UNIVERSITY of MARYLAND BALTIMORE

Date: Thursday, October 17, 2024 12:23:37 PM Print Close

HP-00100473 Introduction Page_V2

Introduction Page

1 * Abbreviated Title:
Leveraging technology to address health outcomes of cancer survivors (POSTHOC)

2 * Full Title:
Leveraging Technology to Address POST-Treatment Health Outcomes of Cancer Survivors (POSTHOC-II): A Phase II Survivorship Care Plan Randomized Controlled Trial (GCCC2280)

3

* Select Type of Submission:

- (●) **IRB Application**
- ( ) Humanitarian Use Device (for FDA approved Indication & non-research purposes ONLY)
- ( ) Single Patient Expanded Access (pre-use)
- ( ) Single Patient Emergency Use (post-use)
- ( ) Unsure if this proposal requires IRB review (Not Human Subject Research)

Note: The Type of Submission cannot be changed after this application has been submitted for review.

4 Original Version #:
21OCT2022

ID: VIEW4DF8709A33C00
Name: v2_Introduction Page

Research Team Information

1 * Principal Investigator - Who is the PI for this study (person must have faculty status)? ***Faculty status is defined as being a full-time (>51% effort) faculty member holding one of the following titles at UM: Professor; Associate Professor; Assistant Professor.***
Amber Kleckner

CITI Training: ID00012414

1.1 * Does the Principal Investigator have a potential conflict of interest, financial or otherwise, related to this research?
◯ Yes ● **No**

2 Point of Contact - Who is the alternative point of contact for the PI? This person can be a study coordinator or any other study team member. In case the IRB cannot contact the PI, this person is a secondary person to contact:
Carin Clingan

CITI Training: ID00013429

2.1 Does the Point of Contact have a potential conflict of interest, financial or otherwise, related to this research?
◯ Yes ● **No**

3 Other Team Members - list all additional members of the research team for this study. DO NOT include the PI or POC in this list:

	Name	Edit Submission	cc on Email	Research Role	Has SFI?	CITI Training
View	Javier Rosales	no	no	Study Coordinator	no	ID00014393
View	Nicolette McGeorge	no	no	Research Team Member	no	ID00014198
View	Howard Rafal	no	no	Technician or Assistant	no	ID00013448
View	Cynthia Renn	no	no	Research Team Member	no	ID00009037
View	Shijun Zhu	no	no	Statistician	no	ID00004186
View	Ahleah Gavin	no	no	Research Team Member	no	ID00009862
View	Paula Rosenblatt	no	no	Research Team Member	no	ID00005264
View	IKMAT ADESANYA	yes	no	Study Coordinator	no	ID00016576
View	Maria Rangwala	no	no	Study Coordinator	no	ID00019750
View	Lauren Quick	no	no	Study Coordinator	no	ID00019912
View	Phillip Desrochers	no	no	Research Team Member	no	ID00019950

IMPORTANT NOTE: All research team members (including PI) must have current CITI and HIPAA training completed.

ID: VIEW4DF85C16F2800
Name: v2_Research Team Information

Resources

If this study is a collaborative UM/VA study, please clarify which resources are being used at each institution.

1 * Describe the time that the Principal Investigator will devote to conducting and completing the research:
The principal investigator will devote 20-30% effort (equivalent to 8-12 hours per week) to this project for the duration of the study to conduct and complete the research.

2 * Describe the facilities where research procedures are conducted:
This study will be conducted out of the University of Maryland School of Nursing (SON). Recruitment will occur primarily from the University of Maryland Greenebaum Comprehensive Cancer Center (UMGCCC) in Baltimore, MD, as well as UMMS satellite sites. Dr. Kleckner has sufficient office space, computers, locked cabinets, and other resources to conduct this study. Dr. Kleckner has access to a dedicated clinical testing room on the 7th floor of the School of Nursing to conduct consents and perform study activities if a participant elects to come in.

3 * Describe the availability of medical and/or psychological resources that subjects might need as a result of anticipated consequences of the human research:
We do not anticipate the need for additional medical or psychological resources due to participation in this study. However, if the need arises, participants will have access to all of the medical and psychological resources available at the University of Maryland Greenebaum Comprehensive Cancer Center (UMGCCC) and the University of Maryland Medical Center (UMMC) more broadly. Participants who experience emotional distress while completing study procedures will be referred to their healthcare provider. In the case of a medical or psychiatric emergency (e.g., verbalization of suicidal thoughts), we will call 911 and ensure safe transport of the participant to a hospital.

4 * Describe the process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions:
Dr. Kleckner will oversee all training of the study team members to ensure proper execution of the consent process and research procedures. All members of the study team will have working knowledge of the protocol and expert knowledge in the areas in which they are directly involved. Dr. Kleckner will meet with the study coordinator(s) at least every two weeks and more frequently as needed to discuss the progress and logistics of the study. Dr. Kleckner will meet with the other members of the study team at a frequency that is decided upon initiation of their involvement, based on their individual role.

ID: VIEW4DF83CB976400
Name: v2_Resources

Sites Where Research Activities Will Be Conducted

1 * Is this study a:

- ○ Multi-Site
- ● **Single Site**

2 * Are you relying on an external IRB (not UM) to be the IRB of Record for this study?

○ Yes ● **No**

3 * Are any other institutions/organizations relying on UM to be the IRB of Record for this study?

○ Yes ● **No**

3.1 Attach the applicable regulatory documents here (i.e., IRB Authorization Agreement (IAA), FWA, local ethics approval, other IRB approvals, etc.). Final UM approval will be contingent upon final execution of all required regulatory approvals:

Name	Created	Modified Date

There are no items to display

4 * Is UM the Coordinating Center for this study? (Applicable for multi-site studies. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.)

○ Yes ● **No**

5 Is VA the Coordinating Center for this study? (Applicable for Collaborative studies between the VA, UM and other sites. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project)

○ Yes ● **No**

6 * Institution(s) where the research activities will be performed:

- ☑ **University of Maryland, Baltimore**
- ☑ **University of Maryland, Upper Chesapeake Kaufman Cancer Center**
- ☐ VAMHCS
- ☐ UMB School of Medicine
- ☑ **Marlene and Stewart Greenebaum Cancer Center**
- ☐ University Physicians Inc.
- ☐ Shock Trauma Center
- ☐ General Clinical Research Center (GCRC)
- ☐ Maryland Psychiatric Research Center (MPRC)
- ☐ Johns Hopkins
- ☐ International Sites
- ☐ UMB Dental Clinics
- ☐ Center for Vaccine Development
- ☐ Community Mental Health Centers
- ☐ Private Practice in the State of Maryland
- ☐ Institute of Human Virology (IHV) Clinical Research Unit
- ☐ Joslin Center
- ☐ UMB Student Classrooms
- ☐ National Institute of Drug Abuse (NIDA)
- ☐ National Study Center for Trauma and EMS
- ☐ Univ of MD Cardiology Physicians at Westminster
- ☐ Nursing Homes in Maryland
- ☐ University of Maryland Biotechnology Institute
- ☐ Maryland Department of Health
- ☑ **Maryland Proton Treatment Center**

- [ ] Mount Washington Pediatric Hospital
- [ ] Institute of Marine and Environmental Technology (IMET)
- [ ] Other Sites
- [x] **University of Maryland Medical System (Select below)**

* UMMS Sites:

- [ ] University of Maryland Medical Center
- [ ] UMMC Midtown Campus (formerly Maryland General Hospital)
- [x] **UM St. Joseph Medical Center**
- [x] **UM Baltimore Washington Medical Center**
- [ ] UM Capitol Region Health
- [ ] UM Charles Regional Medical Center
- [ ] UM Shore Medical Center at Easton
- [ ] UM Shore Medical Center at Chestertown
- [ ] UM Shore Medical Center at Dorchester
- [ ] UM Shore Emergency Center at Queenstown
- [x] **UM Shore Regional Health**
- [ ] University of Maryland Rehabilitation & Orthopaedic Institute (formerly Kernan Hospital)
- [x] **UM Upper Chesapeake Health**
- [ ] UM Upper Chesapeake Medical Center
- [ ] UM Harford Memorial Hospital
- [ ] University of Maryland Community Medical Group

ID: VIEW4DF870DF2C000
Name: v2_Sites Where Research Activities Will Be Conducted

Funding Information

1 * Indicate who is funding the study:

- [x] **Federal**
- [ ] Industry
- [ ] Department / Division / Internal
- [ ] Foundation
- [ ] Private
- [ ] State Agency

2 * What portion of the research is being funded? (Choose all that apply)

- [ ] Drug
- [ ] Device
- [x] **Staff**
- [x] **Participant Compensation**
- [x] **Procedures**
- [x] **Other**

3 Please discuss any additional information regarding funding below:

This study is being supported by NIH NCI with an SBIR grant to Charles River Analytics; UMB is a subcontract.

ID: VIEW4DF85DF452400
Name: v2_Funding Information

DHHS Funded Study

You indicated that this is a Federally funded study.

1 * Is this study sponsored by a Department of Health and Human Services (DHHS) agency?

● **Yes** ○ No

2 You may upload any grant documents here:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4DF87B9560800
Name: v2_DHHS Funded Study

Federal Agency Sponsor Contact Information

You indicated that this is a Federally funded study.

1

* Agency Name:
Charles River Analytics

* Address 1:
625 Mt Auburn St # 3

Address 2:

* City:
Cambridge

* State:
MA

* Zip Code:
2138

* Contact Person:
Jeannie Johnson

* Phone Number:
617.234.5037

* Federal Agency Email:
jjohnson@cra.com

Grant Number 1 (if applicable):
75N91021C00019-0-9999-1- OR - Check here if Grant 1 is not assigned a number. ☐

If Grant 1 has no number, please provide the following information:
Title of Grant 1:

PI of Grant 1:
Amber Kleckner

Grant Number 2 (if applicable):
- OR - Check here if Grant 2 is not assigned a number. ☐

If Grant 2 has no number, please provide the following information:
Title of Grant 2:

PI of Grant 2:

Grant Number 3 (if applicable):
- OR - Check here if Grant 3 is not assigned a number ☐

If Grant 3 has no number, please provide the following information:
Title of Grant 3:

PI of Grant 3:

Grant Number 4 (if applicable):
- OR - Check here if Grant 4 is not assigned a number. ☐

If Grant 4 has no number, please provide the following information:
Title of Grant 4:

PI of Grant 4:

ID: VIEW4DF8584874400
Name: v2_Federal Agency Sponsor Information

Research Protocol

1 * Do you have a research protocol to upload?

- ○ Yes
- ● **No, I do not have a research protocol and will use the CICERO application to enter my study information**

2 If Yes, upload the research protocol:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E00563F8D000
Name: v2_Research Protocol

Risk Level

What is the risk level of your study? (Ultimately, the IRB will determine the appropriate risk level and your designation is subject to change.)

* Choose One:

- (●) **Minimal - The probability & magnitude of harm/discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations/tests.**
- ( ) Greater Than Minimal - Does not meet the definition of Minimal Risk.

ID: VIEW4E02805225800
Name: v2_Risk Level

HP-00100473

Exempt Categories_Fed

Exempt Categories

You indicated on the "Risk Level" page that this study is Minimal Risk.

1 * Please review the following categories to determine if your research may be Exempt from IRB oversight. If you believe that your study qualifies as Exempt, select the Category under which it qualifies. If your research does not qualify as Exempt, select **"The research does not qualify as Exempt".**

☐ **Category 1**: Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ **Category 2**: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7).

☐ **Category 3**: Research involving benign behavioral interventions (brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and not offensive or embarrassing) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7).

☐ **Category 4**: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

i. The identifiable private information or identifiable biospecimens are publicly available.
ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.
iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E [HIPAA], for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b).
iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

☐ **Category 5**: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

☐ **Category 6**: Taste and food quality evaluation and consumer acceptance studies:

i. If wholesome foods without additives are consumed, or
ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S.D.A.

☑ **The research does not qualify as Exempt.**

ID: VIEW8D50FF499486A05
Name: v2_Exempt Categories

Type of Research

1 * Indicate **ALL** of the types of research procedures involved in this study (Choose all that apply):

- [ ] Use of unapproved drug(s)/biologic(s) or approved drug(s)/biologic(s) whose use is specified in the protocol.
- [ ] Evaluation of food(s) or dietary supplement(s) to diagnose, cure, treat, or mitigate a disease or condition.
- [ ] Use of device(s) whose use is specified in the protocol
- [x] **Psychological/Behavioral/Educational Method or Procedure (i.e., survey, questionnaires, interviews, focus groups, educational tests).**
- [ ] Sample (Specimen) Collection and/or Analysis (including genetic analysis).
- [x] **Data Collection or Record Review (i.e., chart review, datasets, secondary data analysis).**
- [ ] None of the above.

2 * Is this study a clinical trial OR will this study be registered at ClinicalTrials.gov?
A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

(●) **Yes** ( ) No

ID: VIEW4E0280569E000
Name: v2_Type of Research

Lay Summary

1 * Provide a summary of the background and purpose of the study in language that can be understood by a person without a medical degree.

At the end of cancer treatment, many patients are still dealing with symptoms of cancer and side effects of treatment. Many are also left in a surreal mental state with uncertainty regarding the future of their health. Survivorship Care Plans are plans that are provided to individuals at the completion of cancer treatment (i.e., chemotherapy, surgery, radiation). Survivorship Care Plans describe the details of a person's diagnosis and treatment, as well as provide recommendations for follow-up appointments, referrals, and healthy behaviors to accelerate recovery and prevent recurrence (e.g., diet, exercise, smoking cessation). Survivorship Care Plans are currently static documents that are provided via paper and become outdated as soon as the person's health status changes. Therefore, there is a need to digitize Survivorship Care Plans to improve the accessibility, modifiability, and longevity of the plan. In addition, with current technology, there is an opportunity for Survivorship Care Plans to be linked with mobile devices and activity trackers so that people can track health behaviors and compare them to their clinical goals, enabling people to take charge of their own health. Charles River Analytics developed an app called POSTHOC (POST-treatment Healthcare Outcomes for Cancer survivors) that digitizes the Survivorship Care Plan with goals to integrate it into the digital medical record. Herein, we are conducting a randomized controlled trial that evaluates the POSTHOC app vs. the traditional Survivorship Care Plan on total symptom burden in the early post-treatment period. We will recruit 54 patients who have recently completed adjuvant therapy for cancer (any type). They will be randomized 2:1, POSTHOC:usual care. Those randomized to the POSTHOC group will be provided with their Survivorship Care Plan via the app, and will choose to focus on nutrition or exercise for the duration of the study, based on their individual plan and personal preferences. At baseline, 6 weeks, and 12 weeks, we will evaluate patient-reported outcomes including total symptom burden, diet, and physical activity. We will also get extensive quantitative and qualitative feedback on the usability of the app from those in the POSTHOC arm in order to improve the app for future implementation studies.

ID: VIEW4E02805CF7000
Name: v2_Lay Summary

Justification, Objective, & Research Design

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the purpose, specific aims, or objectives of this research. State the hypothesis to be tested:

This is a phase I/II feasibility/preliminary efficacy randomized controlled trial in 54 patients with cancer who recently completed adjuvant treatment for cancer (e.g., chemotherapy, radiotherapy, surgery) to compare 12 weeks of the POSTHOC app as part of the Survivorship Care Plan vs. the usual care Survivorship Care Plan on total symptom burden.

Aim 1: To assess how many participants view or log data in the app at least 3 times per week over the 12-week study. We hypothesize that at least 75% of participants (≥27/36) will view or log data in the app at least 3 times per week.

Aim 2: To obtain a preliminary estimate of the effect of the POSTHOC app vs. usual care on cumulative patient-reported symptom burden. We hypothesize that the POSTHOC app will reduce cumulative symptom burden reported by patients compared to usual care, as measured by the sum of severities of the core patient-reported symptoms from the MD Anderson Symptom Inventory, including fatigue, insomnia, pain, appetite loss, dyspnea (shortness of breath), cognitive problems, nausea, distress, and sensory neuropathy.

Aim 3: To obtain a preliminary estimate of the effect of the POSTHOC app vs. usual care on patient-reported and objectively measured health behaviors (physical activity, diet, sleep). We hypothesize that the POSTHOC app will improve health behaviors compared to usual care, as measured by patient-reported physical activity (Global Physical Activity Questionnaire) and sleep (Insomnia Severity Index), as well as objective measurements of physical activity (e.g., daily steps) and sleep (e.g., sleep quality) from the activity tracker and diet (i.e., telephone-administered dietary assessment).

Exploratory aims: To assess the acceptability and usability of the POSTHOC app by participants in the POSTHOC intervention group at week 6 and week 12 using questionnaires.

Mechanistic (exploratory) aims: To obtain preliminary estimates of the effects of the POSTHOC app vs. usual care on patient-reported symptoms including neuropathy (CIPN20), pain (Brief Pain Inventory), cognitive impairment (FACT-Cog), fatigue (Brief Fatigue Inventory), and anxiety and depression (Hospital Anxiety and Depression Scale and Distress Thermometer), as well as clinician-reported patient health (e.g., ECOG performance status), and healthcare utilization (e.g., number of unplanned medical encounters). In addition to questionnaires, we will also assess how key symptoms are affected using ecological momentary assessment.

1 To assess cross-sectional associations between health behaviors (physical activity, diet, sleep) and cumulative symptom burden at baseline.
2 To explore associations between changes in health behaviors (physical activity, diet, sleep) and cumulative symptom burden from baseline to 6 weeks and baseline to 12 weeks.
3 To explore associations between adherence to the intervention and changes in the same measures.

2 * Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.:

This is a phase I/II feasibility/preliminary efficacy randomized controlled trial. Participants will be randomized 2:1, intervention (n=36): usual care (n=18). There is a 67% chance of any given participant to be in the intervention group, and a 33% chance of any given participant to be in the usual care group.

Neither the study PI nor the coordinators will be blinded due to their active involvement in participant interaction and data collection. The participants cannot be blinded due to the nature of the intervention.

3 * Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data:

After completion of cancer treatment, people are faced with many issues including symptoms that may or may not become chronic, many instructions as to what to do next (e.g., follow-up appointments, referrals), and uncertainty regarding the involvement of their oncology team in their health moving forward. Survivorship Care Plans were implemented to help solve these problems.

Survivorship Care Plans are provided at the end of treatment. They include information regarding the person's cancer diagnosis and treatment, names of the clinical care team, details regarding scheduled and to-be scheduled follow-up appointments, and relevant referrals. These plans also often include information regarding healthy behaviors such as diet, exercise, sleep hygiene, and smoking cessation. Indeed, cancer treatment is often a window of opportunity for patients to adopt healthier lifestyle behaviors (Demark-Wahnefried & Jones, 2008). Modern technology gives us opportunities to greatly improve Survivorship Care Plans by digitizing them, making them more readily accessible, modifiable as the person's health status changes, and integrated into popular devices that promote healthy lifestyle behaviors.

Charles River Analytics completed a Phase I project to launch the development of an app to digitize the Survivorship Care Plan. Specifically, the team conducted targeted interviews with clinicians and researchers to understand how providers track symptoms of cancer with their current tools, including the Survivorship Care Plan, and what features could be added to the existing tools and workflows to streamline care. The team identified four key barriers to effective implementation of the Survivorship Care Plan, and designed the POSTHOC platform to address each barrier:
• Care plans are a static document that are out-of-date as soon as the person's health status changes.
o POSTHOC will make the Plan modifiable
• Care team members do not currently possess tools to effectively coordinate multidisciplinary care, which places the responsibility on the survivor to discuss and coordinate with each team member.
o POSTHOC will interface with the electronic medical record so that the primary care physician and other clinicians can view it. If the clinician is not in-network (e.g., community acupuncturist), the digital Survivorship Care Plan will be easily accessible on the person's smartphone to facilitate conversations.
• Adherence is difficult and subjective
o POSTHOC will provide easy-to-digest goals for nutrition and exercise, and the user will be able to easily compare their behaviors with their goals
• There is a dearth of approaches for gathering relevant health metrics outside of the clinic
o POSTHOC will interface with popular wearable devices (e.g., Fitbit) to get ecologically valid data on physical activity, sleep, and diet.

