA at MSK and HH who will be responsible for recruitment, enrollment, data collection and study management at their respective site.

*Head and neck cancer survivors.* We will recruit an additional 45 survivors (30 from MSK and 15 from HH) to participate in Aim 1: Part 2 for feasibility testing. Patients who are eligible, scheduled, or due to be seen at the survivorship clinic at MSK and HH will be invited by mail to participate in the HN-STAR study. The patient will be able to opt out of the study by contacting the RSA. If the patient does not opt out, research staff at MSK or HH will follow-up with a phone call. At least three attempts will be made to reach the patient by phone. When the consenting professional at the respective site reaches the patient by phone, she will describe the study and invite interested and eligible patients to participate. The consenting professional will follow a standard consent script as described above. Patients will be consented over the phone with the RSA from their respective study site before completing the

Survivor Self-Assessment before the clinic visit. However, unlike Aim 1: Part 1, participants can complete the Survivor Self-Assessment online at home or in the waiting room before the clinic appointment.

Similar to Aim 1: Part 1, we will enrich for minorities in the MSK clinic by enrolling no more than 20 white non-Hispanic patients at MSK. After enrolling 20 white non-Hispanic patients from MSK, if we have not yet enrolled 30 total patients from MSK, we will only invite non-white or Hispanic patients to participate until 30 patients enroll. With over 20 new survivors seen in this clinic each month, this will not hinder enrollment.

At each study site, each study participant will receive $50 from the RSA at their study site to provide thanks for their time and effort immediately following completion of the final study survey. This is less than the $100 incentive for patients in Aim 1: Part 1 because the time and effort will be less for these participants.

*NP.* We will be asking the MSK and HH NP to provide feedback (via survey and interview) about their experience using HN-STAR. Through the consent process, participants will understand that their NP will be surveyed and interviewed about HN-STAR as part of the study. The NPs responsible for head and neck cancer survivors will be asked to provide written consent to participate.

*Primary care providers.* After a participant has attended the survivorship clinic visit and received the Survivorship Care Plan, their identified PCP will be mailed the Survivorship Care Plan, consistent with current practice. One week later, at each site, the RSA will contact the primary care provider associated with the participant by mail and follow up by telephone to invite them to complete an online survey. Through the consent process, patient participants will understand that their PCPs will be contacted and surveyed as part of the study. The RSA at each site will attempt to recruit all 45 primary care providers by trying to reach them by phone for at least one month but no more than 6 weeks after the initial call. We will not explicitly consent the PCP"s, because they will not provide any PHI, and the study is minimal risk. Their participation is optional, and we will consider completion of the survey as agreement to participate. We anticipate that not all 45 PCP"s will complete the survey; this is one of the feasibility benchmarks of our study.

PCP"s may complete the survey over the phone with the RSA, by paper form and return by mail, or log in to the survey. After completing the online survey, each participating primary care provider will receive a $100 electronic gift card via email to provide thanks for their time and effort. This anonymous payment procedure has been used successfully in the past as part of protocol (#X09-007, Practice-Based Research Networks (PBRN) Primary Care Providers Survey, PI: Salz).

We anticipate that we will complete recruitment for both Aim 1: Part 1 and Aim 2: Part 2 within 18 months of opening the protocol.

## 7.0 ASSESSMENT/EVALUATION PLAN

Data collection will take place at both MSK and HH by trained RSAs. Patients will be assigned a unique study identification number independent of the patients" medical record number. Data will be stored on the secure MSK network drive housed in the Department of Epidemiology and

Biostatistics at MSK. Interview data will be analyzed jointly with Columbia University, a Data Analysis site.

### 7.1 Usability Assessments

*Aim 1: Part 1: Component pilot testing.* Usability testing will evaluate how easily and appropriately users interact with each component of HN-STAR. We will recruit 10 patients from MSK‟s Head and Neck Cancer Survivorship Clinic to participate in end-user testing of the self-assessment and the Survivorship Care Plan.

***7.1.1*** *Survivor Self-Assessment (Appendix A):* Each survivor will arrive 1 hour before their scheduled routine visit at the clinic. He or she will complete the Survivor Self-Assessment with a RSA in a private room in the Survivorship Clinic before a routine visit.

***7.1.2*** *Survivor Post-Assessment Survey (Appendix D):* Participants will then complete the Survivor Post-Assessment Survey regarding perceptions of information quality, system quality, and usefulness of the Survivor Self-Assessment.[88,89] Feedback from 10 survivors should identify most usability issues with HN-STAR.[90]

***7.1.3*** *Survivor Post-Assessment Interview (Appendix N):* After the survivor completes the Survivor Self-Assessment and the Survivor Post-Assessment Survey, the RSA will interview the survivor, asking whether items were clearly presented, whether any symptoms were missed, and whether response options made sense. This conversation will supplement the Survivor Post-Assessment Survey by providing in-depth information when needed. This interview will be audio-recorded.

***7.1.4*** *Survivorship Care Plan (Appendix C).* After thePost Assessment Interview, the patient will proceed to the clinic visit room for the routine follow-up visit. The NP will use the Interactive Discussion Guide during the clinic visit, and the survivor will receive the automatically generated Survivorship Care Plan at the end of the visit.