The platform includes a mobile app for the survivor, a web portal for the provider, and a server that interfaces with the mobile app, the web portal, and the hospital server. (Note: The app will not interface with the hospital server for this study.) In addition to deciding on the app's features, the study team translated app requirements into effective user interface designs that reflect the needs of the stakeholders. The study team then conducted a formative usability study, further refining the platform.

Phase I of this project included a plan to commercialize the platform including plans for licensing, sales, and distribution strategies. Success of Phase I of the project is allowing us to build upon the platform in Phase II: testing of the app in a clinical population in regard to feasibility, usability, and preliminary efficacy to reduce symptom burden.

4 * Provide the scientific or scholarly background, rationale, and significance of the research and how it will add to existing knowledge:

As of 2019, roughly 17 million Americans had a medical history that included cancer (Miller et al., 2019). By 2026, this number is projected to increase to 20 million, with the greatest gains in cancer prevalence attributed to the high incidence of cancer among the aging Baby-Boomer generation (Bluethmann et al., 2016). This increase referred to as the "silver tsunami," has raised concerns about whether the healthcare industry is adequately prepared to meet the unique healthcare needs of the cancer survivor population. As cancer rates rise and cancer treatment continues to improve, the size of the cancer survivor population and survivorship duration will continue to increase (de Moor et al., 2013). This growth trend necessitates that the healthcare industry finds new tools to support cancer survivors during the post-treatment period, or long term outcomes will suffer.

Cancer survivors continue to cope with symptoms of the disease and treatment years after treatment ends. Cancer and cancer treatment can lead to physical limitations, cognitive sequelae, depression, anxiety, sleep problems, fatigue, sexual dysfunction, and pain. A survey of demographically-diverse cancer survivors estimates that the average survivor suffers from five comorbidities and that 40% of these conditions arise after treatment has ended (Leach et al., 2015). In addition, cancer survivors suffer

from poorer health and more significant functional limitations than their peers who do not have a history of cancer (Yabroff et al., 2004). They are also more likely to be unemployed or underemployed for health-related reasons (Dowling et al., 2010). Post-treatment health and economic impacts significantly disrupt the lives of childhood cancer survivors, as they must deal with the aftereffects for the remainder of their lives (Cheung et al., 2018). At the same time, older cancer survivors must prepare for a higher rate of comorbidities caused by the overlap of cancer and aging. By 2040, it is estimated that 73% of cancer survivors will be over 65 years old and must manage both the effects of treatment and the natural consequences of age (Bluethmann et al., 2016).

The recent public health crisis due to the COVID-19 pandemic further highlights the need for efficient management of survivor health. Survivors that have recently finished treatment or who continue to receive immunosuppressive therapy appear to be at greater risk of infection, complications, and death due to COVID-19 (Nekhlyudov et al., 2020). Healthcare systems must rely on efficient means of identifying and tracking patients at high risk for complications due to comorbidities. Increased efficiency will have the dual benefits of increasing survivorship care standards and freeing up hospital system resources when facing an acute crisis like the COVID-19 pandemic.

The healthcare community has already taken some actions to address the health challenges after treatment ends. According to the Institute of Medicine (IoM), all cancer survivors should receive a Survivorship Care Plan (SCP) from their oncologist after their primary treatment. Following recommendations from IoM and the American Society for Clinical Oncology (ASCO), The American College of Surgeons Commission on Cancer (CoC) required that 75% of cancer survivors receive an SCP outlining post-treatment care. However, since 2016, mandatory compliance with this requirement has been revoked due to widespread difficulties reported in implementing SCPs. Instead, the CoC will require that cancer programs provide three services from a list of services that meet the needs of cancer survivors, including the provision of SCPs, screening services, seminars, support groups, nutrition, and psychiatric services.

In their SCP guidelines, ASCO recommends that survivors receive information regarding future check-ups and tests, the potential late and long term effects of the cancer treatment, and recommendations for improving health after treatment. In addition, care providers should outline plans to transition patient care from the oncologist to primary care providers as appropriate (Blanch-Hartigan et al., 2014). However, current practices for the continued care of survivors are burdensome, complex, must be continuously updated, and require that survivors, oncologists, and primary care providers coordinate efforts to monitor for recurrence, physical and psychosocial effects of treatment, and promote healthy living. Due to this complexity and infrequent communication between survivors and their care team between scheduled check-ups, current practices are not enough to ensure timely symptom identification and adherence.

A recent study examining the adherence to nationally recommended health guidelines by cancer survivors found that only 7.6% were fully compiant (Hyland et al., 2018). Half of the survivors had an unhealthy body mass index and did not engage in the recommended weekly exercise. Various challenges associated with cancer survivorship can be mitigated or managed by adherence to care plans and health guidelines. This has shifted cancer care from focusing on the disease to a focus on patient care that aims for overall wellness. For example, frequent physical activity is a behavior-centered means of managing weight, promoting physical health, and maintaining psychological well-being (Garcia & Thomson, 2014).

The U.S. Department of Health has recommended that cancer survivors adopt regular aerobic exercise and resistance training, where possible (Haskell et al., 2007; Patel et al., 2019). However, only one-third of cancer survivors were estimated to follow this recommendation (Ottenbacher et al., 2015). Similarly, sleep disruption is common among cancer patients and survivors (Jensen, Potosky, et al., 2017), especially in relation to breast cancer. Persistent sleep disruption has been linked to major depressive episodes (Dantzer et al., 2008) and compromised immunity (Gamaldo et al., 2012). Additional tools are needed to supplement the recommendations in the SCP to promote self-management, encourage behavior change, and facilitate the detection of risk for post-treatment complications.

Cell phone usage among adults in the United States continues to rise, suggesting that this technology is primed to assist survivors and providers with managing post-treatment physical, psychological, and psychosocial health outcomes. In 2019, 81% of American adults carried smartphones with internet connectivity and sensors capable of detecting physical activity and heart rate. The percent of individuals carrying smartphones was very similar across White, Hispanic, and Black populations and held for persons between the ages of 50-64 who will be most affected by rising cancer rates. However, persons over 65 (53%), lower-income (<$30,000, 71%), and rural populations (71%) are somewhat less likely to have a smartphone than average (Pew Research Center, 2019). These statistics indicate that smartphone technology has the potential for use as a survivorship tool for over 60% of people from older (50-64), poorer, and more rural populations who also have the greatest need for survivor support (Maly et al., 2017). Smartphone usage is expected to increase in the coming years, and the cost of ownership continues to decline. Mobile health (mHealth) data capabilities have grown significantly due to greater adoption of smart devices, improved mobile network coverage, and increased focus of American culture on self-monitoring and preventative health. These technologies can facilitate communication between survivors and their healthcare professionals and provide personalized tools and curated support to survivors between in-person appointments.

Interest in mHealth interventions to enhance physical activity and reduce sedentary behavior increased exponentially in the last decade (Hardeman, Houghton, Lane, et al., 2019), including among populations of older adults (Muller, Blandford, & Yardley, 2017) and patients with cancer (Loh, Sanapala, Janelsins, et al., 2021). mHealth interventions can complement other behavior change interventions (e.g., in-person) or stand-alone. Mobile apps that promote exercise have a variety of functions, including: easy visualization of step data from an activity tracker, notifications to promote activity (at set times and in response to sedentary behavior, as detected from their activity tracker – “just-in-time adaptive interventions”) (Nahum-Shani, Smith, Spring, et al., 2018), a newsfeed, educational information, easy visualization of their activity compared to goals/prescriptions, peer-support via two-way messaging with other participants and the study coordinator, viewing other participants’ activity data, tracking symptoms, and others (Loh, 2021; Phillips, 2019; Vandelanotte, 2016).

Qualitative and feasibility studies have concluded that participants find these apps useful (Hardeman, 2019; Ferrante, 2020; McCarroll, 2015). However, despite the high number of trials conducted thus far, studies have tended to be small, and many have been underpowered to detect changes in physical activity patterns. mHealth interventions to deliver nutrition/healthy eating interventions are less prevalent than those that deliver physical activity interventions. Many nutrition-related mHealth interventions among cancer survivors have promoted weight loss with preliminary success (Ferrante, 2020; McCarroll, 2015; Fazzino, 2016).

Symptom data have traditionally been collected by asking participants to retrospectively report symptoms over a given period, for example, the last week. However, mHealth allows immediate responses, known as ecological momentary assessment (EMA). In a 2019 review article by Kampshoff et al. (Kampshoff, Verdonck-de Leeuw, van Oijen, et al, 2019), 12 observational studies that utilized EMA were located; of these, there were no randomized controlled trials. Sampling tended to occur 3-5 times per day for 3-14 days. A recent observational study by Pinto et al. (2021) collected EMA data 35 times over a week at baseline and 3, 6, 9, and 12 months. They found correlations between sedentary behavior and symptoms such as fatigue, negative affect, and anxiety. EMA provides an unprecedented opportunity to capture changes in symptoms over a single day and model how symptoms can predict lifestyle behaviors later that day, or how lifestyle behaviors can acutely affect symptoms (Pinto, Kindred, Dunsiger, et al, 2021).

Despite the popularity and opportunities of mHealth, to date, no platform has capitalized on the potential of mHealth data to provide this support and improve the management of health outcomes in cancer survivors. Specifically, mHealth provides an opportunity to deliver an updatable Survivorship Care Plan, transition a person’s care from the oncology care team to the primary care physician, promote healthy lifestyle behaviors, and facilitate conversations between patients and providers regarding healthy lifestyles. To introduce such a capability , three key technical challenges must be addressed. First, it must rely on up-to-date research and easy-to-use tools to gather personalized health information outside the clinic’s walls and provide on-demand, real-time feedback to survivors. These personalized health data permit providers to keep track of emerging symptom patterns and adherence to the SCP and provide support tools as they seek to promote healthy behaviors.

Furthermore, mobile access to an SCP and real-time information about adherence status will assist survivors in engaging in self-management, behavior modification, and proactive reporting of potential health concerns. Second, the platform should provide information and tools to health providers in an easy-to-use format, giving healthcare professionals unprecedented access to survivor data to guide clinical decision-making. Finally, the tool must securely handle personalized health information to protect survivor privacy and security while maintaining interoperability with hospital information technology. This allows the tool to integrate with current clinical workflows, increasing provider efficiency while maintaining the focus on survivor needs.

This study will fill a significant gap in the literature by being the first study, to our knowledge, to digitize the Survivorship Care Plan and test the effects of any mHealth-delivered behavioral health intervention on cumulative symptom burden in cancer survivors.

Supporting Literature

1 * Provide a summary of current literature related to the research: ***If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.***

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Yaw, Y. H., Shariff, Z. M., Kandiah, M., Mun, C. Y., Yusof, R. M., Othman, Z., . . . Hashim, Z. (2011). Weight changes and lifestyle behaviors in women after breast cancer diagnosis: a cross-sectional study. BMC Public Health, 11, 309. https://doi.org/10.1186/1471-2458-11-309

Yeo, I.-K., & Johnson, R. A. (2000). A new family of power transformations to improve normality or symmetry. Biometrika, 87(4), 954-959.

2 If available, upload your applicable literature search:

Name	Created	Modified Date

There are no items to display

ID: VIEW4E02805A7E400
Name: v2_Supporting Literature

Study Procedures

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below. (If this study is a collaborative UM/VA study please list each procedure that is being conducted and the locations where it is being conducted.)

1 * Describe all procedures being performed for research purposes only (these procedures would not be done if individuals were not in the study) and when they are performed, including procedures being performed to monitor subjects for safety or to minimize risks:

This is a Phase I/II feasibility/preliminary efficacy randomized controlled trial in 54 people with cancer who recently completed chemotherapy or radiotherapy to compare 12 weeks of the POSTHOC app as part of the Survivorship Care Plan (intervention arm, N=36) vs. the usual care Survivorship Care Plan (control arm, N=18). The app does two things: 1) stores information from the Survivorship Care Plan, including diagnosis, treatments, and future plans, and 2) collects data regarding ongoing health status, as it pertains to the Survivorship Care Plan (e.g., nutrition, physical activity, sleep habits, symptoms). Data is collected through a combination of manual entry and automatic collections through a Fitbit wearable device. Future initiatives will allow the app to interface with the electronic medical record to facilitate conversations about lifestyle behaviors between the patient and the clinical care team.

Participants will be randomized 2:1 (intervention: control) to allow us to obtain sufficient data on feasibility and acceptability of the app (with more patients receiving the POSTHOC app), while also obtaining preliminary estimates of the effects of the POSTHOC app vs. usual care on study outcomes by randomizing one third of the patients to control. This will be an open-label study because, due to the nature of the intervention, it is not possible to blind participants. Due to the active involvement of the PI in data acquisition, it is not feasible to blind the PI.

The study activities are briefly described here; the study schema is illustrated in Figure 1 (see Other Attachments, schema.pdf). We will recruit 54 people who have had a diagnosis of cancer through clinics of Co-I Dr. Rosenblatt and colleagues and other UMMS sites. Recruitment will be feasible over two years. We will recruit from University of Maryland Medical System (UMMS), which includes UMB's Greenebaum Comprehensive Cancer Center, the Cancer Institute at St. Joseph Medical Center, the Tate Cancer Center at Baltimore Washington Medical Center, and other satellite centers. In 2020, 4292 patients received surgery, radiation, and/or chemotherapy through UMMS and would be eligible to receive a Survivorship Care Plan. Even if only 50% had treatment with curative intent, which is a low estimate, and 10% are not eligible for other reasons, 143 patients would be eligible for our study per month. We will not approach all participants who are eligible. Behavioral interventions typically consent 20% of approached patients, and we expect to approach about 25 patients per month to achieve our goal of 3-5 per month for 12-18 months. We will not be able to approach all participants who are eligible because I expect that we will not have adequate resources to screen all providers' schedules each and every week. We will select who to approach based on our available time and resources, We will also select potential participants to approach in order to achieve a diverse participant cohort in regard to cancer diagnoses. Given the large catchment area (over 5 million people) of UMMS and the remote nature of the intervention, we will also be able to recruit patients from sites outside Baltimore, Maryland (e.g., Hagerstown, Waldorf), including patients who live in rural areas.

During the initial meeting with the patient, we will have a member of the study staff explain the purpose of the study and then, if the person is interested in joining the study, obtain their consent for participation. The initial meeting will occur in person, via telephone, or video conference, depending on participant preference. After consent all participants will receive a paper-based Survivorship Care Plan via MyPortfolio. We will administer questionnaires including an On Study form that includes demographics and clinical characteristics and baseline assessments (approximately 35-50 minutes). Questionnaires will be administered via REDCap unless the participant would prefer paper-based questionnaires through the mail. Questionnaires can be completed on any device that has internet, including their computer, tablet, or smartphone, and do not need to be completed in a single sitting; they can be completed on the participants' own time. Participants will receive a Fitbit smartwatch activity tracker and orientation to use of the tracker. Participants will wear the activity tracker for 7 days to assess physical activity and sleep. We will also conduct ecological momentary assessment (EMA) via the activity tracker and POSTHOC app for these 7 days during which participants will be prompted (via notification) to answer 5 questions per day—the default times will be 9am, 12:30pm, 4pm, and 7:30pm but can be adjusted based on the participant's schedule and preferences (ideally begin 1-2 hours after waking). These questions will capture key symptoms—distress, fatigue, pain, numbness/tingling, and interference of any symptoms with daily activity on a scale from 0-10. Dietary intake data will be collected via telephone or video conference by a study team member using the 24-hour (ASA24) Dietary Assessment Tool at baseline, week 6, and week 12.

During the baseline week, all participants will have a "light" version of the POSTHOC app that only has these initial data collection features (e.g., activity tracking, EMA data collection) during the baseline week.

After baseline data collection, participants will be randomized. Randomization will occur 2:1 for POSTHOC app (N=36) vs. control (N=18). We will use a computer-generated table with random blocks of 3 and 6. We will stratify by whether the participant had chemotherapy or not (yes/no).

Both groups: A member of the study team will call each participant approximately once every two weeks for the 12 weeks to encourage engagement, monitor adverse events, and, as appropriate, get feedback on the usability of the app (see Data Collection Table). At 6 and 12 weeks, we will repeat the baseline assessments, including the 35-50 min of questionnaires, wearing the activity tracker for 7 days, EMA for 7 days, and 24-hour dietary assessment.

Intervention (POSTHOC) group: For participants randomized to the POSTHOC group, the intervention consists of the POSTHOC app, which stores an electronic version of the participant's Survivorship Care Plan and has other useful features available to the participant. Specifically, it will list the names and roles of providers, including an oncologist, primary care providers, and any specialists. It will list upcoming appointments and recommendations for future appointments with the target time frames (e.g., annual mammogram for breast cancer, annual CT scan for colorectal cancer). The Survivorship Care Plan always includes healthy lifestyle behavior goals for nutrition (e.g., losing weight or maintaining a healthy weight), exercise (150 minutes per week or 75 minutes of moderate-vigorous physical activity per week), sleep hygiene, and quitting tobacco products. Upon randomization, the coordinator will ensure that the Survivorship Care Plan is properly entered into the app. The participant will choose whether they want to prioritize nutrition or exercise as part of the study. The coordinator will ensure that the participant understands how to read and interpret either the exercise data or food log data in the app in relation to the goals outlined in their Survivorship Care Plan. The participants in the POSTHOC group who choose to focus on exercise will be encouraged to use their activity tracker for the duration of the 12-week intervention period. The POSTHOC app will pull data from the Fitbit app once both apps are installed and set up, so the participant will not need to enter any activity data manually. Survivorship Care Plans tend to recommend 150 minutes per week or 75 minutes of moderate-vigorous physical activity per week or physical activity. We will not provide the exercise group with any materials or specific exercise regimens. We will listen to what their current activity habits are and how they think they would enjoy increasing their activity to reach the goal. Walking 25 minutes per day will achieve the 150 minutes per week goal, and that will be our first recommendation (e.g., outside, at the mall/Walmart/Home Depot, etc.). Participants who choose to focus on nutrition will be encouraged to answer six brief questions at the end of each day regarding their intake of fruits, vegetables, whole grains, and sweets to daily compare their eating habits to their goals. They will meet a member of the study team to brainstorm how to change their current diet to reach the goals. Participants in the POSTHOC+nutrition group will be told that they do not need to wear the activity tracker except for weeks 6 and 12.

Control (usual care) group: The study coordinator will go through the paper-based Survivorship Care Plan with the participant. The control group will keep the "light" version of the POSTHOC app that has minimal data collection features (e .g., activity tracking, EMA data collection). They will be told that they do not need to wear the activity tracker except for weeks 6 and 12.

After completion of the study, participants will be asked to participate in a semi-structured interview during which we will solicit feedback on the study – what they liked about it, what they did not like about it, whether they would recommend it to friends, etc. This will last approximately 30 minutes. Participants will be compensated for their time if they complete at least ¾ of the baseline ($10), week 6 ($10), and week 12 ($30) study activities (7 days of wearing the activity tracker, questionnaires, and responding to prompts on the app) for a total of $50; we will emphasize the importance of the questions related to symptom burden to answer our primary research questions. As additional compensation, participants will also keep the Fitbit tracker they received upon enrollment in the study. After completion of the study, all participants will be provided with their study data (e.g., EMA assessments, 24-hour dietary assessments) upon request. Those in the usual care group will be provided any study materials related to exercise or nutrition interventions that were provided to the POSTHOC group during the study.

POSTHOC application ("app"). The POSTHOC app is designed to run on both Android and iOS devices that account for more than 90% of all smartphones. A dedicated team of developers will make periodic updates to the app and to the backend server to comply with updates released by Apple and Android.

Clarification as to where activities take place and who is there:
-All activities are planned to be done remotely by default, either via phone or video conference. However, the participant can come to the clinic if they prefer.
-Any discussions (initial meeting, bi-weekly check-ins, post-intervention interview) will be between the study team and the participant at a pre-scheduled time. The questionnaires, wearing the Fitbit, EMA, and daily comparisons of the participants' goals and their actual behaviors will be done by the participant on their own time.

Questionnaires:

Questionnaires will be administered at baseline (Week 0), Week 6, and Week 12. Questionnaires will be administered via REDCap (default) or on paper, and then manually entered into REDCap. There are a total of 14 questionnaires; 12 are self-administered and the remaining 2 are researcher-administered. The On Study form will be completed at baseline only, Healthcare Utilization and Acceptability/Usability of the app will be administered during a routine check-in call at Weeks 6 and 12 only, Acceptability/Usability will be administered to the Intervention group only. The Healthcare Climate Questionnaire (HCCQ) will be administered at week 12 only. The 11 others will be completed at Week 0, Week 6, and Week 12. The battery of questionnaires will include the following:

1. On Study: Demographics and clinical characteristics.

2. MD Anderson Symptom Inventory (MDASI): The 13-item MDASI is a multi-symptom, patient-reported outcome (PRO) symptom assessment scale that assesses the severity of symptoms experienced by patients with cancer and the interference with daily living (e.g., walking, activity, working, housework, relations with other people, enjoyment of life, mood) caused by these symptoms. The sum of the 13-items will be used as the primary aim herein.

3. Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F): The FACIT-F is a 40-item, validated, commonly used measure of fatigue that is comprised of five subscales: physical well-being, social well-being, emotional well-being, functional well-being, and fatigue. It captures symptoms in these categories over the last 7 days.

4. Brief Fatigue Inventory (BFI): The BFI is a 10-item, validated, commonly used measure that captures fatigue now and the usual and worst in the last 24 hours. It also includes 6 single-item questions regarding how fatigue has interfered with general activity, mood, work, etc.

5. Pain Questionnaire: The BPI assesses severity of pain and its impact on functioning. If a person reports feeling pain, it asks what area(s) hurt the most; a pain rating from 0-10 for pain at its least, worse, and average in the last 24 hours; pain right now; medications taken for pain; and how the pain has interfered with general activity, mood, walking, work, relations with other people, sleep, and enjoyment of life. The BPI has been validated in the cancer population and has Cronbach reliability scores that range from 0.77 to 0.91.

6. Insomnia Severity Index (ISI): The ISI is a 7-item questionnaire that assesses sleep quality. It assesses difficulties falling asleep, staying asleep, waking up too early, satisfaction with sleep pattern, how noticeable any sleep problem is to others, worry about sleep problems, and interference of sleep problems with daily functioning. It has been deemed reliable and valid in the cancer population.

7. Global Physical Activity Questionnaire (GPAQ): The GPAQ is a 16-item questionnaire designed to estimate an individual's level of physical activity in three domains: work, transportation, and leisure time, as well as time spent in sedentary behavior. It has been deemed valid and reliable to survey and measure changes in physical activity among many diverse populations. It is commonly used in the cancer literature.

8. Chemotherapy-Induced Peripheral Neuropathy (CIPN-20): The CIPN-20 is a 20-item quality of life questionnaire to elicit patients' experience of symptoms and functional limitations related to numbness, tingling, and other symptoms of chemotherapy-induced peripheral neuropathy.

9. Distress Thermometer (DT): The DT is a self-reported rapid screening tool that uses a rating scale ranging from 0 (no distress) to 10 (extreme distress) that was developed to assess psychological distress in people affected by cancer. Additionally, the patient is prompted to identify sources of distress using a Problem List. This is a very common and useful screening question in the clinic.

10. Healthcare Climate Questionnaire (HCCQ, week 12 only): This is a 6-question survey that inquires about the quality and satisfaction of participants' patient-provider communication. We modified it to ask specifically about oncologist-patient communication regarding healthy lifestyle behaviors.

11. Healthcare Utilization (6 and 12 weeks only): Here, we will inquire about any medical appointments (scheduled or unscheduled), hospitalizations, and out-of-pocket healthcare expenses. We will ask if any of the events was cancer-related or not, or if something in the app triggered the participant to seek medical consultation.

12. Acceptability Survey (6 weeks and post-intervention interview only): We will ask 6 questions to gather feedback about how much the participant liked the app, what features they enjoy/don't use, and if they would recommend it to others.

13. System Usability Scale (SUS) (6 weeks and post-intervention interview only): The System Usability Scale (SUS) is a simple questionnaire giving a global view of subjective assessments of usability. It offers a quick and simple to use questionnaire designed to assess the usability of a particular device or product. The SUS consists of ten usability statements that are rated on a Likert scale of 1 (strongly agree with statement) to 5 (strongly disagree with statement). Answers are coded and a total usability score is derived for the product or device under analysis. The questionnaire also includes an optional free-response comments area.

The self-administered questionnaires that will be completed at Week 0, Week 6, and Week 12 should take approximately 35-50 min in total to complete.

Dietary intake

Dietary intake will be assessed once at baseline, week 6, and week 12. It could occur at the same time as the biweekly check-in or another day that week.
The ASA24® Dietary Assessment Tool is a freely available web-based tool used for epidemiologic, interventional, behavioral, or clinical research that enables multiple automatically coded 24-hour dietary recalls. It will be administered by a trained nutritionist via telephone or video conference and takes approximately 30-45 minutes.

Exit interview

After completion of the study (or earlier if a participant withdraws early from the study), a member of the study team will conduct an exit interview to understand the participants' experience of being in the study. We will ask them what they liked about the study, did not like about it, what features they liked/did not like about the POSTHOC app (for those in the intervention arm), if they would recommend the study to others, etc. This interview will be audio-recorded with explicit permission at the time of the interview, then transcribed for qualitative and mixed methods data analysis.

2 * Describe all procedures already being performed for diagnostic or treatment purposes (if not applicable to the study, enter "N/A"):
N/A

3 * Describe the duration of an individual participant's participation in the study:
Participants will participate in the study for approximately 14 weeks, including consent, baseline assessments, a 12-week intervention, and an exit interview.

4 * Describe the amount of time it will take to complete the entire study:
Upon opening of the study, we expect that approximately 3-5 participants will be recruited per month for approximately 14 months. Data originating from questionnaires, activity trackers, the POSTHOC app, and exit interviews will be entered, processed, and cleaned (as applicable) as they come in. Data analysis will take place soon after all data are collected.

These data will be used to inform a follow-on randomized clinical trial, for example, a phase III or multisite clinical trial. These data will also inform design refinements to improve the POSTHOC app toward supporting the needs of target users. It is anticipated that at least two manuscripts will emerge from this study, the first of which will be submitted for publication within one year of the study closing (the primary aims paper).

5 * Describe any additional participant requirements:
None

Sample Size and Data Analysis

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Provide the rationale and sample size calculations for the proposed target population:

This is a two-arm randomized controlled trial that will assess the feasibility of recruitment and retention to a 12-week behavioral health intervention trial facilitated by the POSTHOC app as well as the preliminary efficacy of behavioral health intervention vs. a control arm on the treatment of cumulative symptom burden in people with cancer.

Under assumptions of ANCOVA and pre-post correlation of 0.65 (Borm et al., 2007), a sample size of n=46 (after 15% missing data) provides 80% power to detect a standardized between-arm difference of 0.50, which corresponds to a medium-sized and clinically meaningful effect (Norman et al., 2003).

Implications for clinical significance:
The cumulative symptom burden is a sum of the severity of 13 symptoms. It has a range of 0-130. Our power calculation is based on data from a single-arm pilot study that we conducted among a similar group of cancer survivors. In order to achieve a standardized between-arm difference of 0.50, which corresponds to a medium-sized and clinically meaningful effect, we assumed a pre-post correlation of 0.5 (typical for this type of patient-reported outcome). With 80% power, we calculated a minimal sample size of n=46 after an estimated 15% attrition. Effect size (ES) corresponds to how many standard deviations in cumulative symptom burden the groups differ by:

ES = (ΔPOSTHOC – Δcontrol) / SDpooled

ΔPOSTHOC = the difference in cumulative symptom burden from pre- to post-intervention in the POSTHOC group
Δcontrol = the difference in cumulative symptom burden from pre- to post-intervention in the control group
SDpooled = the standard deviation of cumulative symptom burden measures for all participants at baseline

From preliminary data generated from a previous study (Kleckner et al., 2022), we had a standard deviation of cumulative symptom burden from a similar symptom inventory of 17.04.

0.50 = (ΔPOSTHOC – Δcontrol) / 17.04

Therefore, (ΔPOSTHOC – Δcontrol) = 8.52

Thus, we expect that the cumulative symptom burden will decrease 8.5 points more in the POSTHOC group compared to the control group from baseline to 12 weeks.

2 * Provide the plan for data analysis. Include in the description the types of comparisons that are planned (e.g., comparison of means, comparison of proportions, regressions, analysis of variance, etc.), which is the primary comparison/analysis, and how the analyses proposed will relate to the primary purposes of the study:

Analysis plan for Aim 1. Assess the feasibility of the POSTHOC app by patients newly transitioning from active cancer treatment (n=36). We will calculate the percentage of patients who used the POSTHOC app at least 3 times per week. When we estimate feasibility, a 95% CI will span approximately ±15%. For example, if we observe 27/36 (75%) participants used the app, the CI will be 58.9-86.2%.

Analysis plan for Aim 2. Our data from Aim 2 will provide estimated effect sizes to inform the sample size of a confirmatory Phase III RCT, per clinical trial guidelines (Freidlin et al., 2012). Our planned sample size is 54 participants total (36 in the POSTHOC group, 18 in the control group); we factor in 15% missing data to yield evaluable data from 46 participants total (31 for POSTHOC, 15 for control). Hypotheses will be tested at α=0.15 (2-tailed) as appropriate for Phase I/II studies of this size (Rubinstein et al., 2005).

Aim: Obtain a preliminary estimate of the effect of the POSTHOC app vs. usual care on cumulative patient-reported symptom burden from the MD Anderson Symptom Inventory (MDASI).
Analysis plan: Cumulative severity is the sum of the individual severity levels from the 13 core symptoms from the MD Anderson Symptom Inventory (ranging 0-130). We will use the analysis of covariance (ANCOVA) with cumulative severity at Week 6 as the outcome, study arm (POSTHOC app vs. usual care) as the main independent variable and cumulative symptom severity at Week 0 as a covariate. In case of significant imbalance in other factors between arms (e.g., age), we might include additional covariates in the model. We chose Week 6 as the primary time point because preliminary data from our group shows greater benefits of behavioral interventions at 6 vs. 12 weeks (Kleckner et al., in preparation). Similar ANCOVA models will evaluate the effects of the POSTHOC app vs. usual care for each outcome at Week 6 and Week 12. To evaluate the longitudinal trajectory of each outcome, we will use repeated measures linear mixed model (LMM) incorporating the specific outcome at all three time points and using a linear contrast to test effects of POSTHOC app vs. usual care. We will use the intent-to-treat principle.

Analyses for Aim 3 and the Exploratory Aims that evaluate symptoms and feelings are analogous to Aim 2, using ANCOVA and LMM to assess the effects of the POSTHOC app vs. usual care control on each outcome. Exploratory analyses will include tests of moderation effects on the POSTHOC app by physical activity adherence, sex, age, etc.

Analysis Plan for Acceptability and Usability: For acceptability, we will estimate the percentage of patients who liked the app (≥3 on a scale of 1-5) or would recommend it to other patients at weeks 6 and 12. A 95% CI will span approximately ±15%, and in Aim 1. For usability, we will calculate simple summary statistics for the quantitative measures. We will review the qualitative data to look for general themes related to specific design features that make the app challenging to use or understand.

Assessing whether any observed differences are clinically meaningful:
There are two methods to define the minimal clinically important difference (MCID)—anchor-based or distribution-based (Fleishmann et al., 2019). It is recommended that are both used when available. The MD Anderson Symptom inventory (MDASI) is has not been validated for an anchor-based threshold for MCID. Therefore, we are relying on distribution-based MCID interpretations. For health-related quality of life measures such as what we are measuring herein, a difference of one-half standard deviation tends to provide consistent discernable differences among patients and correlates strongly with anchor-based methods (Norman et al., 2003). This corresponds to an effect size of 0.5 by definition.

We are not powered to test the effect of the app on any of these outcomes, though we will compare our results to that of published literature:
• For the Global Physical Activity Questionnaire (GPAQ) and step counts, a clinically meaningful increase in steps is 800 steps per day or 15% more for an individual, or half-a-standard deviation more for groups (Kalb et al., 2020).
• For the Insomnia Severity Index, there is a validated anchor-based MCID of 6 points (Yang et al., 2009).
• There is no MCID for the dietary assessment. We will look at whether dietary patterns meet guidelines outlined in the Survivorship Care Plan.

Data handling, rigor, quality, and reproducibility. We will capture patient-reported data electronically using the POSTHOC app or REDCap, and, only if necessary, paper-based forms that will be manually entered into REDCap. We will audit our database and visually inspect all data (e.g., Q-Q plots, box-plots, scatter plots). These inspections will include histograms of various explanatory variables as well as plots of means and fitted regression curves. If distributional assumptions are not met (e.g., normality of residuals), we will use transformations or nonparametric methods. We will assess outliers to determine if they are erroneous. If they are valid, we will conduct sensitivity analyses (with and without outliers). We will use SAS, Stata, JMP, and R for the analyses.

Missing data. We will facilitate completion of all measures. The reasons for missing data will be tabulated according to treatment group and magnitude of missing data will be assessed to select appropriate statistical method (e.g., maximum likelihood weighting, multiple imputations).

Sharing of Results

1 * Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared:

As the overall results of this investigation will not affect the participant's treatment, it will not be necessary to discuss the investigation results with participants or their clinical care team. However, data collected from the Fitbit and Dietary Recalls will be available to the participants at the end of the study upon request.

We will post the final results on clinicaltrials.gov at the completion of the study and share de-identified results as part of abstracts and manuscripts.

The POSTHOC app will not be connected to the electronic medical record.

ID: VIEW4E02808CBD800
Name: v2_Sharing of Results

Psychological/Behavioral/Educational Methods & Procedures

You indicated on the "Type of Research" page that your study involves a psychological/behavioral/educational method or procedure such as a survey, questionnaire, interview, or focus group.

1 * Select all behavioral methods and procedures which apply to this study:

- [x] **Surveys/questionnaires**
- [x] **Key informant or semi-structured individual interviews**
- [ ] Focus groups or semi-structured group discussions
- [x] **Audio or video recording/photographing**
- [ ] Educational tests or normal educational practices (education instructional strategies, techniques, curricula, or classroom management methods)
- [ ] Individual or group behavioral observations
- [x] **Psychosocial or behavioral interventions**
- [ ] Neuropsychological or psychophysiological testing
- [ ] Deception
- [x] **Other psychosocial or behavioral procedures**

ID: VIEW4E09416F57800
Name: v2_Psychological/Behavioral/Educational Methods and Procedures

Surveys/Questionnaires

You indicated that this study involves surveys and/or questionnaires.

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * List all questionnaires/surveys to be used in the study, including both standardized and non-standardized assessments:

- On Study
- MD Anderson Symptom Inventory (MDASI)
- Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F)
- Brief Fatigue Inventory (BFI)
- Pain Questionnaire: Brief Pain Inventory-Short Form (BPI-SF) and Pain Catastrophizing Scale (PCS)
- Insomnia Severity Index (ISI)
- Global Physical Activity Questionnaire (GPAQ)
- Chemotherapy-Induced Peripheral Neuropathy (CIPN-20)
- Distress Thermometer (DT)
- Healthcare Utilization
- Acceptability Survey
- System Usability Scale (SUS)
- Healthcare Climate Questionnaire (HCCQ) - modified
- ASA24 Dietary Assessment Tool
- Ecological Momentary Assessment (EMA) symptom questions

The Daily Nutrition Questions are questions that will come through the app for those in the intervention group who choose to emphasize nutrition.

2 * Upload a copy of all questionnaires/surveys:

Name	Created	Modified Date
2023.02.09-EMA.docx(0.03)	10/20/2022 3:25 PM	2/13/2023 10:22 AM
MD Anderson Symptom Inventory (MDASI)(0.02)	9/6/2022 3:47 PM	1/10/2023 10:08 AM
Chemotherapy-Induced Peripheral Neuropathy (CIPN-20)(0.02)	9/6/2022 3:48 PM	1/10/2023 9:23 AM
Daily-Nutrition-Questions_Questions that will come through the app.docx(0.01)	12/16/2022 2:39 PM	12/16/2022 2:39 PM
On Study(0.02)	9/1/2022 10:40 AM	10/21/2022 1:09 PM
Pain-BPI-PCS.pdf(0.01)	10/20/2022 3:47 PM	10/20/2022 3:47 PM
Distress Thermometer (DT)(0.01)	9/6/2022 3:50 PM	9/6/2022 3:50 PM
Global Physical Activity Questionnaire(0.01)	9/6/2022 3:44 PM	9/6/2022 3:44 PM
ASA24 Dietary Assessment Tool(0.01)	9/1/2022 10:11 AM	9/1/2022 10:11 AM
Insomnia Severity Index (ISI)(0.01)	8/31/2022 3:45 PM	8/31/2022 3:45 PM
Brief Fatigue Inventory (BFI)(0.01)	8/31/2022 3:44 PM	8/31/2022 3:44 PM
Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F)(0.01)	8/31/2022 3:40 PM	8/31/2022 3:40 PM
System Usability Scale (SUS)(0.01)	8/31/2022 3:26 PM	8/31/2022 3:26 PM
Acceptability Survey(0.01)	8/31/2022 3:21 PM	8/31/2022 3:21 PM
Healthcare Utilization(0.01)	8/31/2022 3:21 PM	8/31/2022 3:21 PM

3 * What is the total length of time that each survey is expected to take?

On Study 3-5 min
MD Anderson Symptom Inventory (MDASI) 2-4 min
Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) 4-6 min
Brief Fatigue Inventory (BFI) 2-4 min
Pain Questionnaire 4-8 min
Insomnia Severity Index (ISI) 2-4 min
Global Physical Activity Questionnaire (GPAQ) 2-8 min
Chemotherapy-Induced Peripheral Neuropathy (CIPN-20) 4-6 min
Distress Thermometer (DT) 1 min
Healthcare Climate Questionnaire (HCCQ) 1-3 min
Acceptability Survey 1-2 min
System Usability Scale 4-6 min

Questionnaire packet: 30-50 min

Healthcare utilization: Administered orally and not part of the questionnaire packet: 3-10 min

ASA24® Dietary Assessment Tool: Administered by a trained nutritionist via telephone or video conference: 30-45 min

Automated Self-Administered 24-Hour (ASA24) Dietary Assessment Tool: Administered orally and not part of the questionnaire packet: 30-45 min

See "Other Attachments" for the Data Collection Table

4 * Are any of the questions likely to cause discomfort in participants or cause harm if their confidentiality were breached? (i.e., Illegal activities)

● **Yes** ○ No

5 * Do any questions elicit information related to the potential for harm to self or others?

◯ Yes ● **No**

5.1 If Yes, what procedures are in place to assure safety?

These questionnaires contain information that might be distressing or private (e.g., “I am satisfied with family communication about my illness” from the FACIT-F). Participants are able to skip any questions they are not comfortable answering, and they can take a break or stop answering the questionnaires at any time.