***7.1.5*** *Survivor Post-Visit Survey (Appendix E)*: Following thevisit , the participant will return to the private room with the RSA to complete the Survivor Post-Visit Survey. The Survivor Post-Visit Survey elicits participant opinion on the role of the Survivor Self-Assessment in the clinic visit and the ease of use of, satisfaction with, and perceived usefulness of the Survivorship Care Plan.[88,89,91,92]

***7.1.6*** *Survivor Post-Visit Interview (Appendix O):* After the survivor completes the Post-Visit Survey, the RSA will interview the survivor, asking about the ease of use of, satisfaction with, and perceived usefulness of the visit and Survivorship Care Plan. This conversation will supplement the Survivor Post-Visit Survey by providing in-depth information when needed. This interview will be audio-recorded.

***7.1.7*** *Nurse Practitioner Post-Visit Survey.(Appendix F):* Directly after each clinic visit, the NP will complete one brief online survey for each participant. The Nurse Practitioner Post-Visit Survey focuses on the experience using the Interactive Discussion Guide during the visit. Specifically, it will assess whether the Interactive Discussion Guide presented a complete list of issues for the patient, whether it contained irrelevant information, and the length of the visit.[93-95] Survey responses will be recorded and stored electronically with Web Core.

***7.1.8*** *Nurse Practitioner Interview*: After all 10 participants have completed usability testing, the RSA will conduct a qualitative interview with the NP (Ms. McKiernan) to evaluate any problems with, or strengths of, the Interactive Discussion Guide and whether the usefulness or usability of the Interactive Discussion Guide varied by type of patient seen in clinic. This interview will take place with the RSA and the NP in a private office and will be audio recorded. The interview guide is included as Appendix K.

**7.2 Feasibility Assessments**

*Aim 1: Part 2: Feasibility in clinical practice*

Feasibility testing involves evaluating whether HN-STAR can move forward to evaluation in a clinical trial setting. Before beginning Aim 1: Part 2, we will address findings from Aim 1: Part 1 by making changes to HN-STAR and the accompanying surveys. This will be done once, after the completion of Aim 1: Part 1.

***7.2.1*** *Survivor Post-Assessment Survey.(Appendix D)* After integrating feedback from Aim 1: Part 1 into HN-STAR and the accompanying surveys, an additional 45 survivors (30 from MSK and 15 from HH) will be recruited and will provide informed consent over the phone (see section 6.0). The participants will complete the Survivor Self-Assessment online (on a computer or tablet, at home or in the clinic waiting room) within two weeks of a routine scheduled visit. The Survivor Post-Assessment Survey (adapted, if needed, from Aim 1: Part 1) will immediately follow the Survivor Self-Assessment.[88,89] Survey responses will be recorded and stored electronically with Web Core.

***7.2.2*** *Survivor Post-Visit Survey. (Appendix E)* When the patient comes for the visit, the RSA will be at the clinic and available to answer questions about the study and direct the integration of study flow in clinical practice as needed. Each patient will see the NP (who will use the Interactive Discussion Guide during the visit) and receive the Survivorship Care Plan. The RSA will then bring the patient to the waiting room to complete the Survivor Post-Visit Survey (adapted from Aim 1: Part 1) on a computer or IPad.[96] [88,89,91,92] Survey responses will be recorded and stored electronically with Web Core. The RSA will then provide the patient incentive when the survey is complete.

***7.2.3*** *Primary Care Provider Survey. (Appendix G)* Two weeks after the visit (when the Survivorship Care Plan is mailed to the PCP), each patients" PCP will be invited to complete a brief online survey regarding whether they received and reviewed the Survivorship Care Plan, as well as the ease of use of, satisfaction with, and perceived usefulness of the Survivorship Care Plan.[93,95,97] Survey responses will be recorded and stored electronically by Web Core. The PCP may complete the survey at any time within two months following enrollment.

***7.2.4*** *Nurse Practitioner Post-Visit Survey.(Appendix F):* Directly after each clinic visit, the NP will complete one brief online survey for each participant. The Nurse Practitioner Post-Visit Survey focuses on the experience using the Interactive Discussion Guide during the visit. Specifically, it will assess whether the Interactive Discussion Guide presented a complete list of issues for the patient, whether it contained irrelevant information, and the length of the visit.[93-95] Survey responses will be recorded and stored electronically with Web Core.

***7.2.5*** *Nurse Practitioner Interview*: After all participants in Part 2 have completed usability testing, the RSA will conduct a qualitative interview with the NPs (Ms. McKiernan and Ms. Walker) to evaluate any problems with, or strengths of, the Interactive Discussion Guide and whether the usefulness or usability of the Interactive Discussion Guide varied by type of patient seen in clinic. This interview will take place with the RSA and the NP in a private office and will be audio recorded. The interview guide is included as Appendix K.

***7.2.6.*** *Survivor Follow-up Interview:* Six months after the visit, the RSA will conduct a brief interview with the patient to determine adherence to the recommendations in the Survivoship Care Plan. Using the Survivorship Care Plan as a guide, the RSA will ask about whether the patient completed each task that was recommended and whether other providers were involved.

### *7.3* Passively Collected Data

In addition to surveys, patient and nurse practitioner data will be recorded through the web interfaces of HN-STAR. In addition, NPs will document clinic notes as part of routine care. These data will be used to inform feasibility of HN-STAR and contribute to power calculations for the future multi-site randomized controlled trial.