All data from the POSTHOC app (e.g., EMA data) will be stored on HIPAA-compliant UMB servers; none will be stored off site. Questionnaires will be administered via REDCap, which is also HIPAA-compliant.

ID: VIEW4E09460F5EC00
Name: v2_Surveys/Questionnaires

Interviews

You indicated that this study involves key informant or semi-structured individual interviews.

1 * Are any of the questions likely to cause discomfort in participants or cause harm if their confidentiality were breached? (i.e., Illegal activities)

● **Yes** ○ No

2 * Upload a copy of the interview script or guide that will be used to guide the interviews:

Name	Created	Modified Date
Exit Interview Guide-Tracked Changes(0.01)	5/3/2023 3:56 PM	5/3/2023 3:56 PM
Exit Interview Guide(0.03)	6/17/2022 11:22 AM	5/3/2023 3:56 PM

3 * What is the individual duration of each interview and what is the entire duration of the interviews?

After completion of the study, participants will be asked to participate in a semi-structured interview during which we will solicit feedback on the study - what they liked about it, what they did not like about it, if they would recommend it to friends, etc.

Duration: 30-45 minutes

4 * How will the interview responses be recorded and by whom?

A member of the study team will conduct the interview in person, via phone, or video conference visit. He or she will take notes during the interview, and record the interview with an audio-recorder (video will not be recorded). The recording will later be transcribed into a coded file (e.g., PST33) for qualitative and mixed methods data analysis.

5 * Do any questions elicit information related to the potential for harm to self or others?

○ Yes ● **No**

5.1 If Yes, what procedures are in place to assure safety?

ID: VIEW4E0947A633C00
Name: v2_Interviews

Audio or Video Recording/Photographs

You indicated that this study involves audio or video recording/photographing.

1

* Indicate the type of recording (check all that apply):

- ☐ Video
- ☑ **Audio**
- ☐ Still Photo
- ☐ Other

1.1

If Other, specify:

2

* What is the purpose of the recording? (i.e., for therapeutic purposes, to establish treatment fidelity, or to establish reliability of assessments)

The semi-structured interview (above) will be audio-recorded upon specific permission from the participant. Audio files will be transcribed for use in mixed methods analyses.

3

* Could the recording be likely to cause discomfort in participants or cause harm if their confidentiality were breached?

◯ Yes ● **No**

4

* How will individuals' identities be protected?

Files with interview questions + notes taken during the interview will only be identified with a participant ID (e.g., PST01). Audio files will be transferred from the recorder to a UMB-issued (password-protected, HIPAA-compliant) computer within two business days of acquisition, and then will be promptly deleted from the device. Audio files will be transcribed, resulting in coded transcriptions of conversations for use in data analysis. Because voices can be identifiable, no audio clips will ever be played in public or in presentations.

ID: VIEW4E094C128C800
Name: v2_Audio or Video Recording / Photographs

Behavioral Intervention

You indicated that this study involves psychosocial or behavioral interventions.

1 * Describe the intervention (duration, number of sessions, focus, etc.):

Participants will be randomized to one of two arms: POSTHOC app or usual care. Both arms will be provided with a version of the POSTHOC app – participants in the usual care group will only have access to the data collection features, while those in the intervention group will have access to all features. Through the app, both arms will be able to log data, e.g., ecological momentary assessment of symptoms.

POSTHOC app arm: The intervention arm will have their Survivorship Care Plan entered into the app by the study coordinator or another study team member. The participant will be asked to choose whether they want to prioritize nutrition or exercise as part of the study. The team member will ensure that the participant understands how to read and interpret either the exercise data or food log data in relation to their goals. The participants in the POSTHOC group will be told that they can use their activity tracker throughout the 12-week trial as much or as little as they like between the baseline, week 6, and week 12 data collection time points.

Usual care arm: The usual care arm will not be encouraged or discouraged from making changes to their daily routines or lifestyle behaviors. We will emphasize the importance of their participation because we do not know a lot about the relationships between healthy lifestyle behaviors (e.g., nutrition, physical activity, sleep) and symptoms in early survivorship.

ID: VIEW4E0BC12A9F800
Name: v2_Behavioral Interventions

HP-00100473 Other_V2

Other Psychosocial or Behavioral Procedures

You indicated that this study involves other psychosocial or behavioral procedures.

1 * Describe the other psychosocial or behavioral procedures that will be involved in the research:

Physical activity and sleep will be measured via an activity tracker, a dietary recall will be administered by a study team member, and ecological momentary assessment will be assessed via the POSTHOC app.

Activity tracker: The participants will be asked to wear a Fitbit activity tracker for 7 days during week 0 (baseline), week 6, and week 12. The activity tracker will provide data on physical activity and sleep parameters.

This will not cost the participant any time, other than to charge it every few days.
Very low potential for causing discomfort from the activity tracker (more like annoyance once in a while).

24-Hour Dietary Recall: A member of the study team will perform a 24-hour dietary recall using the standardized 5-pass method and ASA24® Dietary Assessment tool. This is a free, online tool developed by the National Cancer Institute (NCI). The participant will not be told that we will be performing a dietary recall. The interviewer will lead the participant to report everything they have eaten and drunk in the last 24 hours including dietary supplements. The interviewer will specifically probe for add-ins (e.g., sugar to coffee), snacks, and beverages.

Duration: Approximately 30-45 minutes.
Not likely to cause harm.

Ecological Momentary Assessment (EMA): At four time points every day for seven days (at baseline, week 6, and week 12), we will ping the participant to report the severity of 4 common symptoms—distress, fatigue, pain, numbness/tingling, and interference of any symptoms with daily activity on a scale from 0-10. While research studies have shown success with this type of data collection (Kampshoff et al., 2019), participants will have the option to “turn off notifications” if it is too burdensome.

Duration: 30 seconds four times per day for 7 days at baseline, week 6, and week 12.
Not likely to cause harm.

2 Upload any relevant materials:

Name	Created	Modified Date

There are no items to display

3 * What is the individual duration of each procedure and what is the entire duration of all procedures?

Baseline (week 0): The initial meeting after consent will last about 20 minutes to explain the study and the baseline activities. The baseline 24-hour dietary recall will take 30-45 minutes and may or may not be done in the same sitting. Baseline questionnaires will take approximately 30-50 minutes and can be done either in a single sitting or spread throughout the week. The activity tracker will take no time other than to charge it every few days. EMA will take approximately 30 seconds four-times per day. In total, baseline procedures will last about 1-2 hours.

After baseline: The initial meeting after randomization will take approximately 30 minutes for those in the control group and 60 minutes for those in the intervention group.

12 week intervention: The amount of time that each participant spends with the app will be an outcome of the study and can be a minimum of 0 minutes while still being compliant with study requirements. (This is true for participants in both arms.) As part of the app for those who prioritize nutrition, they will have the option to answer a few short questions regarding their diet each day (30-60 seconds per day). In total, the time commitment will be a few minutes per week.

A member of the study team will call each participant approximately every 2 weeks to check in, assess adverse events, troubleshoot any issues with the app (if applicable), etc. This phone call can last only 5 minutes or much longer, depending on how much there is to talk about.

6-week midpoint: The 24-hour dietary recall will take 30-45 minutes and may or may not be combined with a telephone check-in. The Healthcare Utilization questionnaire will be administered during the 6-week check-in, this will extend the phone call about 3-10 minutes. Questionnaires will take approximately 30-50 minutes and can be done either in a single sitting or spread throughout the week. The activity tracker will take no time other than to charge it every few days. EMA will take approximately 30 seconds four-times per day. Thus, 6-week study activities will take about 60-90 minutes in total.

12-week endpoint: The 24-hour dietary recall will take 30-45 minutes and may or may not be combined with a telephone check-in. The Healthcare Utilization questionnaire will be administered during the 6-week check-in, this will extend the phone call about 3-10 minutes. Questionnaires will take approximately 35-50 minutes and can be done either in a single sitting or spread throughout the week. The activity tracker will take no time other than to charge it every few days. EMA will take approximately 30 seconds four-times per day. Thus, 12-week study activities will take about 60-90 minutes in total.

Exit interview: The exit interview will last about 30-45 minutes.

In total, we expect that participants will spend about 6-9 hours completing study activities over a 14-week period.

4 * Are any of the procedures (or do any of the procedures elicit information) likely to cause discomfort in participants or cause harm?

○ Yes ● **No**

4.1 If Yes, what procedures are in place to assure safety?

ID: VIEW4E0BC6EF1E800
Name: v2_Other Psychosocial or Behavioral Procedures

HP-00100473

Data Collection_Record_V2

Data Collection/Record Review

You indicated on the "Type of Research" page that your study involves data collection or record review (i.e., chart review, not self-report).

1 * What type of data will be collected/analyzed in this study? (Check all that apply)

- ☐ Retrospective/Secondary Analysis (data has already been collected at the time of initial IRB submission)
- ☑ **Prospective (data is not yet in existence and/or collected)**

2 * Will this study involve adding data to a registry or database for future use?

○ Yes ● **No**

3 * Will the data be released to anyone not listed as an investigator on the protocol?

○ Yes ● **No**

3.1 If Yes, give name(s) & affiliation(s):

ID: VIEW4E0E25A8CA400
Name: v2_Data Collection / Record Review

Prospective Data

You indicated that the study involves the collection of prospective data.

1 * Where is the data being collected from? (Check all that apply)

- [x] **Medical records**
- [ ] Medical images
- [ ] Commercial (for profit) entity
- [ ] Publicly available records
- [ ] Schools
- [ ] Other

1.1 If Other, please specify:

2 * What data fields will you have access to/collect for the study? For example, name, initials, date of birth, Social Security number, income, demographic information, family units, housing, etc.

The On Study form will be self-report. It will contain date, name, address, living situation, employment status, education, race and ethnicity, previous treatment for cancer, questions regarding being a “morning” or “night” person, sleep habits, expectation of benefit, reason for joining the study.

Medical records:
The Clinical Record form will be completed by the study staff at baseline. It contains demographics, height, weight, current menopausal status, Karnofsky Performance Status or Eastern Cooperative Oncology Group (ECOG) Performance Status, medical history (e.g., prior myocardial infarction), comorbidities (hypertension, diabetes, etc.), cancer type, cancer stage, surgical procedures, types and doses of treatments (e.g., chemotherapy type and dosing, hormone therapy, radiotherapy regimen), most recent blood work (e.g., hemoglobin, hematocrit, lymphocytes, etc.), and medications.

At weeks 6 and 12, a member of the study team will record Healthcare Utilization, including the number of unplanned medical encounters such as emergency department, urgent care, oncologist, and primary care visits over the previous 6 weeks.

At week 12, we will note the provider-rated ECOG status (or equivalent).

Fitbit: The Fitbit device collects data related to physical activity (daily steps, daily minutes of moderate-vigorous physical activity), and sleep quality.

POSTHOC app: The POSTHOC app collects data regarding symptoms, nutrition, physical activity, and sleep habits.

Questionnaires: Please see section 5, Surveys/Questionnaires

Adverse events: severe adverse events (e.g., hospitalization) as defined by the CTCAE v 5.0. Please see section 12, Study Monitoring.

You can also upload a copy of the data fields/variables to be collected for the study:

Name	Created	Modified Date
Clinical Record Form(0.02)	9/1/2022 10:41 AM	9/29/2022 4:43 PM

ID: VIEW4E0E25B643800
Name: v2_Prospective Data

Clinical Trial Registration

You indicated on the "Type of Research" page that your study is a clinical trial.

1 * Does the UM Clinical Trials Registry policy require registration of this trial?

● **Yes** ○ No

2 * Has this trial been registered?

● **Yes** ○ No

ID: VIEW4E093BF078C00
Name: v2_Clinical Trial Registration

Clinical Trial Registration Information

You indicated that this clinical trial has been registered.

1 * Was this trial registered at www.clinicaltrials.gov?
(●) **Yes** ( ) No

2 If no, was this trial registered on a site other than clinicaltrials.gov?
( ) Yes ( ) No

2.1 If Yes, specify the name of the other site:

2.2 Provide justification for registering this trial on this site:

3 * Registration Number
NCT05499663

ID: VIEW4E093BF1D0800
Name: v2_Clinical Trial Registration Information

Participant Selection

1 * How many local potential participants (or specimens/charts) do you anticipate will be screened for this study? ***Screening includes determining potential participants' initial eligibility for and/or interest in a study.***
500

2 * How many participants (or specimens, or charts) will be enrolled/used for this study? ***A local prospective participant is considered enrolled in the study when a UM-approved Informed Consent Document (not including separate screening consent forms) is signed.***

Local - the number being enrolled at this site:
54

Worldwide - the number being enrolled total at all sites (including local enrollment):
54

3 * Gender:

- [x] **Male**
- [x] **Female**

4 * Age(s):

- [ ] 0 to 27 days (newborn infants)
- [ ] 28 days to 12 months (Infant)
- [ ] 13 months to 23 months (Toddler)
- [ ] 2 to 5 years (Preschool)
- [ ] 6 to 11 years (Child)
- [ ] 12 to 17 (Adolescents)
- [x] **18 to 88 years (Adult)**
- [x] **89 years and older**

5 * Race/Ethnicity:

- [x] **All Races Included**
- [ ] American Indian or Alaskan Native
- [ ] Asian/Other Asian
- [ ] Asian/Vietnamese
- [ ] Black or African American
- [ ] Hispanic or Latino
- [ ] Mixed Race or Ethnicity
- [ ] Native Hawaiian or Pacific Islander
- [ ] White or Caucasian

6

* Language(s):

- [x] **English**
- [ ] Chinese
- [ ] French
- [ ] Italian
- [ ] Japanese
- [ ] Korean
- [ ] Local Dialect
- [ ] Spanish
- [ ] Vietnamese
- [ ] Other

6.1 Specify Other:

7

* Are you excluding a specific population, sub-group, or class?

○ Yes ● **No**

7.1

If Yes, indicate your justification for excluding a specific population, sub-group, class, etc.:

ID: VIEW4E0E519C1D000
Name: v2_Participant Selection

Vulnerable Populations

1 * Will you be targeting ANY of the following Vulnerable Populations for enrollment? (Select all that apply)

- [ ] Employees or Lab Personnel
- [ ] Children (Minors)
- [ ] Cognitively Impaired/ Impaired Decision Making Capacity
- [ ] Pregnant Women/Fetuses
- [ ] Wards of the State
- [ ] Students
- [ ] Prisoners
- [ ] Nonviable Neonates or Neonates of Uncertain Viability
- [ ] Economically/Educationally Disadvantaged
- [x] **None of the above**

Only select populations which you will be targeting for enrollment. Do not include populations that may be enrolled incidentally. Enrollment of a vulnerable population is considered to be "targeted" if the study team will be aware that a subject is from a vulnerable group as a result of interaction with the subject or collection of specific information about the subject, and the research team does not wish to exclude them. "Incidental" enrollment is limited to situations where a study team is unaware that a subject is from a vulnerable group.

ID: VIEW4E0E519917800
Name: v2_Vulnerable Populations

HP-00100473 Eligibility_V2

Eligibility

1 * Do you have an existing Eligibility checklist(s) for this study?

◯ Yes ● **No**

1.1 If Yes, upload here. If you need a template, you can download it by clicking **HERE**. The checklists you upload will also be available under the Documents tab of this application.

Name	Created	Modified Date
There are no items to display		

1.2 If No, create an eligibility checklist below:

List inclusion criteria (List each Inclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	Have had a cancer diagnosis (any type)
View	2	Will soon or have recently completed treatment (within the past 12 weeks) with chemotherapy, radiotherapy, or surgery with curative intent
View	3	Must have received, plans to receive, or is open to receiving a Survivorship Care Plan (SCP) as per their provider
View	4	Have access to an Android or Apple smartphone and reliable Internet access
View	5	Be at least 18 years of age
View	6	Be able to read and understand English, and
View	7	Be able to provide written informed consent

List exclusion criteria (List each Exclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	Have planned surgery, radiotherapy, or chemotherapy during the study period (hormonal and biologic therapy is allowed)

After entering the inclusion and exclusion criteria above, click the Save link. CICERO will automatically generate a printable Eligibility Checklist for you to use in your research. To review the checklist, click on the resulting link below. This checklist is also available under the Documents tab of this application.

Eligibility Checklist for HP-00100473_6 v8-6-2024-1722950513225(0.01)

ID: VIEW4E0E5185F9000
Name: v2_Eligibility

Recruitment

1 * Describe plans for recruitment, including the identification of potential participants (or acquisition of charts/records/samples) and initial interactions with them: (If this study involves the VA please list all sites at which recruitment will take place.):

1) Identification
Before recruitment, approval will be obtained by UMGCCC Clinical Research Center (CRC), the University of Maryland School of Nursing (UMSON), and the UMB Institutional Review Board (IRB). The study team will recruit participants using UMSON Department of Pain and Translational Symptom Science established procedures. Potential participants will be identified using four methods: a) screening medical records, b) direct referral from providers (e.g., nurses, nurse navigators, physicians), c) flyers, d) advertising via standard UMB- and ICTR-networks (e.g., ResearchMatch, Twitter).

Subject population. Our sample will include many underserved and minority patients per UMB's catchment population. We anticipate that the sample for the current study will be approximately (self-identified):

- Sex: 50% female
- Race: 32% Black/African American, 65% White
- Ethnicity: 11% Hispanic/Latino

a) Identification via medical records
Potentially eligible participants receiving care at UMGCCC and UMMS satellite sites will be identified HIPAA-compliant by study personnel via review of scheduled outpatient appointments (via EPIC) with Dr. Rosenblatt, an oncologist on the study team. If other clinician(s) would like to participate in our study, we will obtain permission to access their clinic schedule(s). Medical records typically show time since completion of adjuvant therapy (e.g., surgery, chemotherapy). If an individual appears to be eligible, the study team will contact the oncologist (or a designee) to notify them of a potential candidate and obtain approval to contact the patient via myPortfolio, email, or letter.

b) Identification via direct referral from clinicians (e.g., physicians, physician assistants, nurses)
The study team is working with several oncologists (including, but not limited to Dr. Rosenblatt) and primary care physicians to identify potential patients and their medical teams (e.g., nurses, physician assistants) to identify potential patients at UMGCCC, St. Joseph's Medical Center, and other UMMS satellite campuses who are likely eligible for our study. If the patient is eligible based on information in the medical records, the provider will be asked to refer the person to the study team, tell the person about the study at their appointment (in person or telehealth), or give them a flyer. The medical team is not expected to field detailed questions related to the study.

c) Flyers
Flyers advertising our study will be placed in locations designated for such use. Potential participants can contact a member of the study team directly via phone or email for more information. Their medical provider will be contacted to ensure that the study is appropriate for the potential participant before consenting them.

d) Email and Social Media advertising
We will advertise our trial via email through the UMB Office of Communications and Public Affairs's Elm Weekly and ICTR's relationship with ResearchMatch. We might also post via Twitter and tag pages such as UMGCCC, UMMS, and University of Maryland Baltimore Washington Medical Center (UMBWMC). As with flyers, potential participants can contact a member of the study team directly for more information. Their medical provider will be contacted to ensure that the intervention is appropriate for the potential participant before consenting them.

2) Recruitment
a) If the provider gives the study team permission to contact the participant, we will mail them a recruitment letter, send them a message via myPortfolio, and/or email them to briefly introduce the study and ask if they want more information.

b) If the provider introduced the study to the participant and has gotten permission for us to contact them, we will either meet them at/after their oncology appointment, send them an email, or call them.

Initial contact will assess whether the participant has any interest in participating in a clinical trial to investigate relationships between health behaviors (e.g., physical activity, diet, sleep) and symptoms (e.g., neuropathy, pain, fatigue, distress), as well as test a new smartphone app that helps a person follow the Survivorship Care Plan in the few months after the end of treatment. After a potential participant has shown an initial interest in the study, we will review eligibility and discuss the study activities. If the person volunteers to participate, study personnel can obtain informed consent then or at a later date. After consent is provided, the participant will be provided with study materials.

3) Screening
For convenience to the potential participant, the person's clinic appointment might be combined with their screening and consent, or participants can undergo the screening and consent process remotely via phone and eConsent. To protect the privacy of potential participants, face-to-face recruitment discussions will be conducted in a private location.

A member of the study team will meet the potential participant in person or talk to them over the phone to explain the project and invite them to participate. It is expected that some patients will decline to participate, and some will not be eligible; approaching the same individual twice will be avoided by keeping a screening log containing the following information:
• Screening ID (1, 2, 3,…)
• Name
• Date of contact
• Medical record number
• How the participant learned of the study (e.g., our team, provider, flyer)
• Where/how we talked to the potential participant (e.g., clinic location, phone)
• Whether the patient was eligible or not
• If ineligible, the reason they are ineligible
• Whether the patient ultimately consented or declined
• If declined consent, the reason for declining consent
• If consented, the participant ID in the study (e.g., PST01, PST02, PST03, …)

Patients will need medical clearance from their provider to participate in the study.

2 * Describe measures that will be implemented to avoid participant coercion or undue influence (if not applicable to the study, enter "N/A"):
To minimize coercion, the study team will emphasize that participation is completely voluntary, and their cancer care will not be affected by their participation in the study.

3 * Who will recruit participants (or acquire charts/records/samples) for this study? (Check all that apply)

- [x] **PI**
- [x] **Study Staff**
- [ ] Third Party

3.1 If you are using a third party, specify Third Party Recruiters:

4 Upload any recruitment tools such as screening/telephone scripts and introductory letters (do not upload advertisements here):

Name	Created	Modified Date
Recruitment-letter.docx For people whom we have gotten permission to contact from the oncology care team(0.02)	8/31/2022 4:18 PM	2/14/2023 2:26 PM
myPortfolio-For people who we have permission to contact(0.02)	10/21/2022 12:21 PM	2/14/2023 2:26 PM
Telephone-Script-2_For people who call us for more information(0.01)	8/19/2022 12:01 PM	8/19/2022 12:01 PM
Telephone-Script-1_For people who have provided permission for us to contact them(0.01)	8/19/2022 12:00 PM	8/19/2022 12:00 PM
Email-Script_For people who have contacted us about the study via email(0.01)	8/19/2022 11:58 AM	8/19/2022 11:58 AM

ID: VIEW4E0BCAA0A6C00
Name: v2_Recruitment

HP-00100473

Advertising_V2

Advertising

1 * Will you be using advertisements to recruit potential participants?

(●) **Yes** ( ) No

ID: VIEW4E0BCCF811000
Name: v2_Advertising

Advertising Detail

You indicated that you will be using advertisements to recruit potential participants.

1.1 * Select the mode(s) of advertising (check all that apply):

- [ ] Radio
- [x] **Internet**
- [x] **Print**
- [ ] Television
- [x] **Other**

1.1.1 If Other, specify:
Email, social media, the Elm, ResearchMatch

1.2 * Provide exact text of all proposed advertisement(s):
Brochure:
CANCER SURVIVORS: Have you recently completed cancer treatments but still experiencing symptoms or side effects? Are you feeling uncertain about the future of your health?

JOIN A RESEARCH STUDY at the University of Maryland, Baltimore that aims to test a new smartphone app that will help you manage the details of your care going forward. The app also links with activity trackers so that you can track health behaviors and compare them to your goals, enabling you to take charge of your own health.

Who is eligible?
• Cancer survivors 18 years and older who finished chemotherapy, radiation, and/or surgery within the last 12 weeks
• People who are experiencing some lingering side effects or symptoms from their cancer or cancer treatment
• People who have access to an Android or Apple smartphone and reliable Internet access

What do I have to do?
• Participate in a 12-week study that collects data on food intake, physical activity, sleep patterns, and common cancer-related symptoms such as distress, fatigue, pain, and numbness/tingling
• Provide feedback on a new smartphone app that monitors your symptoms for one week at the beginning, middle, and end of the study
• Wear a Fitbit smartwatch (that we provide) that monitors activity and sleep patterns for one week at the beginning, middle, and end of the study
• Meet with a nutritionist for 30 minutes at 3 time points to answer questions about your diet (the meeting can take place in-person, via phone or videoconference, your choice)
• Fill out questionnaires related to your eating patterns, fatigue, and other symptoms at the beginning, middle, and end of the study

Do I get paid to participate?
Yes, up to $50. You also get to keep the Fitbit once all study requirements have been completed.

Can I participate remotely?
Yes, all research activities can be done at home.

Interested?
Contact the study chair, Dr. Amber Kleckner, at amber.kleckner@umaryland.edu

Twitter post:
POSTHOC: Leveraging technology to address post-treatment outcomes of cancer survivors: A clinical trial
The Survivorship Care Plan helps you transition from being on active cancer treatment to long-term post-treatment survivorship and promotes healthy diet and exercise behaviors. We are testing a paper-based vs. digital Plan. Get $50 and a free Fitbit smartwatch.
Contact nrsmetriccs@umaryland.edu

1.3 * Upload advertisement(s) here:

Name	Created	Modified Date
Elm Weekly Page WriteUp.docx(0.03)	12/16/2022 2:09 PM	2/14/2023 2:25 PM
Twitter post(0.04)	8/26/2022 7:38 PM	2/14/2023 2:25 PM
Study-Advertisement_Brochure(0.02)	8/19/2022 12:07 PM	2/13/2023 10:33 AM
ResearchMatch_Contact-Message.docx(0.01)	12/16/2022 2:09 PM	12/16/2022 2:09 PM
ResearchMatch_Welcome-Message_For people who have indicated interest in our study via the RM Contact message.docx(0.01)	12/16/2022 2:09 PM	12/16/2022 2:09 PM
Elm-Weekly-Newsletter-Blurb.docx(0.01)	12/16/2022 2:09 PM	12/16/2022 2:09 PM

ID: VIEW4E0BCE82B8C00
Name: v2_Advertising Detail

Research Related Risks

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.

1 * Individually list each research-related risk, using a separate line for each. Next to each risk, delineate the likelihood/seriousness of the risk, and the provisions for minimizing the risk:

a) Risk of emotional distress. This is a difficult transition period for many people as they attempt to "move on" from the cancer experience. Some people embrace the new identity of being a cancer survivor while others struggle to determine how much energy they should spend thinking about cancer. Participants will be reminded at least biweekly that they are part of this study and will be asked regularly about their symptoms. For some, being part of this study will provide a distinct area to place their energy (i.e., the study and their health behaviors), which can be empowering and facilitate the transition. On the other hand, others may feel like the study is drawing out the cancer experience. Participants will receive feedback and reports about their progress against guidelines in a Survivorship Care Plan in accordance with principles of behavioral science. There is a chance that participants could become emotionally distressed by the focus on their symptoms (is my symptom "normal"?), the expectation to wear an activity tracker, or the periodic behavioral health questions via the POSTHOC app.

Likelihood: Low

Severity: Low

Provisions for minimizing risk: To reduce the risk and consequences of emotional discomfort, participants will not be withdrawn from the study for not completing study activities, and they will be able to stop participation at any time. Should a clinician or study administrator notice signs of distress, the clinician will stop the use of the app immediately. If a participant elects to leave the study at any time, we will debrief, pay, and dismiss the participant. Participants will be informed that they may choose not to answer any questions.

b) Risks to confidentiality and privacy. There is a risk that participant privacy or confidentiality may be breached; personal data may be seen by unintended parties.

Likelihood: Very low

Severity: Low to high

Provisions for minimizing risk: Participants' privacy and confidentiality will be protected in several ways. At the beginning of a session, each participant will be assigned an alphanumeric code that will be written on all their response materials (except for their consent form) and data files instead of their names. This procedure will ensure that participants' identities will never be directly associated with their specific data. To protect participant confidentiality, all paperwork that could directly be linked to the participant personally (such as a signed consent form or payment documentation forms) will be stored in the investigators' locked filing cabinets. All other data will be coded (i.e., identified by code rather than with personal information) and stored in a locked cabinet (different from the cabinet where data that could be linked personally to the participant is stored) or on a computer where a password is required for entry and decryption. The Site PI, Dr. Kleckner, will distribute passwords and keys. Only adequately trained study staff who require data access to complete the study will receive a password or key.

All data collected by the POSTHOC app (i.e., physical activity, diet, and EMA data) will be stored on a HIPAA-compliant server at UMB. Charles River Analytics will not have access to any of the data collected in this study. Responses to questionnaires (e.g., On Study), as well as the Clinical Record Form, will be collected via REDCap, and therefore will be stored on UMB servers and will not be accessible by the team at Charles River.

Privacy will be ensured by making appointments with participants to call them or have a video conference about the study. This will ensure that participants will not be caught off-guard and feel pressured to take a study call in public. If a participant elects to come in, our clinical suites are located in a discrete laboratory in the School of Nursing.

There are no known risks to eating or engaging in physical activity in compliance with recommendations in the Survivorship Care Plan.

There are no known risks to wearing the Fitbit device.

ID: VIEW4E1B52509F000
Name: v2_Research Related Risks

Potential Benefits and Alternatives

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the potential direct benefit(s) to participants:
For those in the POSTHOC arm, it is our hope that participants will directly benefit from the POSTHOC app, which is designed to accelerate the amelioration of symptoms after cessation of cancer treatment.

2 * Describe the importance of the knowledge expected to result from the study:
Indirect benefits to participants: Participation in the study has the potential to facilitate the transition from active cancer treatment to early survivorship via regular communication with our study team. All participants will be able to keep their smartwatch after the study has ended, which provides them with powerful aids for monitoring health.

If successful, the study will contribute to a user-centered design of a platform for a digital Survivorship Care Plan. In addition, it can assist cancer survivors with engaging in healthy behaviors and facilitate communication between the survivor and the person's clinical care team, including their primary care physician. This study will provide evidence about the effects of self-management of health on healthcare usage and treatment symptoms. This knowledge will be integral to later, larger randomized controlled studies, integration with the electronic medical record, and nationwide implementation.

3 * Describe how the potential risks to participants are reasonable in relationship to the potential benefits:
The physical and emotional risks to the participants are low. Many people take pride in contributing to research and knowing that their time and effort in a study might help patients in the future. As a result of participating in this study, participants may adopt positive health behaviors that persist after study completion.

4 * Describe the alternatives to participation in this study. If there are no alternatives, state that participation is voluntary and the alternative is not to participate. For intervention studies, describe appropriate alternative clinical procedures or courses of treatment available to subjects.
Participation in this study is voluntary and the alternative is not to participate. While there are not any apps or programs to our knowledge that help deliver a modifiable Survivorship Care Plan, survivors can seek other services at UMMC and in their communities that promote healthy lifestyle. The participant may choose to not participate in the study without penalty or effects on their medical care.

ID: VIEW4E1B5251B0400
Name: v2_Potential Benefits and Alternatives

Withdrawal of Participants

If the questions below are not applicable to the research (i.e., chart review), enter "N/A".

1 * Describe anticipated circumstances under which subjects will be withdrawn from the research without their agreement:

The participant can be removed from the study by the investigator or sponsor. A participant may be withdrawn from the study if their disease becomes worse or if their doctor feels that staying in the study is harmful to the participant's health. The study team also holds the discretion to withdraw a participant from the study if their participation becomes harmful to a study team member. It is unlikely but possible that the entire study may be stopped by the sponsor, the investigator, the Institutional Review Board, the facility where the study is being carried out, or the University. In that case, participants' participation will end.

If a person is eligible and begins the study, and then becomes ineligible for any reason (e.g., surgery is scheduled during the study), they will be able to continue participation if they want to and their medical provider deems participation safe.

2 * Describe procedures for orderly termination:

Upon completion of data collection, each participant will be thanked for their participation in the study, allowed to keep the activity tracker gratis, provided with their study data upon request, and compensated for their time.

If a participant withdraws (or is withdrawn) before the end of the study, they will be paid for the data they have provided, and the study team will not contact the person anymore. A 10-20% withdraw rate is built into the study design and recruitment goal, so there should not be a need to replace participants who withdraw before completing the study.

3 * Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection:

If a participant wishes to withdraw from the study, we will ask if the participant would like to continue in some but not all the research activities. If they would like to participate in only some of the research activities, we will note which ones and the participant will not be formally withdrawn from the study. If they wish to withdraw completely, a written withdrawal request is required and should be sent to the site PI (email preferred). The written request for withdrawal will be included in the participant's study record as documentation of the reason for removing a participant from the study. If a participant makes a verbal request and does not provide a written request, the verbal request will be documented by the study team member who receives the request and added to the participant's study record. Data that have been collected thus far will be analyzed.

ID: VIEW4E1B52531F800
Name: v2_Withdrawal of Participants

Privacy of Participants

If the study does not involve interaction with participants, answer "N/A" to the questions below.

1 * Describe how you will ensure the privacy of potential participants throughout the study ***(privacy refers to persons and their interest in controlling access to themselves):***

Privacy will be ensured by making appointments with participants to call them or have a video conference about the study. This will ensure that participants will not be caught off-guard and feel pressured to take a study call in public. If the location is not adequately private, we will reschedule.

If a participant elects to come in, our clinical suites are located in a discrete laboratory in the School of Nursing.

2 * Describe the location where potential participants will receive research information and detail the specific actions the study team will take to ensure adequate privacy areas:

For phone calls and video conferences, we will set up an appointment with the participant to ensure that they can be in a location where they feel safe.

For in-person appointments, participants will learn about the study in a private consult or examination room in the UMGCCC or UMMS satellite location, other private room in the hospital, a clinical testing room in the Department of Pain and Translational Symptom Science (School of Nursing), or via telephone or video conference. After baseline assessments, the participant will be randomized and instructions will be given regarding the study activities for the next 13 weeks. This information will be similarly provided in a private room in UMGCCC or the School of Nursing or via the telephone or video conference. For in-person meetings, we will close the door and only the study staff and participant (and person(s) accompanying the participant, if desired) will be present; no members of the clinical care team or hospital staff will be present unless specifically invited by the potential participant.

3 * Describe potential environmental stressors that may be associated with the research:

There will be no more environmental stressors than typically experienced at a doctor's appointment. For phone and videoconferences, we will make appointments to ensure that the participant can plan to be in a comfortable location. For in person appointments, we will do what we can so that the room is comfortable to facilitate conversation regarding the study and its components (good lighting, comfortable temperature). We will make accommodations (as able and reasonable) for people with disabilities (e.g., comfortable place to sit, space to maneuver wheelchair, etc.).

4 * Will this study have a site based in the European Union?

○ Yes ● **No**

5 * Will the study have planned recruitment or data collection from participants while they are located in the European Union?

○ Yes ● **No**

Access link below for information about the EU General Data Protection Regulations to assist in answering these questions.
https://www.umaryland.edu/oac/general-data-protection-regulation/

ID: VIEW4E1B525B87C00
Name: v2_Privacy of Participants

HP-00100473

Confidentiality of Data_V2

Confidentiality of Data

1 * Will stored research data contain identifiers or be able to be linked to and identify individual participants (either directly or through a code/research ID)?

- (●) **Yes**
- ( ) No, the data will be stored de-identified/anonymous (stripped of all identifiers, no way to identify individual participants)

2 * Where will research data be kept (address electronic and paper data as applicable)? (If this is a VA study please list specific sites that data will be kept.)

Electronic data, including POSTHOC data, REDCap data, and study team-created files, will be stored on HIPAA-compliant UMB servers.

Paper data will be stored in a locked filing cabinet in Dr. Kleckner's laboratory/offices in the School of Nursing.

The audiorecorder will be stored in a locked cabinet in Dr. Kleckner's laboratory/offices in the School of Nursing; files will be deleted as soon as they are transferred to the computer.

3 * How will such data be secured?

Paper-based data will be stored in a locked cabinet in Dr. Kleckner's office in the Department of Pain and Translational Symptom Science in the School of Nursing. Questionnaire data will collected via REDCap. Electronic data will be stored on a UMB-issued computer as part of Dr. Kleckner's lab in the School of Nursing. The School of Nursing is secured by electronic key cards and a security guard at the front desk. Dr. Kleckner and her coordinator's personal offices are secured by traditional keys; Dr. Kleckner's file cabinet is secured by a unique traditional key; and computers in Dr. Kleckner's lab are password-protected. Electronic research records are stored on UMB's password-secured and firewall-protected networks. These are the same methods of security used for patient medical records. POSTHOC app data will be stored in a HIPAA-compliant server at UMB. All study data will be kept for at least six years after the study and all reports and publications are complete.

4 * Who will have access to research data?

Only members of the study team will have access to the stored data. All individuals who have access to the data will need to complete human research participant training as required by UMB.

Any investigator who is not on the study team and would like access to de-identified data must submit a request to the study chair (i.e., Dr. Amber Kleckner) via a written request (e.g., email). If Dr. Kleckner considers the project appropriate, she will approve a release of the data and transfer it in a safe, HIPAA-compliant manner according to UMB rules (e.g., data use agreement if outside UMB).

To clarify, the POSTHOC app will pull activity data from the Fitbit app, but POSTHOC data will not be shared with or synced with the Fitbit app; therefore, none of our data will be shared with Fitbit/Google.

Also to clarify, the POSTHOC app does not connect with the participant's electronic medical record.

5 * Will study data or test results be recorded in the participant's medical records?

( ) Yes (●) **No**

6 * Will any data be destroyed? ***(Please note that data for FDA regulated research cannot be deleted however, VA data must be destroyed according to the VHA Records Control Schedule (RCS) 10-1)***

(●) **Yes** ( ) No

6.1 If Yes, what data (e.g., all data, some recordings, interview notes), when and how?

Audio-recordings of exit interviews will be transferred to the computer and then deleted off the recording device.

7 Do you plan to obtain a Certificate of Confidentiality?

(●) **Yes** ( ) No

7.1 If Yes, upload your Certificate of Confidentiality. If you have not yet obtained the Certificate, please note that once it is obtained, you will need to submit an amendment to attach the document, make any needed changes to the submission and make needed changes to the Informed Consent Document.

Name	Created	Modified Date
CoC(0.01)	10/21/2022 3:29 PM	10/21/2022 3:29 PM

8 * Discuss any other potential confidentiality issues related to this study:

We will only collect the data we need to answer the research question(s) and no superfluous data. Presentation of data in the form of posters, presentations, grant applications, and manuscripts, either in private or public settings, will not have any identifiable information.

Fitbit has been used in more than 1400 research studies (https://healthsolutions.fitbit.com/research-library/). Fitbit will only have access to any personal health information and personally identifiable information that the participant provides, and it is not necessary that they provide any personal information for the purposes of this study. For example, if they want to make up an anonymous email address for the purposes of this study alone, they can. Data (e.g., daily step counts) are private unless they choose to share them with friends as part of Fitbit communities. The Fitbit app will not have access to any study data other than what the Fitbit device collects, e.g., no information about medical history. Fitbit has security features to ensure that users' data are safe, for example two-factor authentication. We as study staff will not restrict use of any of the features of the Fitbit device such as sharing data within Fitbit "communities," and it will be up to the participant to decide how many other features they would like to use, and how they would like to use them.

The POSTHOC app will be vetted through Android and Apple procedures, which include customer safety of data, before they will be available for download. At this stage in development, the POSTHOC app will not be available to the public, only for this specific study. It will be hosted on UMB servers and Charles River Analytics will not have access to any participant data from the app or otherwise. No other apps will be able to "see" data that are in the POSTHOC app.