***7.3.1*** For all visits at MSK, preceding the patient visit, the NP will verify the Automated Treatment Checklist. When the NP makes any changes to imported data and verifies the final Treatment Checklist, these data will be collected. These data will inform the accuracy of the automatically generated treatment summary and the time required to verify the information.

***7.3.2*** For all visits at HH, preceding the patient visit, the NP will complete the Manual Treatment Checklist. Data will be collected regarding the time required to complete the checklist.

***7.3.3*** All patients will complete the Survivor Self-Assessment before their clinic visit. HN-STAR will record the amount of time taken, the items skipped, and the proportion of the Self-Assessment completed.

***7.3.4*** As part of routine care, the NP will record topics addressed and actions taken in the clinic note for each visit. Clinic notes regarding the identification and management of late effects will be abstracted.

### *7.4* Preliminary metrics for future trial

Abstracted clinic note data and HN-STAR data will inform feasibility of data collection and assess preliminary outcomes for Aim 2.

***7.4.1*** Clinic note data will be used as part of a pretest-posttest design, described in further detail in the Biostatistics section 11.3. At each clinic visit, the NP will record actions from the visit, including referrals, prescriptions, and other management plans in the clinic note as part of routine care. The RSA at each site will retrieve data regarding late effects identified and addressed in the year preceding the study visit and during the study visit, to assess changes before and after the HN-STAR intervention. The RSA will also assess

oncologic surveillance occurring in the year preceding the study visit and during the study visit from the medical record. RSAs will use the Medical Record Data Abstraction Form (Appendix H).

***7.4.2*** The receipt of routine preventive care, including cancer screening tobacco cessation, immunizations, and routine general testing, is not routinely collected in the clinic note and will instead by collected from HN-STAR. We will only collect these outcomes once (before the HN-STAR visit), and they will not serve as outcomes for the pretest-posttest study.

### 7.5 Columbia University as data analysis site

All survey data collected via WebCore will be analyzed at MSK, as will the NP interview data. Usability data and interview data with patients and the NP from Aim 1: Part 1 in the MSK survivorship clinic will be analyzed by Dr. Rebecca Schnall at Columbia University. All of the data will be identified by a unique participant identifier and the date of assessment. Data will be stored at MSK and shared with Dr. Schnall using the MSK secure file-transfer system, ShareBox.

## 8.0 TOXICITIES/SIDE EFFECTS

We do not anticipate any toxicities or side effects from participating in this study. Although unlikely, there is a chance patients may experience emotional distress while discussing their symptoms or health condition. In any case of participant distress, we will encourage the patient to discuss his or her concerns with the NP, or other members of the clinical team. Referral to appropriate staff will be facilitated if necessary including social work, psychology or psychiatry.

## 9.0 PRIMARY OUTCOMES

The following table shows the timing of each assessment in the study. The content and sources for each assessment are described in Section 7.1, 7.2, 7.3, and 7.4 above.

***Figure 4. Outcome collection***

| **Assessment** | **Source** | **Timing (including end of data collection window)** |
|---|---|---|
| **Aim 1: Part 1: Component pilot testing** | | |
| Survivor Post-Assessment Survey | Patient | Upon completion of Survivor Self-Assessment |
| Survivor Post-Assessment Interview | Patient | Upon completion of Survivor Post-Assessment Survey |
| Survivor Post-Visit Survey | Patient | After clinic visit, and after receiving Survivorship Care Plan |
| Survivor Post-Visit Interview | Patient | Upon completion of Survivor Post-Visit Survey |
| Nurse Practitioner Post-Visit Survey | NP | Following each clinic visit, within 2 days of clinic visit |
| Nurse Practitioner Interview | NP | After 10 patients have completed Aim 1: Part 1, within 1 month of last patient completing Aim 1: Part 1 |
| **Aim 1: Part 2: Feasibility in Clinical Practice** | | |

| Assessment | Source | Timing (including end of data collection window) |
|---|---|---|
| Survivor Post-Assessment Survey | Patient | Upon completion of Survivor Self-Assessment, before the clinic visit |

***Figure 4 continued. Outcome collection***

| Assessment | Source | Timing (including end of data collection window) |
|---|---|---|
| Survivor Post-Visit Survey | Patient | Following clinic visit, before leaving clinic |
| Primary Care Provider Survey | PCP | At least one week after being mailed Survivorship Care Plan, within a month of enrollment into study |
| Passively collected feasibility metrics | HN-STAR | Immediate concurrent data collection via Webcore |
| Nurse Practitioner Interview | NP | After 30 patients have completed Aim 1: Part 2 at MSK and 15 patients have completed Aim 1: Part 2 at HH, within 1 month of last patient completing Aim 1: Part 2 at the respective site |
| Survivor Follow-up Interview | Patient | Six months after the clinic visit |
| **Preliminary metrics for future trial (Aim 2)** | | |
| Oncologic metrics: Late effects identified and addressed, receipt of head and neck surveillance and appropriate follow-up (e.g. dental exam for those who underwent radiation therapy) | Clinic notes, prescriptions or referrals | Abstracted from any time in the year before the visit (pretest) and in the note pertaining to the clinic visit (posttest) |
| Non-oncologic metrics: Receipt of routine preventive care (e.g., cancer screening, tobacco cessation) | Survivor Self-Assessment | After completion of the Survivor Self-Assessment |

## 10.0 CRITERIA FOR REMOVAL FROM STUDY

In the unlikely event that researchers or the NP observe acute individual distress during the interviews or clinic visit, they will ask participants whether they wish to continue. Researchers will conclude the interview upon participant request. The patient may voluntarily discontinue participation in the study at any time.