ID: VIEW4E1B5265E0400
Name: v2_Confidentiality of Data

HP-00100473

Monitoring Plan Selection_V2

Monitoring Plan Selection

1 * Type of data safety monitoring plan for the study:

- ○ Will use/defer to the external sponsor's Data Safety Monitoring Plan
- ● **Data Safety Monitoring by a Committee**
- ○ Data Safety Monitoring by an Individual
- ○ There is no data safety monitoring plan in place

ID: VIEW4E1B00E30D400
Name: v2_Monitoring Plan Selection

HP-00100473

Monitoring Plan - Committee

You indicated that the monitoring will be done by a Committee.

1 * Will the Committee be Internal or External?

- (●) **Internal DSMB**
- ( ) External DSMB

2 * What data will be reviewed?

- [x] **Adverse Events**
- [x] **Enrollment Numbers**
- [ ] Patient Charts/Clinical Summaries
- [ ] Laboratory Tests
- [ ] Medical Compliance
- [ ] Procedure Reports
- [ ] Raw Data
- [ ] Outcomes (Primary, Secondary)
- [ ] Preliminary Analyses
- [ ] Other

2.1 If Other, specify:

3 * What will be the frequency of the review?

- ( ) Annually
- (●) **Bi-Annually**
- ( ) Other

3.1 If Other, specify:

4 * Safety monitoring results will be reported to:

- [x] **IRB**
- [ ] GCRC
- [ ] Sponsor
- [ ] Other

4.1 If Other, specify:

ID: VIEW4E1B025761800
Name: v2_Monitoring Plan - Committee

Monitoring Plan - Internal DSMB

You indicated that the monitoring committee will be an internal DSMB.

1 * List Internal DSMB Members:

Name
View Susan Dorsey, PhD, RN
View Caitlin Eggelston, BS
View Olga Goloubeva, PhD, MS
View Petr Hausner, MD
View Laura Hearson, RN, OCN
View Yixing Jiang, MD, PhD
View Myounghee Lee, PharmD, PhD
View Heather Mannuel, MD, MBA
View Gautam Rao, MD
View David Reidel, MD
View Katherine Tkaczuk, MD
View Michael Kleinberg, MD, PhD
View John Baddley, MD
View Amin Benyounes, MD
View Jacqueline Bork, MD

2 * Confirm that no financial or other conflicts of interest exists for the above individuals.

● **Yes** ○ No

3 * Will there be an interim efficacy analysis?

○ Yes ● **No**

3.1 If Yes, when?

4 * Briefly describe the DSM review process itself. Will it be an open or closed review to the investigator? Blinded/unblinded data? How will confidentiality of individual participant data be maintained?

The UMGCCC DSM/QAC will provide independent monitoring. The below items are considered in DSM/QAC annual review. The semi-annual review will include only those items below related to safety.
• A cover form (Annual Renewal DSM/QAC) completed by the study team summarizing the activities of the prior reporting period.
• All severe adverse events (SAEs) and protocol-designated expeditiously reportable adverse events (AEs), internal and external, including those that have previously been reported to the DSM/QAC. The DSM/QAC will have a full report on all internal SAEs concerning that clinical trial, including the nature of the SAE, grade, therapeutic agents involved, whether they were reported to all appropriate agencies within the mandated timeframes, and the investigator's assessment of whether the toxicity was study-related. The DSM/QAC may recommend to the CRC to close studies with adverse event profiles that deviate in a substantial way from expected patterns of events.
• The consent form to determine if modifications are needed based on the accumulated AEs and SAE information.
• A summary of protocol deviations that have not yet been reviewed by the DSM/QAC.
• If available, interim outcomes and other results are assessed to see if response rates conform to estimates used to develop the statistical analysis. The DSM/QAC may recommend study closure to the CRC for studies with poorer than expected response rates that cannot meet stated outcomes targets even if the trial accrued fully. Conversely, response rates significantly greater than expected may lead to early termination of trials to prevent further assignment of patients to the inferior treatment arms in comparative trials.
• Periodic audit results, if available. The DSM/QAC may recommend study closure to the CRC for studies when the PI or research teamshow a pattern of persistent non-compliance with Good Clinical Practices policies.

Upon conclusion of review, the DSM/QAC decides one of the following:
• Award final DSM/QAC approval to the protocol
• Find that minor revisions are needed for final DSMB approval
• Find that major corrections are needed to the protocol
• Suspend immediately to prevent harm to subjects or others
• Recommend closure of the protocol to the CRC due to GCP non-compliance or low accrual.
• Refer the protocol back to the CRC for scientific re-review if new information has called into question the original study hypothesis.

DSM/QAC actions are approved by majority committee member vote. Members with conflicts of interest will not serve as reviewers for protocols for which they are conflicted and will recuse themselves from discussions and voting on such studies.

The record of DSM/QAC actions for a protocol consist of:
• Chair notes, consisting of findings of the DSM/QAC reviewer, discussions and decisions by the DSM/QAC and specific issues requiring remediation
• DSM/QAC correspondence with the PI, specifying the actions to be taken (if applicable) and the acceptable turnaround time for response
• PI responses to DSM/QAC inquiries are reviewed at the next DSM/QAC meeting
• Final DSM/QAC review outcome provided to the PI

Records of these reviews are made available to the IRB for consideration in their deliberations.

5 * What are the criteria defined in the protocol to be used for decision making regarding continuation, modification, or termination of study?

A possible modification may be made to the protocol if we are recruiting fewer than one participant per month for 3 consecutive months.

ID: VIEW4E1B0261D9400
Name: v2_Monitoring Plan - Internal DSMB

HP-00100473

Research Related Costs_V2

Research-Related Costs

1 * Is the study's financial supporter (e.g., commercial sponsor, federal or state grant or contract, private foundation, physician-sponsor) covering any research-related costs?

- ○ No
- ● **Yes**

1.1 If Yes, check all that apply:

- ☑ **Research-Related Services (personnel costs, tests, supplies, exams, x-rays, or consultations required in the study)**
- ☑ **Investigational or Study Device**
- ☐ Investigational or Study Drug
- ☐ Investigational Procedure(s)

1.2 If No, who is responsible for payment?

2 * Who is responsible for the uncovered research-related costs?

- ☐ Participant
- ☐ Sponsor
- ☐ UM
- ☐ Other
- ☑ **There will be no uncovered research-related costs**

2.1 If Other, specify:

3 If the participant is responsible for any research-related costs, identify and estimate the dollar amount:

ID: VIEW4E1B5D9641800
Name: v2_Research Related Costs

Compensation for Research-Related Injury

1 * Is this study under a master agreement that includes a provision requiring the sponsor to provide compensation to participants for research-related injury?

◯ Yes ● **No**

1.1 If Yes, please provide the date and title of the agreement and upload the portion of the contract language relevant to compensation for research-related injury:

Name	Created	Modified Date
There are no items to display		

1.2 If No (the study is not under a master agreement), is there proposed contract language concerning payment to participants for treatment in the event of a research-related injury?

◯ Yes ● **No**

1.2.1 If Yes, indicate the status of the contract review/approval with the ORD and upload the proposed language relevant to compensation for research-related injury:

1.2.2

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E1B629EEC000
Name: v2_Compensation for Research-Related Injury

Payment/Reimbursement to Participants

1 * Will participants receive payment (money, gift certificates, coupons, etc.) or reimbursement for their participation in this research?

● **Yes** ○ No

ID: VIEW4E1C52A5D7800
Name: v2_Payment to Participants

HP-00100473 Payment Detail_V2

Payment/Reimbursement Detail

You indicated that participants will receive payment (money, gift certificates, coupons, etc.) or reimbursement for their participation in this research.

1 * Payment/reimbursement to participants will be for: (check all that apply)

- [ ] Travel
- [x] **Parking**
- [ ] Meals
- [ ] Lodging
- [x] **Time and effort**
- [ ] Other

1.1 If Other, specify:

2 * What is the total dollar value of the payments/reimbursements over the duration of the study? ***Total payment(s) for participation in research of $600 or more in a calendar year is required to be reported on an IRS Form 1099.***

$50

3 * Describe the timing and distribution plan for the payment/reimbursement (schedule, means, etc.)?

Participants will be paid $50 for completing the study, allowing for proration if necessary. We will begin to issue the payment within one week of study completion (12 week assessments + exit interview). Participants will also be allowed to keep the Fitbit activity tracker. The Fitbit activity tracker has a retail value of approximately $200.

The default compensation will be an electronic gift card. We will also offer cash (they would need to come to the SON to pick it up) or a check mailed to their house. We will ask their preference at the exit interview.

If they can download the app and do not complete the entire study they can still keep the Fitbit and we will prorate compensation based on how much they completed. We will compensate them $15 for baseline assessments and $15 for midpoint assessments. Payment will be issued one week after their scheduled week 12 (if loss to follow-up) or upon their withdraw of the study.

If a participant cannot download the app due to incompatibility issues with their phone and the app, they may complete the baseline questionnaires and the exit interview to receive $25.

4 * Method(s) of payment/reimbursement to be Used:

- [x] **Cash**
- [x] **Check**
- [ ] Money Order
- [x] **Gift Certificate/Gift Card**
- [x] **Other**

4.1 If Other, specify:

$50 will be paid by electronic gift card, check, or cash. In addition to payment in the amount of $50, participants will be allowed to keep the activity tracker upon study completion. They will also receive parking vouchers, one per visit, if they come in for help with the app, REDCap, etc.

ID: VIEW4E1C54A6ACC00
Name: v2_Payment Detail

HP-00100473 HIPAA_V2

HIPAA (Health Insurance Portability and Accountability Act)

1 * Are you affiliated with, or will you be accessing data from a HIPAA-covered entity? A covered entity might be a hospital, a physician practice, or any other provider who transmits health information in electronic form.

• At UMB, this includes UMB schools designated as covered entities (School of Medicine and School of Dentistry) and entities under the University of Maryland Medical System (UMMS). The Baltimore VA Medical Center is also a covered entity.

• If you are a researcher from any school that is not a covered entity but is accessing electronic medical records from a covered entity (such as UMMC), HIPAA would be applicable. Please see a list of covered entities included under UMMS here: *executed-ace-designation-042018.pdf*

● **Yes** ○ No

2 * If Yes, will the study view, access, share, collect, use, or analyze health information that is individually identifiable under HIPAA?

● **Yes** ○ No

ID: VIEW4E1B0A2114400
Name: v2_HIPAA

HP-00100473 Protected Health Information_V2

Protected Health Information (PHI)

You indicated that HIPAA applies and the study will view, access, share, collect, use, or analyze health information that is individually identifiable.

1 * Which PHI elements will be used or disclosed in this study? (Check all that apply)

- [x] **Name**
- [x] **Address (if more specific than Zip Code)**
- [x] **Dates**
- [x] **Ages over age 89**
- [x] **Telephone numbers**
- [ ] Fax numbers
- [x] **Email addresses**
- [ ] Social Security numbers
- [x] **Medical record numbers**
- [ ] Health plan beneficiary numbers
- [ ] Account numbers
- [ ] Certificate/license numbers
- [ ] Vehicle identifiers and serial numbers, including license plate numbers
- [ ] Device identifiers and serial numbers
- [ ] Web universal resource locators (URLs)
- [ ] Internet protocol (IP) address numbers
- [x] **Biometric identifiers, including fingerprints and voiceprints**
- [ ] Full-face photographic images and any comparable images
- [ ] Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification
- [ ] None

2 * Why is the PHI necessary for this research?

If SSNs are going to be used, describe the specific use and type of SSN to be used (real, scrambled, last 4 digits).

Name - to identify, recruit, and communicate with the participant
Address - to mail activity trackers if the participant chooses not to come in
Dates - dates of cancer treatment are necessary for eligibility determination and will be part of the Survivorship Care Plan
Age - while the study team will know the person's birthdate, including year, we will not report any specific ages in our presentations or manuscripts. Only averages or categories will be presented.
Telephone number - we will check in with each participant approximately every 2 weeks via phone
Email - we will email questionnaire links to the participants
Medical record number - we will access participants' medical records as part of the study
Biometric identifiers - we will have audio-recorded interviews and, in some cases, paper-based forms with handwriting. All these data will be transferred to electronic forms so that they are not identifiable during analysis.

3 * What is the source(s) of the PHI?

Name - medical record
Address - on study form (patient-report)
Dates - medical record
Age - medical record
Telephone number - on study form (patient report)
Email - on study form (patient report)
Medical record number - EPIC
Biometric identifiers - audio-recordings from interviews, paper-based data collections forms

4 * Provide written assurance that Protected Health Information will not be reused. (Note: this refers to re-use on another study or for a purpose which has not been approved, not to the re-use of screening data during the current study).

Protected Health Information that is collected for this study will be used only for this study and not for any ongoing or future studies.

5 * How will permission to allow the use/disclosure of the individual's protected health information (PHI) be obtained? (Choose all that apply:)

- [x] **Obtain written authorization** ***(upload authorization form at the end of the application under "Consent and HIPAA Authorization Forms")***
- [x] **Requesting waiver/alteration of authorization (includes waiver of authorization for recruitment only)**
- [ ] Qualifies as a limited data set (LDS)

5.1 If you are using a limited data set (LDS), please attach the Data Use Agreement (DUA):

Name	Created	Modified Date

There are no items to display

ID: VIEW4E1B0A24AA400
Name: v2_Protected Health Information

Waiver/Alteration of Authorization

You indicated that a waiver/alteration of authorization is requested.

1 * Provide rationale for how the research presents no more than minimal risk to the privacy of individuals:

A waiver of authorization will be requested for screening purposes only. Our screening log contains the following information:
- Screening ID (1, 2, 3,…)
- Name
- Date of contact
- Medical record number
- How the participant learned of the study (e.g., our team, provider, brochure)
- Where/how we talked to the potential participant (e.g., clinic location, phone)
- Whether the patient was eligible or not
- If ineligible, the reason they are ineligible
- Whether the patient ultimately consented or declined
- If declined consent, the reason for declining consent
- If consented, the participant ID in the study (e.g., PST01, PST02, PST03, …)

2 * Describe the plan to ensure the protection of PHI collected during this study from improper use and disclosure:

The screening log will be stored on a HIPAA-compliant OneDrive, and will only be accessible with individuals whom Dr. Kleckner shares the file (e.g., coordinators).

3 * Describe the plan to destroy the PHI collected during this study at the earliest opportunity consistent with the conduct of the research. If there is a need to retain PHI, provide a justification:

With regard to the conduct of the research, the screening log may be destroyed after publication of the CONSORT diagram, which will likely be published as part of the primary aims manuscript. We will retain the data longer if deemed necessary by the sponsor or university.

4 * Why could the research not practicably be done without access to and use of this PHI?

It is necessary to have a member of the study team screen and identify potential participants. If we had to rely on clinicians to do this job, the rate of recruitment will be greatly hindered.

5 * Why could the research not practicably be done without the waiver or alteration?

Recruitment will occur much slower if we rely on participants to contact us in response to advertising or if we have to rely on clinicians, who are very busy, to identify potential participants.

6 * Will the subjects' PHI be disclosed to (or shared with) any individuals or entities outside of UM?

○ Yes ● **No**

6.1 If Yes, describe the individuals or entities outside of UM to whom PHI will be disclosed.

ID: VIEW4E1B0A2896400
Name: v2_Waiver/Alteration of Authorization

Informed Consent Process

If the study does not involve interaction with participants or a waiver of consent is being requested , answer "N/A" to the questions below.

1 * Indicate the type(s) of consent that will be involved in this study: (check all that apply)

- [ ] Not applicable (study may qualify as exempt)
- [ ] Request to Waive Consent/Parental Permission (Consent is not being obtained)
- [ ] Request to Alter Consent (Some Elements of Consent Waived)
- [ ] Request to Waive Documentation of Consent (Verbal/Oral Consent)
- [x] **Written Consent Form**
- [x] **Electronic Consent**

2 * Describe the Informed Consent process in detail:

1) Leading up to consent
If a member of the study team sees a potential participant after a doctor's appointment, consent can be done at that time or at a later date (either in person or eConsent).

If a member of the study team and a potential participant talk on the phone, regardless of who called whom, the participant will have the option of completing eConsent or in-person consent. After explaining the details of the study, if the person is interested, we will send a pdf copy of the consent and make a future appointment (in-person or phone/videoconference) to conduct the consent.

2) Obtaining consent
a) Written consent
For people who are interested in participating, a member of the study team will meet with the potential participant in a private room. She or he will go through the consent form with the patient face-to-face to ensure comprehension. They will then be given the option to sign the consent form. Members of the study team including Dr. Kleckner (PI) will be available to answer any questions the potential participant may have about any aspect of the study prior to consenting and throughout the entire study period. The participants will also have access to the dietitians at UMMC if they have other diet-related questions. Potential participants will be allowed to take the consent form home to think about and discuss with family or friends; each potential participant will have sufficient time to consider participation.

b) eConsent
Instead of the paper-based consent document, consent may occur using the IRB-approved eConsent document provided via REDCap. The study staff will screen for potential participants using the above screening procedures and initiate initial contact via the following methods: i) the treating oncologist or a member of the medical team (e.g., nurse practitioner) will introduce the study to the participant via a clinic appointment (in person or telehealth) and inquire if it would be okay for our study team to contact them, ii) with approval of the treating oncologist or a designee, a recruitment letter will be sent to the potential participant briefly describing the study and asking them to contact us if they would like more information, and iii) with approval of the treating oncologist or a designee, a message will be sent to the potential participant via MyPortfolio briefly describing the study and asking them to contact us if they would like more information. If a potential participant is interested, the study team will talk to the person on the phone and obtain verbal permission from the patient to send a copy of the eConsent via email, stating, "Because UMB can't control the security of email once we send them, we need your permission to text or email you. Do you want to receive a copy of the consent document and a link to the eConsent via email?" (or something to that effect). Verbal permission from the patient will be documented. We will email the eConsent in the form of a pdf document and set up a phone call or video conference (participant's choice) to formally go over the consent document. In a separate email, we will provide a link to the eConsent document as well as instructions on how to access the eConsent—we will use verification with a passcode based on available information (e.g., the patient's home zip code). No personal health information will be sent via any emails. The eConsent documents may be viewed on computers, electronic tablets, or smartphones. The pdf copy of the eConsent and the REDCap eConsent will have identical information; it will be optional for the person to review the consent before the study team discusses it with them. After a member of the study team reviews the consent document with the participant over the phone or computer, they will have the opportunity to electronically sign the eConsent via REDCap. The person obtaining consent will initiate the eConsent process from within REDCap for their name and a timestamp to appear on the study participant's signed consent form. In order to authenticate that the person signing is that person, we will again use a passcode based on known information (e.g., the participant's year of birth). Once the eConsent form is signed and submitted, the patient will be able to receive a print out of the paper copy, download a pdf, and receive an email with a PDF attachment of the signed consent form.

3) The consent document
Consent is a process that occurs throughout the life of the study. We will ensure that participants are aware that consent is a voluntary process and that they can withdraw at any time. Because this study includes only one "phase," we will not ask participants to re-consent during the study unless there is a change to the study procedures or other pertinent information that would change a person's decision to participate in the study. The consent form will also contain information regarding HIPAA authorization.

For individuals who are eligible and who provide informed consent, the following information will be entered into a secure electronic database (e.g., password-protected Excel file on a password-protected computer). This information is needed in case contact is required after the study and the participant requires payment through the mail.
• Participant ID number (used to identify the participant on all study forms and notes)
• Name
• Participant phone number
• Participant home address
• Participant email address
• Medical Record number
• Date of informed consent
• Date of registration

3 * Confirm that the consent process will explain the following:

- The activities involve research.
- The procedures to be performed.
- That participation is voluntary.
- The name and contact information for the investigator.

(●) **Yes** ( ) No

4 * Describe who will obtain Informed Consent:
PI or study staff

5 * If obtaining consent from a legally authorized representative (LAR), describe how you will confirm that the individual is the LAR and can provide legally effective informed consent. *(Answer "N/A" if not obtaining consent from LARs)*
N/A

6 * Describe the setting for consent:
In-person consent will take place in a private consult or examination room at one of the UMMC hospitals, another private room, or a clinical room in the Department of Pain and Translational Symptom Science in the UM School of Nursing (across the street from UMGCCC).

Remote consent will take place wherever the potential participant wishes. An appointment to conduct remote consenting will be set up before consenting takes place to ensure the participant is not caught off guard and in an undesirable location.

The consenting appointment can always be rescheduled if the setting is not conducive to effective information transfer.

7 * Describe the provisions for assessing participant understanding:
A member of the study team will go through the consent document in real time with the participant and the participant will be encouraged to ask questions throughout the whole consenting process. At the end of the consent form, before the signatures, the participant will be asked several questions that ensure comprehension (e.g., I understand that participation in this research is completely voluntary - yes or no; see consent form).

8 * Describe the consideration for ongoing consent:
Consent is an ongoing process that occurs throughout the life of the study. Because this is a single-phase study that requires approximately 14 weeks of participation, we expect that written consent will only be provided by participants at the beginning of the study. However, we may need to re-consent should a change occur to a study procedure or if new knowledge arises that may change a person's decision to participate.

ID: VIEW4E1C661D0AC00
Name: v2_Informed Consent Process

Electronic Consent

1 You indicated that consent will be obtained electronically. Please confirm the following:

- Electronic consent document includes all elements of informed consent disclosure.
- The date of the electronic signature will be captured (N/A if waiver of documentation of consent is requested).
- Questions or methods to gauge subject comprehension of key study elements are clearly defined in the informed consent procedures.
- Electronic consent process includes age appropriate materials to facilitate comprehension.
- Electronic consent process is suitable to the study population or procedures are outlined to accommodate subject's needs.
- Electronic consent document/process allows subjects to proceed forward or backward or pause for review later.
- Measures are present to ensure that subjects have access to all of the consent related materials, including hyperlinks or other external documents.
- Plans are adequate to maintain external hyperlinks or documents and subject access to these documents throughout the lifespan of the study until completion are detailed in the informed consent procedures.
- The informed consent process outlines in detail how any included documents will be utilized.
- Measures are present to ensure that the identity of the signer and the integrity of the data can be verified when consent is not witnessed by the study team.
- For FDA-Regulated Clinical Trials including children as research subjects, if the parent or guardian initially documents the child's assent, procedures are in place to verify the child's identity and assent when the child initially presents to the investigator (N/A if the research is not an FDA-Regulated Clinical Trial).

* ● **Yes** ○ No

ID: VIEW8D7A331327BE44D
Name: v2_Electronic Consent

HP-00100473

undefined

Consent Forms - Draft_V2

Organization Review Requirements (other than IRB)

Answer the following questions to determine additional organizational review requirements:

1 **Department/Division Review** - All research submissions are required to undergo department/division/institutional review prior to IRB review. The following entity is listed as the required department/division/institutional review:

SON Pain & Trans Symptom Sci

If this information is incorrect, please notify the HRPO office.

2 **RSC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Radiation Safety Committee may be required.

* 2.1 Does the research involve the use of ionizing radiation? ○ Yes ● **No**

2.2 Does the research involve the sampling of radioactive human materials for subsequent use or analysis in a laboratory?

3 **IBC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Institutional Biosafety Committee may be required.

* 3.1 Does the research involve human gene transfer? ○ Yes ● **No**
-OR-
Does the research specifically apply to human studies in which induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, and such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected? This type of research is often referred to as recombinant vaccine trials.

3.2 Does the research involve the exposure of human subjects to pathogenic microorganisms, or the exposure of research staff to human subjects or samples known or reasonably expected to carry infectious disease(s)?

3.3 Does the research involve the sampling of materials from persons with no known infectious disease and where the only risk to study staff is occupational exposure to bloodborne pathogens as defined by the OSHA Bloodborne Pathogen Standard?

4 **Cancer Center Criteria** - Answer the following to determine if review by the Cancer Center (Hematology-Oncology) may be required.

* Does the protocol involve in any way studies related to the prevention, treatment, diagnosis, or imaging of neoplastic diseases? ● **Yes** ○ No

5 **General Clinical Research Center Review Criteria** - the GCRC offers free and/or cost shared resources for patient-oriented research. Click Here for more information.

Answer the following to determine if review by the GCRC may be required.

* Will the General Clinical Research Center (GCRC) facility or resources be used to conduct this activity? ○ Yes ● **No**

6 **VA Review Criteria** - Answer the following questions to determine if review by the VAMHCS R&D Committee may be required.

* 6.1 - Will the research be conducted by VA Investigators including PIs, Co-PIs, and Site Investigators on VA time (serving on compensated, WOC, or IPA appointments)? ○ Yes ● **No**

* 6.2 - Will the research utilize VA resources (e.g., equipment, funds, medical records, databases, tissues, etc.)? ○ Yes ● **No**

* 6.3 - Will the research be conducted on VA property, including space leased to and used by VA? ○ Yes ● **No**

PLEASE NOTE that the research may be funded by VA, by other sponsors, or may be unfunded.

ID: VIEW4E1AF91AB2400
Name: v2_Organization Review Requirements (other than IRB)

Summary of Required Reviews (other than IRB)

1 **Additional Committee Reviews** - Based on your responses to the previous questions, you have identified the following additional reviews. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's webpage.

Name of Related Submission

This protocol has no related submissions (RSC, GCRC, IBC, etc)

2 **Required Department and Specialty Reviews** - Based on the PI's organization (department, division, etc.) affiliation and answers to previous questions (use of Cancer Center, etc.), the organizations listed below are required to review this application. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	**Review Status**
SON Pain & Trans Symptom Sci	Complete
SOM Oncology Program	Complete

ID: VIEW4E1C8D9AE4000
Name: v2_Summary of Required Reviews (other than IRB)

Additional Documents

1

Upload all additional documents here:

Name	Created	Modified Date
Desrochers_Group1Biomed_CITI.pdf(0.01)	7/23/2024 5:21 PM	7/23/2024 5:21 PM
Desrochers_GCP_CITI.pdf(0.01)	7/23/2024 5:21 PM	7/23/2024 5:21 PM
Desrochers_NIH FCOI.pdf(0.01)	7/23/2024 5:21 PM	7/23/2024 5:21 PM
Desrochers_HIPAA 201.pdf(0.01)	7/23/2024 5:21 PM	7/23/2024 5:21 PM
Desrochers_HIPAA 125.pdf(0.01)	7/23/2024 5:21 PM	7/23/2024 5:21 PM
rosenblatt-COI-2.pdf(0.01)	6/26/2023 8:38 AM	6/26/2023 8:38 AM
james-gcp.pdf(0.01)	6/6/2023 3:42 PM	6/6/2023 3:42 PM
oppermann-HIPAA201.png(0.01)	6/2/2023 7:58 PM	6/2/2023 7:58 PM
oppermann-HIPAA125.png(0.01)	6/2/2023 7:58 PM	6/2/2023 7:58 PM
oppermann-GCP.pdf(0.01)	6/1/2023 5:19 PM	6/1/2023 5:19 PM
oppermann-citi.pdf(0.01)	6/1/2023 5:19 PM	6/1/2023 5:19 PM
james-hipaa201-25MAY2023.pdf(0.01)	6/1/2023 5:19 PM	6/1/2023 5:19 PM
james-hipaa125-25MAY2023.pdf(0.01)	6/1/2023 5:19 PM	6/1/2023 5:19 PM
james-citi-08MAY2023.pdf(0.01)	6/1/2023 5:19 PM	6/1/2023 5:19 PM
McGeorge-CITI-UMB.pdf(0.02)	5/1/2023 10:43 AM	5/19/2023 5:56 PM
POSTHOC User Guide 2 - FullAccess.docx(0.01)	5/3/2023 3:59 PM	5/3/2023 3:59 PM
POSTHOC User Guide 1 - All.docx(0.01)	5/3/2023 3:59 PM	5/3/2023 3:59 PM
rafal-Non-UMB SFI Disclosure Form.docx(0.01)	5/1/2023 10:44 AM	5/1/2023 10:44 AM
rafal-COI.pdf(0.01)	5/1/2023 10:44 AM	5/1/2023 10:44 AM
Rafal_HIPAA 201.pdf(0.01)	5/1/2023 10:44 AM	5/1/2023 10:44 AM
Rafal_HIPAA 125.pdf(0.01)	5/1/2023 10:44 AM	5/1/2023 10:44 AM
Rafal_GCP.pdf(0.01)	5/1/2023 10:44 AM	5/1/2023 10:44 AM
Rafal_CITI.pdf(0.01)	5/1/2023 10:44 AM	5/1/2023 10:44 AM
mcgeorge-Non-UMB SFI Disclosure.pdf(0.01)	5/1/2023 10:43 AM	5/1/2023 10:43 AM
mcgeorge-COI-training.pdf(0.01)	5/1/2023 10:43 AM	5/1/2023 10:43 AM
McGeorge_HIPAA_MGH.pdf(0.01)	5/1/2023 10:43 AM	5/1/2023 10:43 AM
McGeorge_CITI_GCP.pdf(0.01)	5/1/2023 10:43 AM	5/1/2023 10:43 AM
clingan-Hipaa201.PNG(0.01)	2/14/2023 10:44 AM	2/14/2023 10:44 AM
clingan-Hipaa125.PNG(0.01)	2/14/2023 10:44 AM	2/14/2023 10:44 AM
Study Packet(0.03)	8/31/2022 4:19 PM	2/13/2023 11:25 AM
Zhu_CITI.pdf(0.01)	1/10/2023 9:22 AM	1/10/2023 9:22 AM
2280GCCC_CRC determination letter_9.28.2022.doc.pdf(0.01)	12/16/2022 2:33 PM	12/16/2022 2:33 PM
Table 2: Comparison of tools available to the intervention and control groups(0.02)	6/17/2022 7:38 PM	9/29/2022 4:58 PM
Schema(0.02)	6/17/2022 7:32 PM	9/29/2022 4:57 PM
Data Collection Table(0.02)	6/17/2022 7:32 PM	9/29/2022 4:55 PM
Daily-Nutrition-Questions-Tips-Sheet(0.01)	8/31/2022 4:14 PM	8/31/2022 4:14 PM

ID: VIEW4E0962513A000
Name: v2_Additional Documents

Final Page of Application

You have reached the final page of this application. It is recommended that you click on the "Hide/Show Errors" link on the upper or lower breadcrumb row of this page. The "Hide/Show Errors" will do a search of your application, and highlight areas that are required or need to be completed prior to submitting.

By submitting this application, you are electronically routing the protocol for departmental scientific review and all other necessary reviews. According to information you have provided, this application will be routed to the following Departments for review prior to being forwarded to the IRB for review. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	**Review Status**
SON Pain & Trans Symptom Sci	Complete
SOM Oncology Program	Complete

Required Safety Committee Reviews - In addition to the IRB, the following committees must review this submission. Each additional committee has a separate online form that the study team will be required to fill out. All committee applications (IRB plus those listed here) must be completed properly before the 'package' of applications can be submitted. The team may complete these additional forms in any order or at any time prior to submission of the IRB Application. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's Workspace.

Name of Related Submission

This protocol has no related submissions (RSC, GCRC, IBC, etc)

You may check the progress of your application at any time by returning to the Workspace of this submission. A detailed history, including notes, dates, and times of events, is provided to you for this purpose.

If a reviewer returns the application to you, you must address their concerns and resubmit the protocol for review to all designated departments. After all departments have reviewed the application, it will automatically be sent to the IRB for review. Changes made to the submission after its approval must be submitted as modifications.

Investigator Attestation
By submitting this application, I, the Principal Investigator (PI), certify that the information provided in this application is complete and correct. Research will be conducted according to the submission as described, only by the approved principal investigator and study team members.

In addition, I agree to the responsibilities of a PI, including:

- Obtaining informed consent (if applicable) from all subjects as outlined in the submission.
- Reporting new information to the IRB per the requirements of the Investigator Manual.
- If Required, obtaining renewal of the protocol prior to the expiration of the approval period or halt all study activities upon study expiration.
- Accepting ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study and the ethical performance of the project.
- Ensuring performance of all research activities by qualified personnel according to the IRB approved submission.
- Ensuring that research personnel have or will receive appropriate training.
- Ensuring no changes will be made in the research until approved by the IRB (except when necessary to eliminate apparent immediate hazards to subjects).

Click the "Finish" button and then click "Submit Application" in the submission Workspace.

ID: VIEW4E1B10C500000
Name: v2_Final Page of Application

Add a Team Member

1 * Select Team Member:
Javier Rosales

2 Research Role:
Study Coordinator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
full-time coordinator in our department

Add a Team Member

1 * Select Team Member:
Nicolette McGeorge

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
App designer

Add a Team Member

1 * Select Team Member:
Howard Rafal

2 Research Role:
Technician or Assistant

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
◯ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
◯ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
◯ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
app designer and troubleshooter

Add a Team Member

1 * Select Team Member:
Cynthia Renn

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
TBD

Add a Team Member

1 * Select Team Member:
Shijun Zhu

2 Research Role:
Statistician

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
TBD

Add a Team Member

1 * Select Team Member:
Ahleah Gavin

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
TBD

Add a Team Member

1 * Select Team Member:
Paula Rosenblatt

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
◯ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
◯ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
◯ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
TBD

Add a Team Member

1 * Select Team Member:
IKMAT ADESANYA

2 Research Role:
Study Coordinator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
● **Yes** ○ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
nurse and PhD student

Add a Team Member

1 * Select Team Member:
Maria Rangwala

2 Research Role:
Study Coordinator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
nursing student

Add a Team Member

1 * Select Team Member:
Lauren Quick

2 Research Role:
Study Coordinator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
nursing student

Add a Team Member

1 * Select Team Member:
Phillip Desrochers

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
App developer from Charles River Analytics

Figure 1. Study Schema

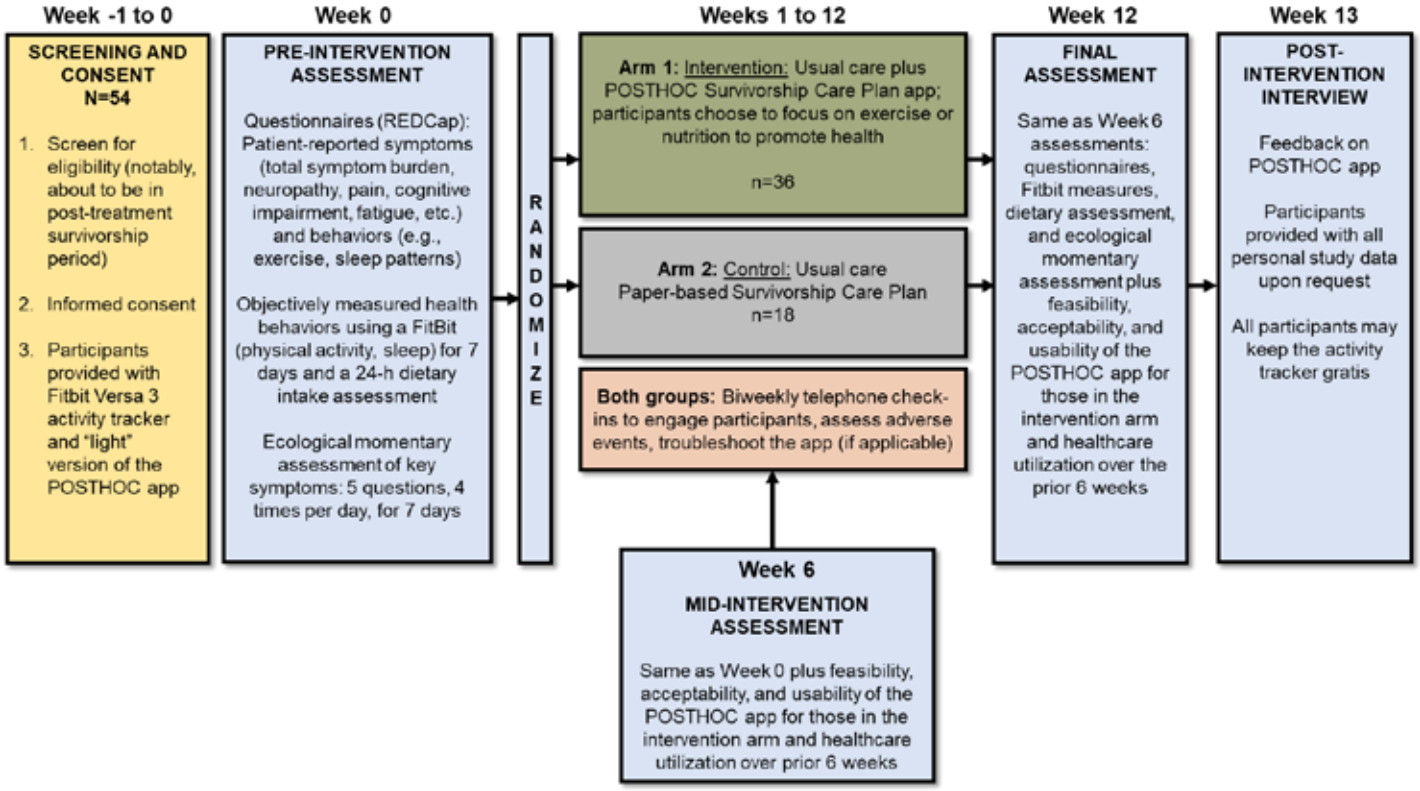


Table 1. Data collection table

Assessment or Activity	Study Goal	Assessment Location	Baseline (Week 0)	Intervention (Weeks 1-12)	Week 6	Week 12	Post-intervention (approx. Week 13)
Coordinators only							
Clinical Record Form	Demographics and clinical characteristics	REDCap	'				
	Healthcare utilization	REDCap			'	'	
	Clinician-reported patient health (i.e., ECOG performance status)	REDCap	'			'	
Participants							
On Study	Demographics and clinical characteristics	Clinic or home (REDCap*)	'				
Acceptability & Usability of POSTHOC app (intervention arm only)	Aim 1	Clinic or home (REDCap*)			'	'	
MD Anderson Symptom Inventory (MDASI)	Aim 2	Clinic or home (REDCap*)	'		'	'	
Smartwatch/ Activity Tracker (Fitbit Versa 3)	Aim 3	Home	'		'	'	
24-hour Dietary Assessment	Aim 3	Home	'		'	'	
Godin Leisure-Time Questionnnaire (GLTEQ)	Aim 3	Clinic or home (REDCap*)	'		'	'	
Ecological Momentary Assessments (EMA)	Exploratory	Home	'		'	'	

The Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F)	Exploratory	Clinic or home (REDCap*)	'		'	'	
Insomnia Severity Index (ISI)	Exploratory	Clinic or home (REDCap*)	'		'	'	
Chemotherapy-Induced Peripheral Neuropathy (CIPN-20)	Exploratory	Clinic or home (REDCap*)	'		'	'	
Brief Pain Inventory-Short Form (BPI)	Exploratory	Clinic or home (REDCap*)	'		'	'	
Brief Fatigue Inventory (BFI)	Exploratory	Clinic or home (REDCap*)	'		'	'	
Distress Thermometer (DT)	Exploratory	Clinic or home (REDCap*)	'		'	'	
Healthcare Utilization	Exploratory	Clinic or home via phone			'	'	
Telephone check-in (Intervention & Usual Care)	Compliance Booster/Troubleshooting	Home		Biweekly for 12 weeks			
Exit Interview	Exploratory	Clinic or home					' **

*If a participant prefers, they may complete paper-based versions of these assessments and return them to the study team in-person or in a postage-paid envelope.
**Or earlier if the participant withdraws early.