## 11.0 BIOSTATISTICS

***11.1*** **Sample size.** This feasibility study is not powered to test formal hypotheses. Instead, it will provide feedback regarding the HN-STAR process. We will enroll 10 patients in Aim 1: Part 1. In Aim 1: Part 2, we will enroll 45 additional patients: 30 from MSK and 15 from HH. The MSK clinic sees over 20 patients per month, ensuring that enrollment is attainable. The HH clinic sees approximately 8 patients per month. We anticipate that enrolling 45 patients will not take longer than 6 months. Enrolling PCPs may be more difficult; we anticipate that not all 45 PCPs will complete the Primary Care Provider Survey. Part of our feasibility study is to test whether this method of recruitment and level of incentives will be adequate to recruit PCPs in a future study, and the level of participation will inform this feasibility outcome. Both NPs are integrally involved in implementing HN-STAR in their clinics.

### *11.2* Analysis Aim 1: Parts 1 and 2

The structured survey questions (asked of survivors, NPs, and PCPs in Aim 1: Parts 1 and 2) will be summarized using descriptive statistics. Quantitative outcomes will include survivors‟ rates of completion of the self-assessment, survey completion rates for survivor, NP, and Primary Care Provider Surveys in the feasibility study.[98] The number of questions to answer is different between surveys and even between respondents, based on skip patterns built into the electronic survey platform. Each survey will be considered complete if at least 75% of questions that are asked are answered. WebCore will automatically capture the percentage of questions that are answered for each survey administered. We will also look at survivor responses by race and ethnicity. Other quantitative outcomes include the median time survivors required to complete the self-assessment, the accuracy of the automated treatment summary (verified against the EMR), the time required for NP verification of the treatment summary, and the length of HN-STAR visits.

Each component of HN-STAR will be evaluated individually for feasibility. We will consider the Survivor Self-Assessment feasible for subsequent effectiveness testing if the following criteria are met:

- >75% survivors completed >75% of self-assessment. The survivor self-assessment has multiple components that include a total of 47 items for men and 49 items for women. We will only include items that are asked of every participant (i.e. no sub questions) for this metric. We will consider 75% of the self-assessment complete if 36 items (for men) and 37 items (for women) are completed.
- The mean proportion of assessment completed >75%.
- The median time to complete self-assessment <15 minutes.
- >50% of survivors rate the Self-Assessment visit positively on the Survivor Post Assessment Survey (Appendix D). For items #13, a response of “No” is positive, for item #14, a response of “yes” is positive, for item #15, a response of ”Just right” is positive, and for items 16-18, a response of “Agree” or “Strongly agree” is positive. We will consider a positive overall rating if >50% of responses are positive.

We will consider the Automated Treatment Checklist feasible if the following criteria are met:

- >90% of the treatment summaries were deemed accurate .
- The median time to verify the summary <20 minutes.

We will consider the Manual Treatment Checklist feasible if the following criteria are met:

- The median time to complete <30 minutes. (In practice, survivorship care plans typically take an hour or more to complete.[46])

The Interactive Discussion Guide will be considered feasible if the following criteria are met:

- >75% of discussion guides did not miss relevant information. We will determine whether relevant information was covered using item #6 from the Nurse Practitioner Survey (Appendix F) for this metric. Responses of "Agree" or "Strongly agree" to the item, "the discussion guide missed important information about the patient will be measured as missing relevant information.
- >50% of survivors rate the survivorship visit positively on the Survivor Post Assessment Survey (Appendix E). For items #1-8, a response of "Agree" or "Strongly agree" is positive. We will consider a positive overall rating if >50% of responses are positive.
- The median visit time <50 minutes (current visit time average is 40 minutes).

The Survivorship Care Plan will be deemed feasible if the following criteria are met:

- >50% of survivors rate the Survivorship Care Plan positively. For survivors, item response will be defined as positive if they report that they strongly agree or agree with the items #25-29 on the Survivor Post-Visit Survey (Appendix E). A survivor will be considered as having a positive overall rating of the Survivorship Care Plan if at least 3 of the five responses are positive.>50% of primary care providers rate the Survivorship Care Plan positively. For primary care providers, item response will be defined as positive if they report that they strongly agree or agree on items #2, 4-6, 8-14. Because of the wording, for items #3 and 7 responses of disagree or strongly disagree will defined as positive on the Primary Care Provider Survey (Appendix G). If at least 7 of 13 items are positive, we will consider this a positive overall rating to the survivorship care plan.
- If any component does not meet all criteria, we will consider further adapting the component as needed and testing them further in a future protocol.

We will use qualitative data from study interviews to supplement our understanding of usability issues for both the NP and survivors in Aim 1: Part 1. We will use grounded theory to identify salient themes regarding the usability of the Survivor Self-Assessment, the Automated Treatment Checklist, the Interactive Discussion Guide, and the Survivorship Care Plan from the perspectives of both the survivors and the NP.

***11.3* Analysis Aim 2: Collection of preliminary metrics of health care actions.** As described in Section 9.0, relevant metrics for Aim 2 are both oncologic and non-oncologic. We will collect oncologic metrics from any clinic notes that appear in the patient"s chart in the year preceding the HN-STAR visit and for the HN-STAR visit itself. Non-oncologic metrics will be collected only from the HN-STAR patient assessment completed before the HN-STAR visit. We will use descriptive statistics to report receipt of oncologic and non-oncologic care.

Also as described in Section 9.0 and listed completely in Appendix H, oncologic outcomes include late effects (symptoms) **identified** and **addressed**, receipt of head and neck surveillance and appropriate follow-up (e.g. dental exam for those who underwent radiation therapy). Non-oncologic outcomes include receipt of recommended routine preventive care (e.g., cancer screening, tobacco cessation).

**11.3.1 Oncologic outcomes.** We will only investigate late effects that we assess in HN-STAR. (If usability testing identifies additional late effects we did not target in our Survivor Self-Assessment, we will add them to the Survivor Self-Assessment for Aim 1: Part 2 and include them in Appendix H.) For each late effect, we will consider it identified if it was mentioned in a clinic note, and we will consider it addressed if there was a referral,

recommendation, education, or explicit acknowledgement of inaction. (Inaction may be appropriate, because in some cases, when symptoms are persistent and intractable, no intervention may be recommended.) For each patient, we will first count the number of late effects identified. We will then calculate the proportion of identified late effects that are addressed.

We will use descriptive statistics to report each element of oncologic care listed in Appendix H (i.e. smoking cessation, dental exam, blood work for thyroid studies, endoscopic exam, and head and neck physical exam). Each patient may not require every element of follow-up, depending on their primary tumor site or treatment received. We will use the number of recommended elements of care as the denominator, and we will calculate the proportion of these elements that are performed.

**11.3.2 Non-oncologic outcomes.** The non-oncologic outcomes in HN-STAR are collected only once. They include cancer screening, vaccination, and other preventive care elements that are explicitly collected in the Survivor Self-Assessment. Only some of these elements will be recommended for each patient, depending on their age, sex, and behaviors. We will calculate the proportion of recommended elements of non-oncologic care that are performed per patient. In addition, for each element of non-oncologic care, we will calculate the proportion of patients who receive it as recommended.

Findings from Aim 2 will inform whether these metrics can be collected from the EMR and HN-STAR. In addition, they will inform the statistical analysis for the future trial. For oncologic metrics only (Section 9.0, Figure 4), we will calculate the difference before HN-STAR use and after. Differences in oncologic metrics will be used in the power calculation for the proposed randomized trial. Non-oncologic metrics will be reported descriptively to inform the feasibility of collecting these data from self-report.

***11.4*** **Adaptation of and advance of HN-STAR.** If HN-STAR is deemed feasible for further effectiveness testing, we will use our findings to adapt the content of HN-STAR. We will then advance HN-STAR to a randomized clinical trial to assess its effectiveness in improving the health outcomes assessed in Aim 2.

## 12.1 RESEARCH PARTICIPANT REGISTRATION AND RANDOMIZATION PROCEDURES

### 12.2 Research Participant Registration

Confirm eligibility as defined in the section entitled Criteria for Patient/Subject Eligibility.

Obtain informed consent, by following procedures defined in section entitled Informed Consent Procedures.

During the registration process registering individuals will be required to complete a protocol specific Eligibility Checklist.

The individual signing the Eligibility Checklist is confirming whether or not the participant is eligible to enroll in the study. Study staff are responsible for ensuring that all institutional requirements necessary to enroll a participant to the study have been completed. See related Clinical Research Policy and Procedure #401 (Protocol Participant Registration).

### 12.3 Randomization

Participants in this study will not be randomized.

## 13.1 DATA MANAGEMENT ISSUES

### 13.1.1 Data and Source Documentation

The participating site(s) will enter data remotely into an electronic database using the internet based systems, HN-STAR, which operates using Web Core. Data entry guidelines have been generated for this study and site staff will receive database training prior to enrolling its first participant. The participating site PI is responsible for ensuring these forms are completed accurately and in a timely manner. A schedule of required forms is shown in section 13.0.3. In addition, research staff at MSK will maintain a minimal CRDB dataset for both sites.

An RSA will be assigned to the study at each site. The responsibilities of the RSA include project compliance, data collection, abstraction and entry, data reporting, regulatory monitoring, problem resolution and prioritization, and coordinate the activities of the protocol study team.

Online data collected using the following study assessments at MSK and HH will be stored with Web Core as described in sections 7.1, and 7.2:

- Survivor Self-Assessment (Appendix A)
- Treatment Checklist (Appendix B)
- Survivor Post-Assessment Survey (Appendix D)
- Survivor Post-Visit Survey (Appendix E)
- Nurse Practitioner Post-Visit Survey (Appendix F)
- Primary Care Provider Survey (Appendix G)

Similarly, data collected during the NP Interview, the Survivor Post-Assessment Interview, and the Post-Visit Interview will be stored in a secure folder in the Department of Epidemiology & Biostatistics at MSK. Only study investigators and research staff at MSK will have access to the folder. All of the data will be identified by a unique participant identifier and the date of assessment.

Passively collected data described in section 7.3 will be recorded through the web interfaces of HN-STAR and in clinic notes. Some data from the following components will be collected passively:

- Treatment Checklist (Appendix B) (e.g., time required to complete or verify)
- Survivor Self- Assessment (Appendix A) (e.g., time required to complete, proportion completed)
- Clinic notes regarding late effects will be abstracted.