NOTE: Orange shading in column 1 indicates questionnaires

UNIVERSITY of MARYLAND BALTIMORE

RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Title:
Leveraging technology to address health outcomes of cancer survivors (POSTHOC)

Study No.: HP-00100473

Principal Investigator: Amber Kleckner, PhD, 410-706-5961

Sponsor: National Cancer Institute (NCI), National Institutes of Health (NIH), United States Department of Health and Human Services (HHS)

This Consent document describes a research study, what you may expect if you decide to take part, and important information to help you make your decision. Please read this form carefully and ask questions before you agree to participate.

CONCISE SUMMARY:

At the end of cancer treatment, many people are still dealing with symptoms of cancer and side effects of treatment. Survivorship Care Plans are plans that are provided to individuals at the completion of cancer treatment and describe the details of a person's diagnosis and treatment, as well as provide recommendations for follow-up appointments, referrals, and healthy behaviors to quicken recovery and prevent the cancer from coming back. In this study, we will be testing the effects of the established paper-based Survivorship Care Plan vs. a new smartphone app on symptoms and mood in early post-treatment survivorship.

The study lasts approximately 14 weeks. At the beginning of the study, you will be asked to:

- Complete online questionnaires related to your symptoms and feelings,
- Have a phone call or video session (your choice) with a study team member to talk about your typical dietary habits and explain the study,
- Wear a Fitbit smartwatch on your wrist to assess your physical activity and sleep, and
- Answer five questions, four times per day, about key symptoms (you pick the times, for example 9am, 12:30 pm, 4 pm, and 7:30pm), via a smartphone app that we provide.

After the first week, you will be randomly assigned to one of two groups: a paper-based or app-based Survivorship Care Plan. Those in the app group will choose to focus on nutrition or exercise for the duration of the study. At the middle (week 6) and end (week 12) of the study, we will ask you to complete the same study activities as at the beginning (online questionnaires, diet, wear the Fitbit, answer the symptom questions). Study materials may be provided in-person or via mail – your choice (i.e., you do not have to come in). You will be paid a total of $50 for your time to complete the study activities, and you can keep the smartwatch.

Key risks: emotional distress; breach of confidentiality; injury from physical activity.

Participating in this research study is voluntary. Your decision to participate will not affect your healthcare or treatment for your cancer in any way.

CONTACT INFORMATION:

Study team: nrsPOSTHOC@umaryland.edu
Principal investigator: Amber Kleckner, PhD, (410) 706-5961, amber.kleckner@umaryland.edu

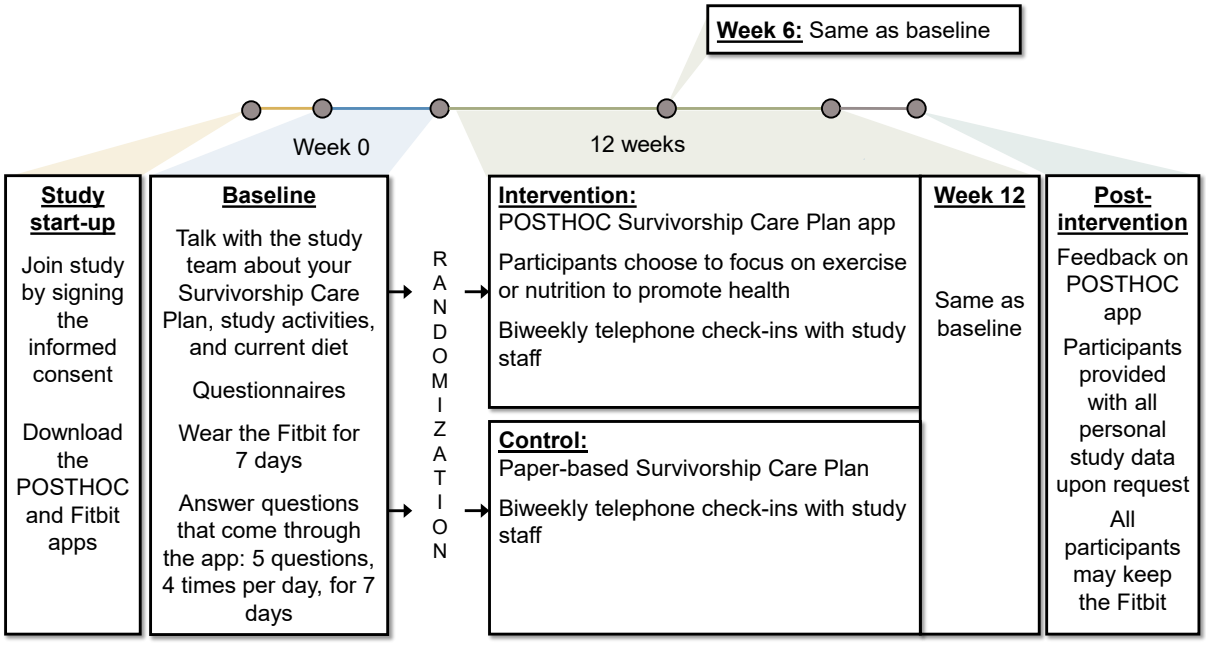
PURPOSE OF STUDY

In this study, we want to test the effects of the traditional paper-based Survivorship Care Plan compared to a new smartphone application ("app"), "POST-Treatment Health Outcomes of Cancer survivors" or "POSTHOC," on overall symptom burden in the early post-treatment cancer survivorship period. We want to collect feedback on the app's features so that it can maximally help people transition between active cancer treatment and early survivorship. Also, we want to get more information on the relationships between lifestyle behaviors (i.e., nutrition, physical activity, and sleep) and common cancer-related symptoms such distress, fatigue, pain, numbness/tingling, and how much these symptoms interfere with daily life; this will allow us to design more effective survivorship programs.

Approximately 54 participants will be recruited to take part in this study from the University of Maryland Medical System.

PROCEDURES

Here are the study activities and timeline. Each of the activities is described in more detail below.



The Survivorship Care Plan: Everyone in the study will receive a Survivorship Care Plan, either on paper, which is standard, or via the app, if you are in the app group. Specifically, the Survivorship Care Plan will list the names and roles of your providers, including your oncologist, primary care provider, and any specialists you have. It will list upcoming appointments and recommendations for future appointments with the target time frames (e.g., annual mammogram for breast cancer, annual CT scan for colorectal cancer). The Survivorship Care Plan also includes healthy lifestyle behavior goals for nutrition, exercise, sleep hygiene, and quitting tobacco products.

Fitbit: The Fitbit is a smartwatch that is used to track physical activity and sleep patterns. We will ask you to wear a Fitbit on your wrist every day for weeks 0, 6, and 12. We will help you set up the Fitbit app, and the POSTHOC app will automatically pull your activity data from the Fitbit app; no activity data will need to be entered by you. The Fitbit is not intended to be used as a medical device.

Questionnaires: We will ask you to complete 9-11 online questionnaires (depending on the time point) that ask about your symptoms, feelings, and habits. These will take approximately 35-50 minutes to complete—you can do them all at once or spread them out throughout the week. You also have the choice to complete these on paper. We will ask you to complete questionnaires three times throughout the study—at weeks 0, 6, and 12.

24-Hour Dietary Recall: A member of our study team will perform a 24-hour dietary recall with you during either a phone call or video session (your choice) three times throughout the study period. This will take approximately 30-45 minutes to complete.

Ecological Momentary Assessment: At four time points every day for seven days (at weeks 0, 6, and 12), we will "ping" you through the POSTHOC app to report the severity of four common symptoms—distress, fatigue, pain, numbness/tingling—and how much these symptoms are interfering with your daily activities on a scale of 1-10. We expect that you respond promptly (within 10 minutes or so) to the notifications.

Randomization and the two study groups: After the first week, you will be randomly assigned to one of two groups: the digital Survivorship Care Plan (i.e., the "POSTHOC app") group or the paper-based Survivorship Care Plan (i.e., the control group). No one on the study team knows which group you will be in until after week 0. The group you will be in is chosen by chance, like drawing a number out of a hat. There is a two-thirds (67%) chance you will be in the POSTHOC app group and a one-third (33%) chance you will be in the control group.

- POSTHOC app group: If you are assigned to the app group, the study team will input your Survivorship Care Plan into the app. You will choose whether you would like to prioritize nutrition or exercise as part of the study. We will set goals with you based on your Survivorship Care Plan, and teach you how to read and understand either the exercise data or food log data in the app. If you choose to focus on exercise, you will be encouraged to wear your Fitbit for the duration of the study (not just weeks 0, 6, and 12). If you choose to focus on nutrition, you will be encouraged to answer a few short questions regarding your diet at the end of each day, which will take approximately 30-60 seconds. In total, the time commitment will be a few minutes per week. You will also have access to other features of the app, such as logging symptoms.
- Control group: If you are assigned to the control group, you will not be asked to make any changes to your diet or exercise pattern.

Contact with the study team: We will call you about every two weeks to check in and see how you are doing. You may also call or email the study team in between these check-ins if you have any questions or concerns.

Exit interview: At the completion of the study, we will "interview" you about your experience in the study. We will ask you what you liked about it, what you didn't like about it, and ask for feedback on the POSTHOC app. If you were in the POSTHOC app group, we will ask you about your experiences with

the app. This interview will take 15-30 minutes and we will record the audio of the conversation (not video) if that is okay with you.

All of these research activities can be done remotely. However, you are welcome to come in and we will help you download the app onto your device, show you how to use the app, complete questionnaires, and/or complete other study activities. We are located in the School of Nursing, across the street from Greenebaum Comprehensive Cancer Center.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible for participating in the study activities, as outlined above.

POTENTIAL RISKS/DISCOMFORTS:

As with all research studies, there are risks associated with the study activities. We have taken measures to minimize all anticipated risks. Please consider these risks while deciding if you want to participate.

1. *Emotional distress*
   You could become upset or overwhelmed by the expectation to answer questions about your cancer experience and cancer-related symptoms. However, we want to emphasize that you are not "in trouble" if you do not follow the procedures exactly. We want to use what we learn from this study to improve the procedures for the next study.

   Our questionnaires contain information that might be distressing or private (e.g., "I am satisfied with family communication about my illness"). You do not have to answer any questions you are not comfortable answering, and you can take a break or stop answering the questionnaires at any time.

2. *Breach of confidentiality*
   There is always a risk of a breach of confidentiality in which sensitive medical information could become known to people outside the research team. To avoid leakage of sensitive information, only Dr. Kleckner (the study chair), the study coordinator(s), and any individual designees will have access to the screening log and the file that links your name with your subject number (both will be encrypted); these files will be stored on password-protected computers in their private offices. All data files will reference you by a non-identifiable Participant ID and will be stored on Dr. Kleckner's computer and secure servers at UMB. All consent forms will be stored in a locked cabinet also in her or her staff's office. All audio-recorded interviews will be transferred to Dr. Kleckner's secure computer and server at UMB within 2 business days of the interview and then immediately deleted from the recorder. All interview file names will not include your name or any identifying information. If Dr. Kleckner shares data with any other researcher for analyses, all data will be de-identified (i.e., <u>will not</u> have your name, birthdate, contact information, etc.). Presentation of study findings in the form of talks and manuscripts, either in private or public settings, will not have any identifiable information, nor will any audio clips ever be played in public. Dr. Kleckner and all other co-investigators participate in ethical training in accordance with institutional policies.

All data from the Fitbit will be continuously and passively streamed to the Fitbit servers. Other data collected from the study, including on the POSTHOC app, will not be shared with Fitbit.

POTENTIAL BENEFITS

You might or might not benefit from being in this research study. You may become more aware of your diet, physical activity, and sleep patterns, which can contribute to overall health. You may also feel a sense of satisfaction from contributing to research that is designed to help patients in the future.

ALTERNATIVES TO PARTICIPATION

This is not a treatment study, and the alternative is to not participate. Instead of participating, you may choose to log your diet, physical activity, and sleep patterns on your own, and/or see a clinician (e.g., dietitian, primary care physician) to explore how your diet, physical activity, and sleep patterns may be contributing to your overall symptoms.

CONFIDENTIALITY AND ACCESS TO RECORDS

Using your medical record number, we will access your electronic medical record so that we can get information regarding your cancer diagnosis, cancer treatment history, medical history, and social history. We will collect your name, address, phone number, and email address in order to contact you for scheduling and reminders of upcoming study activities. Only Dr. Amber Kleckner, the principal investigator, and her trained and designated research personnel will have access to confidential information. All confidential information that includes personally identifiable information will be coded with a study ID number. The principal investigator and study coordinator(s) will be the only individuals with access to the key of the assigned ID numbers. All confidential information will be locked in a cabinet in a secured location at the University of Maryland, School of Nursing. Your personally identifiable information will not be used for this study's analyses, but it will be kept on file if federal agencies or the Institutional Review Board (IRB) are mandated to review any information.

All study records will be considered confidential, and all participants' names and personally identifiable information will not be used in reports or publications. Efforts will be made to limit access to your personal information, including research study records, to people involved with the study who have a need to review this information. We cannot promise complete secrecy. Entities that may inspect and copy your information include the IRB and other representatives of this organization. Those designated from the University of Maryland will be allowed to examine certain research records of this study; however, anyone inspecting this information is required to keep this personal information confidential. Your personal information will not be released unless mandated by law. By signing this document, you are authorizing this access to the monitors, auditors, and the IRB.

All de-identified data from federally funded studies are required to be made publicly available, effective January 25, 2023. The majority of this study was federally funded before that date. However, deidentified transcripts of the exit interviews may be made posted in a public database.

The data from the study may be published. However, you will not be identified. People designated from University of Maryland and people from the sponsor will be allowed to inspect sections of your medical

and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

A description of this clinical trial is available on https://www.clinicaltrials.gov, identifier NCT05499663, as required by U. S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

We are using the POSTHOC app to deliver a digital version of your Survivorship Care Plan. In addition, we are using the app to collect data regarding the severity of four common symptoms – distress, fatigue, pain, numbness/tingling, and how much these symptoms are interfering with your daily activities. The POSTHOC app was developed by researchers at Charles River Analytics in Cambridge, Massachusetts. However, all your data from the app will be stored locally at UMB. **Charles River Analytics will not be able to view any personally identifiable information (e.g., name) or medical information (e.g., details of your cancer diagnosis) or any details that you or we input into the app.**

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator, Dr. Amber Kleckner, at 410-706-5961. To discontinue your participation in the study, a written withdrawal is requested, sent to Dr. Amber Kleckner at amber.kleckner@umaryland.edu.

If you withdraw from this study, already collected data will not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, these data will be handled the same as research data.

You will be told of any significant new findings that develop during the study that may affect your willingness to continue participation.

CAN I BE REMOVED FROM THE RESEARCH?

You may be withdrawn from the study if your health becomes worse or if your doctor feels that staying in the study is harmful to your health. The study team also holds the discretion to withdraw you from the study for any reason. For example, if you do not complete the first questionnaire and attempt to use the app within 3 weeks of consenting to the study, we will remove you from the study

The sponsor can also end the research study early. The study chair will tell you about this and you will have the chance to ask questions if this were to happen.

COSTS TO PARTICIPANTS

There will be no fee to enroll in the study. However, you or your insurance will be billed for costs of medical care that you would have needed or received if you were not in the study.

PAYMENT TO PARTICIPANTS

You will be compensated for your time to complete the study activities. We will pay you a total of $50 to complete all study activities. Payment will be delivered at the end of the third assessment (after Week 12) in the form of cash, electronic gift card, or check. All subjects who complete the study can keep the Fitbit activity tracker for free. If you decide to withdraw before completion of the study, your compensation will be prorated.

STUDY-RELATED INJURY

If you have an injury, promptly seek medical care from any healthcare provider. <u>If you have an emergency, call 911 or go to the nearest emergency room.</u> You should tell the healthcare provider that you have participated in a research study.

If you believe the injury is related to the study, notify the PI, Dr. Amber Kleckner, at 410-706-5961. UMB, if requested, will assist you to get medical care or referrals.

UMB and/or its affiliated healthcare facilities or healthcare providers will not provide any financial compensation or reimbursement to you for the cost of medical care or other expenses arising from an injury.

In such cases, you or your insurance may be billed for the costs of medical care.

UNIVERSITY STATEMENT

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research studies all rights due to them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in this study. This study has been reviewed and approved by an Institutional Review Board (IRB). The IRB is a group of scientists, physicians, experts, and community representatives. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research studies.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland, Baltimore
Institutional Review Board
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____
Participant's Signature

Date: _____

_____
Investigator or Designee Obtaining Consent Signature

Date: _____

Health Insurance Portability and Accountability Act (HIPAA)
AUTHORIZATION TO OBTAIN, USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH

Name of Study Participant: _____

Date of Birth: _____ **Medical Record Number: _____**

Name of this Research Study: *Leveraging technology to address health outcomes of cancer survivors*

UMB IRB Approval Number: *HP-00100473*

Researcher's Name: *Amber Kleckner, PhD*

Researcher's Contact Information: *Department of Pain & Translational Symptom Science*
University of Maryland School of Nursing
655 W. Lombard St.
Baltimore, MD 21201
410-706-5961

This research study will use health information that identifies you. If you agree to participate, this researcher will use just the health information listed below.

The specific health information to be used or shared:

- Demographics (e.g., height, weight, age, race, ethnicity, education, marital status)
- Details regarding cancer diagnosis and treatment (e.g., cancer site, cancer stage, chemotherapy type and dosing, surgical procedures, hormone therapy)
- Clinical characteristics (e.g., current menopausal status, Karnofsky Performance Status)
- Most recent blood work (e.g., hemoglobin, hematocrit, lymphocytes, etc.)
- Medical history (e.g., prior myocardial infarction, diabetes status)

Federal laws require this researcher to protect the privacy of this health information. She will share it only with the people and groups described here.

People and organizations who will use or share this information:

- Dr. Amber Kleckner and her research team
- The sponsor of the study, or its agents, such as data repositories or contract research organizations
- Organization that will coordinate health care billing or compliance such as offices within University of Maryland School of Nursing; the University of Maryland, Baltimore (UMB); University Physicians, Inc. (UPI) and the faculty practices of the UMB; and the University of Maryland Medical System (UMMS)

This Authorization will not expire, but you can revoke it at any time.
To revoke this Authorization, send a letter or email to this researcher stating your decision. She will stop collecting health information about you, and she will not allow you to continue in this study. She can use or share health information already gathered.

Additional information:

- You can refuse to sign this form. If you do not sign it, you cannot participate in this study. This will not affect the care you receive at:
    - University Physicians, Inc. (UPI)
    - University of Maryland Medical System (UMMS)

  It will not cause any loss of benefits to which you are otherwise entitled.
- Sometimes, government agencies such as the Food and Drug Administration or the Department of Social Services request copies of health information. The law may require this researcher, the University of Maryland School of Nursing, UPI, or UMMS to give it to them.
- This researcher will take reasonable steps to protect your health information. However, federal protection laws may not apply to people or groups outside the University of Maryland School of Nursing, UMB, UPI, or UMMS.
- Except for certain special cases, you have the right to a copy of your health information created during this research study. You may have to wait until the study ends. Ask this researcher how to get a copy of this information from her.

My signature indicates that I authorize the use and sharing of my protected health information for the purposes described above. I also permit my doctors and other health care providers to share my protected health information with this researcher for the purposes described above.

Signature: _____ Date: _____

Name (printed) _____

Privacy Questions? Call the UMSOM Privacy Official (410-706-0337) with questions about your rights and protections under privacy rules.

Other Questions? Call the researcher named on this form with any other questions.