As described in section 7.4, the Medical Record Data Abstraction Form (Appendix H) will be completed by the RSAs at MSK and HH after each participant has completed participation. This Word document will be stored on secure folders at MSK and HH. Only investigators and research staff will have access to these folders. The completed Medical Record Data Abstraction Word document will be sent to MSK from HH using Sharebox.

### 13.1 Quality Assurance

Registration reports will be generated to monitor patient accruals and completeness of registration data. The RSA will conduct monthly data quality scans to check the accuracy and completeness of data entry in HN-STAR and Medical Record Data Abstraction Forms. The principal investigator will regularly review registration report and data quality scans with the RSA.

In addition to registration reports and data quality scans, elements of the data process will be designed to minimize inaccuracies and inconsistencies and to maximize completeness. The databases created by HN-STAR will also be designed to automatically notify the person entering data when fields have been left blank or if the entry is out of a designated range.

Random-sample data quality and protocol compliance audits will be conducted by the study team on an annual basis.

### 13.2 Data and Safety Monitoring

The Data Safety and Monitoring (DSM) Plans at Memorial Sloan Kettering Cancer Center were approved by the National Cancer Institute in September 2001. The plans address the new policies set forth by the NCI in a document entitled “Policy of the National Cancer Institute for Data and Safety Monitoring of Clinical Trials.” The DSM Plans at MSK were established and are monitored by the Office of Clinical Research. The MSK Data and Safety Monitoring Plans can be found on the MSK Intranet at https://one.mskcc.org/sites/pub/clinresearch/Documents/MSKCC%20Data%20and%20Safety%20Monitoring%20Plans.pdf.

There are several different mechanisms by which clinical trials are monitored for data, safety and quality. There are institutional processes in place for quality assurance (e.g., protocol monitoring, compliance and data verification audits, therapeutic response, and staff education on clinical research quality assurance) and departmental procedures for quality controls, as well as two institutional committees that are responsible for monitoring the activities of our clinical trials programs. The committees – Data and Safety Monitoring Committee (DSMC) for Phase I and II clinical trials, and the Data and Safety Monitoring Board (DSMB) for Phase III clinical trials – report to the Center"s Research Council and Institutional Review Board. During the protocol development review process, each protocol will be assessed for its level of risk and degree of monitoring required. Every type of protocol (e.g., NIH sponsored, in-house sponsored, industrial sponsored, NCI cooperative group, etc.) will be addressed and the monitoring procedures will be established at the time of protocol activation.

The Principal Investigator at MSK and site investigators will provide oversight and monitoring of all data collection. Forms will be kept in a secured location and will be available only to study members. The study team will have access to participants" PHI.

## 13.3 Regulatory Documentation

Prior to implementing this protocol at MSK, the protocol, informed consent form, HIPAA authorization and any other information pertaining to participants must be approved by the MSK Institutional Review Board/Privacy Board (IRB/PB).

MSK Alliance sites will rely on the MSK IRB. Prior to implementing this protocol at a participating MSK Alliance site, all internal site approvals (e.g., HSP training and conflict of interest review) must be on file at MSK, and the MSK IRB must have granted approval for the site to open. Alliance site‟s compliance to Health Insurance Portability and Accountability Act (HIPAA) will be ensured by the Alliance site‟s privacy board.

Upon receipt of the required documents, MSK will formally contact the MSK Alliance site and grant permission to proceed with enrollment.

**Amendments**

Each change to the protocol document must be organized and approved by the MSK IRB/PB before changes can be implemented at the Alliance site.. Upon receipt of MSK IRB/PB approval, MSK will notify the MSK Alliance site.

**Continuing Review Approval**

The MSK IRB will review the study at least annually. The MSK primary site is responsible for submitting continuing review reports to the MSK IRB/PB.

**Deviations and Violations**

A protocol deviation on this study is defined as any incident involving noncompliance with an IRB approved protocol. Deviations typically do not have a significant effect on the rights, safety, or welfare of research participants or on the integrity of the resultant data. Deviations may be intentional or unintentional and they may be identified before or after they occur (prospective or retrospective).

A prospective deviation is any event that impacts eligibility, informed consent, or the intervention. IFor MSK sponsored multicenter studies, prospective deviations at the participating sites must be approved by the MSK IRB prior to implementation at the site; and reported to the site IRB according to site guidelines.

Retrospective deviations are all other deviations that do not adversely affect the rights, safety, or welfare of participants and do not result in a complete modification to the IRB approved protocol.

Retrospective deviations that represent non-compliance, unanticipated problems involving risks to participants or others, or serious adverse events will be reviewed in accordance with their respective policies and procedures. For MSK sponsored multicenter studies, retrospective deviations at the participating sites should be reported to the MSK IRB per the guidelines in this document and reported to the site IRB according to site guidelines.

**Document maintenance**

The MSK PI and the MSK Alliance Site PI will maintain adequate and accurate records to enable the implementation of the protocol to be fully documented and the data to be subsequently verified.

A regulatory binder for each MSK Alliance site will be maintained onsite at the MSK Alliance site. An electronic regulatory binder will also be maintained at MSK.

After study closure, the participating site will maintain all source documents, study related documents and CRFs for 3 years.

**Noncompliance**

If a MSK Alliance site is noncompliant with the protocol document, accrual privileges may be suspended and/or contract payments may be withheld (if applicable), until the outstanding issues have been resolved.

## 14.1 PROTECTION OF HUMAN SUBJECTS

We aim to protect the rights of the participants with a comprehensive informed consent procedure. A printed consent form and letter of invitation will be provided to all participants (including primary care providers). The PIs and RSA will be available to respond to questions or concerns of the participants. Individuals will be informed that participation is voluntary. The purpose of the study and potential risks and benefits will be explained during the informed consent process. All potential patients will be informed as to their rights as volunteers in a research study. The right to refuse or withdraw at any point during the study, without compromising medical and other care will be explained. The purpose of the study and potential risks and benefits associated with it will be stated.

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 anticipated toxicities or side effects from this nontherapeutic study. We do not anticipate any serious adverse events needing to be reported. However, a patient could experience severe anxiety, for example, when reporting any current symptoms. If such an SAE occurs, we will report it as described in section 14.2 below.

As an alternative to participation, any patient may choose not to participate or to terminate participation at any time. The patient would then receive usual care in the survivorship clinic. Participation is completely voluntary. We will inform patients of this during the informed consent process.

Participants may benefit from this study. The NP will receive an Interactive Discussion Guide summarizing medical history, relevant symptoms, and recommendations for care (including symptom management, routine oncologic follow-up, and recommended preventive care). This may help the NP and survivor focus on the most salient issues while promoting the survivor‟s involvement in his or her care. This may also serve to ensure adherence to current guidelines and promote standardized care for survivors. After the visit, the cancer survivors will receive a Survivorship Care Plan with a plain-language treatment summary and personalized recommendations for ongoing care, which may help the survivors, their primary care providers, and oncology providers plan ongoing management strategies. In Aim 1: Part 2, participants‟ primary care providers will also receive a Survivorship Care Plan. In addition, survivors will have the opportunity to report their symptoms, engaging the patient in their survivorship care. Further, for the NP who is tasked with providing Survivorship Care Plans as part of routine care in the survivorship clinic, HN-STAR alleviates or minimizes the burden of manual data entry. For primary care providers, they will receive personalized information to help guide the ongoing care of their patients who completed treatment for head and neck cancer.

Another benefit is the knowledge gained from the study. Following curative therapy, head and neck cancer survivors can face significant challenges that impact both quality of life and overall survival. HN-STAR may improve our ability to address oncologic and non-oncologic issues – including surveillance for recurrence, management of late effects of therapy, screening for second cancer, and prevention and treatment of co-morbid illness – during routine survivorship care. This study will evaluate if HN-STAR is feasible in actual practice, if it improves the care provided during the clinical encounter, and if the resulting Survivorship Care Plan is useful to stakeholders. Results from this study will provide critical feedback for modifying HN-STAR and implementing and evaluating it as an intervention in a future multi-center trial.

There will be no financial costs or burdens to the participants. For those participants in Aim 1: Part 1, who are asked to arrive for their clinic visit one hour early and stay 30 minutes after, and who drive to their visit will receive payment for parking as an incentive to participate.
Confidentiality will be maintained at all times during the study administration. The WebCore platform has been reviewed by the MSKCC Information Security Department and conforms to current MSK and HIPAA standards for the protection of PHI. Participant interviews will take place in a private clinic room. Participants will be informed that information collected during their participation in this study is considered confidential. All data gathered will be kept in a secured location. Confidentiality of each participant‟s data will be protected with utmost care. Participants will specifically not be identified in manuscripts or public presentations.

### 14.2 Privacy

MSK‟s Privacy Office may allow the use and disclosure of protected health information pursuant to a completed and signed Research Authorization form. The use and disclosure of protected health information will be limited to the individuals described in the Research Authorization form. A Research Authorization form must be completed by the Principal Investigator and approved by the IRB and Privacy Board (IRB/PB).

### 14.3 Serious Adverse Event (SAE) Reporting

It is not anticipated that any SAEs will result from the processes described in this protocol (i.e., related to completing online assessments and interviews). A hypothetical example, albeit unlikely,

might be severe anxiety or distress as a result of the completing the surveys. Although it will be the responsibility of the investigators to report any such SAE resulting from processes described in this protocol, it will not be their responsibility to report serious adverse events related to treatments or underlying disease in patients who are participating in this study. Patients enrolled in this study may be receiving treatments for cancer late effects or other conditions, but these treatments are not directed or provided by the research described in this protocol, and are at the discretion of clinical staff separate from the investigators on this study. Adverse events related to those interventions should be managed by the clinical staff as a part of standard care, via routine approaches.

An adverse event is considered serious if it results in ANY of the following outcomes:

- Death
- A life-threatening adverse event
- An adverse event that results in inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- Important Medical Events (IME) that may not result in death, be life threatening, or require hospitalization may be considered serious when, based upon medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition

Note: Hospital admission for a planned procedure/disease treatment is not considered an SAE.

SAE reporting is required as soon as the participant signs consent. SAE reporting is required for 30-days after the participant"s last investigational treatment or intervention. Any events that occur after the 30-day period and that are at least possibly related to protocol treatment must be reported.

If an SAE requires submission to the IRB office per IRB SOP RR-408 „Reporting of Serious Adverse Events", the SAE report must be sent to the IRB within 5 calendar days of the event. The IRB requires a Clinical Research Database (CRDB) SAE report be submitted electronically to the SAE Office as follows:

For IND/IDE trials: Reports that include a Grade 5 SAE should be sent to saegrade5@mskcc.org. All other reports should be sent to saemskind@mskcc.org.

For all other trials: Reports that include a Grade 5 SAE should be sent to saegrade5@mskcc.org. All other reports should be sent to sae@mskcc.org.

The report should contain the following information:

Fields populated from CRDB:

- Subject"s initials
- Medical record number

- Disease/histology (if applicable)
- Protocol number and title

Data needing to be entered:

- The date the adverse event occurred
- The adverse event
- The grade of the event
- Relationship of the adverse event to the treatment (drug, device, or intervention)
- If the AE was expected
- The severity of the AE
- The intervention
- Detailed text that includes the following
    - A explanation of how the AE was handled
    - A description of the subject‟s condition
    - Indication if the subject remains on the study
- If an amendment will need to be made to the protocol and/or consent form
- If the SAE is an Unanticipated Problem

The PI‟s signature and the date it was signed are required on the completed report.

**SAE Reporting for MSK Alliance Sites**

- MSK Alliance sites must adhere to the SAE reporting requirements under the MSK IRB. Sites should use the SAE Report Form found in MSK‟s internet-based Clinical Research Database, CRDBi-Multicenter to report SAEs to MSK as detailed above.
- MSK Alliance sites are responsible for reporting all SAEs to the MSK PI via e-mail within 3 calendar days of learning of the event.
- When a death is unforeseen and indicates participants or others are at increased risk of harm, the MSK Alliance sites should notify the MSK PI as soon as possible but within 24 hours of the time the site becomes aware of the event.
- MSK Alliance sites should also report SAEs to their own IRB per local guidelines.
- Local IRB SAE approvals/acknowledgments must be sent to the MSK Alliance Program Manager upon receipt.

**Responsibilities of MSK**

- The MSK PI is responsible for informing all MSK Alliance sites about unexpected SAEs that are either possibly, probably, or definitely related to the study intervention within 30 days of receiving the stamped SAE from the MSK IRB/PB.
  The MSK PI is responsible for informing all sites within 24 hours or on the next business day about a death that is unforeseen and indicates participants or others are at increased risk of harm.

**Safety Reports**

MSK must submit outside safety reports to the MSK IRB/PB according to institutional guidelines. The MSK PI will notify the MSK Alliance site PIs of any safety report requiring a protocol amendment as soon as possible. All outside safety reports will be made available to the MSK Alliance sites.

**14.2.1**

Not applicable

## 15.1 INFORMED CONSENT PROCEDURES

Before protocol-specified procedures are carried out, consenting professionals will explain full details of the protocol and study procedures as well as the risks involved to participants prior to their inclusion in the study. Participants will also be informed that they are free to withdraw from the study at any time. All participants must sign an IRB/PB-approved consent form indicating their consent to participate. This consent form meets the requirements of the Code of Federal Regulations and the Institutional Review Board/Privacy Board of this Center. The consent form will include the following:

1. The nature and objectives, potential risks and benefits of the intended study.
2. The length of study and the likely follow-up required.
3. Alternatives to the proposed study. (This will include available standard and investigational therapies. In addition, patients will be offered an option of supportive care for therapeutic studies.)
4. The name of the investigator(s) responsible for the protocol.
5. The right of the participant to accept or refuse study interventions/interactions and to withdraw from participation at any time.

Before any protocol-specific procedures can be carried out, the consenting professional will fully explain the aspects of patient privacy concerning research specific information. In addition to providing verbal consent, all participants must agree to the Research Authorization component of the informed consent form.

Each participant will provide verbal consent prior to participation and the consenting professional will sign the verbal script. The participant will receive a written copy of the informed consent.

*In following the Code of Federal Regulations Title 45, Part 46, Subpart A, which states that an IRB may waive the requirement for an investigator to obtain a signed consent form for some or all subjects if it finds that the research presents no more than minimal risk of harm to subjects*

*and involves no procedures for which written consent is normally required outside of the research context, a signed consent may not be required for this study.*

As described in Section 6.0, we will obtain informed consent for the NP, but not for the PCP"s.

For MSK Alliance sites, the investigators will be listed on the site-specific Alliance face sheet and approved by the MSK IRB.

A copy of the verbal consent, signed by the consenting professional, should be maintained on file at MSK. Another copy will be confidentially maintained by the MSK Alliance site.

A note will be placed in the medical record documenting that informed consent was obtained for this study, and that the participant acknowledges the risk of participation.

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## 17.0 APPENDICES

Appendix A: Survivor Self-Assessment
Appendix B: Treatment Checklist
Appendix C: Survivorship Care Plan (Template)
Appendix D: Survivor Post-Assessment Survey
Appendix E: Survivor Post-Visit Survey
Appendix F: Nurse Practitioner Post Visit-Survey
Appendix G: Primary Care Provider Survey
Appendix H: Medical Record Data Abstraction Form
Appendix I: Sample Recruitment LetterPart 1
Appendix J: Sample Recruitment LetterPart 2
Appendix K: Nurse Practitioner Interview Guide
Appendix L: Sample Primary Care Provider Letter
Appendix M: Interactive Discussion Guide
Appendix N: Survivor Post-Assessment Interview
Appendix O: Survivor Post-Visit Interview
Appendix P: Voicemail Script

Appendix Q: Survivor Self-Assessment Follow-up Part 2