Study Title: **Simplifying Survivorship Care Planning; Comparing the Efficacy and Patient-Centeredness of Three Care Delivery Models**

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# JHM IRB - eForm A – Protocol

- **Use the section headings to write the JHM IRB eForm A, inserting the appropriate material in each. If a section is not applicable, leave heading in and insert N/A.**
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## 1. Abstract

a. Provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.

BACKGROUND: Each year, approximately 1.6 million people are diagnosed with cancer and the relative 5-year survival rate across all cancer types approaches 70%. As of 2014, there were almost 15 million Americans living with a history of cancer. Cancer survivors face a variety of health care needs, including surveillance for recurrence, treatment for long-term and late effects of cancer and its treatment, general primary and preventive care, management of any comorbidities, encouragement of healthy lifestyle behaviors, and attention to psychosocial issues. In 2005, the Institute of Medicine (IOM) report 'From Cancer Patient to Cancer Survivor: Lost in Transition' highlighted the challenges that cancer survivors face as they transition from acute treatment (Hewitt, M., Greenfield, S., & Stovall, E., 2005). The completion of acute cancer treatment is a critical juncture at which patients are in need of better support and communication to ensure optimal health and quality of life outcomes as they transition to long-term survivorship. Cancer survivors face substantial deficiencies in the quality of care that they receive, including both underuse of recommended care and overuse of services that are not recommended for routine follow-up. The 2005 IOM report called for all patients completing acute treatment to be provided with a survivorship care plan (SCP) that summarizes treatments received and outlines future healthcare priorities in order to facilitate effective management of health care between survivors and their oncology and primary care providers.

OBJECTIVE: The purpose of this study is to identify an SCP process that is patient-centered, effective in promoting appropriate survivorship care and can be successfully implemented for patients with different types of cancer who are being treated in a broad range of clinical settings. There is a need for research related to SCP that prioritizes outcomes that are most highly valued by patients, caregivers and clinical stakeholders.

METHODS: In Year 1, we have worked with clinical partners and our Stakeholder Advisory Board, which consists of survivors, caregivers, members of the oncology team and primary care providers, to refine the three SCP approaches that will be tested in this trial. In addition, we conducted 6 focus groups (under IRB approval from the Johns Hopkins Bloomberg School of Public Health IRB #6805), four with patients and two with caregivers, to solicit patient and caregiver perspectives on the content, timing and delivery of survivorship care planning. We will now conduct a randomized controlled trial (RCT) to compare the impact of three models of varying intensity for SCP implementation, each of which is consistent with

current care practices. We will collect both quantitative (included here) and qualitative (to be added through a later amendment) assessments of the three SCP models.

**2. Objectives** (include all primary and secondary objectives)

The research is organized around three aims as outlined below:

AIM 1: Compare patients' receipt of follow-up care across the three models of SCP provision.

We will evaluate the effectiveness of three SCP models in facilitating patients' receipt of recommended health services in the 18 months following their completion of acute treatment. We will measure whether the mechanism of provision of the SCP to the patient is associated with their receipt of cancer-related follow-up care as outlined on their SCP (primary outcome). Secondary outcomes include avoidance of services that are not recommended and receipt of primary and preventive care.

AIM 2: Compare patient-reported outcomes across the three models of SCP provision.

We will also compare relevant patient-reported outcomes (PROs) across the three intervention arms (secondary outcomes). We will assess knowledge about and confidence in follow-up care using the Preparing for Life as a (New) Survivor (PLANS); cancer worry and health worry with the Assessment of Survivor Concerns (ASC); and information needs with the Follow-up Care Use among Survivors (FOCUS) questionnaire.

AIM 3: Assess patients' perspectives on the value of survivorship care planning

We will conduct qualitative interviews with a subset of patients (n=40) to assess which aspects of the SCP process are most valued and explore whether there are different perspectives on the value of SCPs between institutions or by cancer type or study arm. This aim is not included in this protocol. It will be submitted as an amendment as the interview guide will be informed by the implementation of the trial.

Data from the 3 aims will identify attributes of SCP models and implementation processes that can be used to promote feasible and effective patient-centered survivorship care planning processes across a range of clinical settings, cancer types, and populations served. Determination of the preferable mode of SCP delivery will be based off of the primary endpoint (receipt of recommended follow-up care over 18 months).

**3. Background** (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

The SCP is intended to provide clear instructions as to what screening, surveillance, health maintenance, wellness activities and psychosocial care are necessary going forward, with the goal of promoting appropriate clinical service use, reducing overlaps in care, improving patient and provider communication, and ultimately enhancing quality of life through the survivorship trajectory. Our review of the literature indicated a wide variation in rates of compliance with surveillance recommendations. Previous studies show that that patient adherence in the survivorship period is varied, depending on the cancer type and/or the type or procedure or office visit to be completed. For example, colorectal cancer survivors completed recommended follow up care with adherence rates varying from 16.7% (Saloum et al, 2012) to 46.7% to 92.3% (Cooper et al, 2008). Rates for breast cancer patients are generally higher, but also very variable (Cooper et al 2008; Snyder et al, 2009; Grunfeld et al, 2010). Thus, we considered a range of adherence probabilities and varying differences in our analytic plan.

One challenge for the field is that the IOM's recommendation was based on "face validity", rather than scientific evidence. Data as to the impact of SCPs on health care delivery and survivorship outcomes remain quite sparse and findings have been mixed. Moreover, the time and resources required for survivorship care planning present substantial barriers to implementation. Nevertheless, the American College of Surgeons' (ACS) Commission on Cancer is now mandating SCPs for all eligible patients by 2019. As of 2013, only 21% of American College of Surgeons Commission on Cancer member organizations reported having developed SCPs (American College of Surgeons Commission on Cancer, 2016). Thus, research on the simplest, most effective approaches for conducting survivorship care planning is critically needed.

**4. Study Procedures**

a. Study design, including the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care).

OVERVIEW: The primary aim of this trial is to assess whether there is a difference among three SCP models of varying levels of resource intensity and patients' receipt of recommended health services in the months following completion of acute treatment. We will conduct a randomized controlled trial (RCT) to measure whether the provision of the SCP to the survivor and PCP is associated with survivors' receipt of cancer follow-up care as outlined on their SCP (primary outcome). Avoidance of non-recommended care, receipt of recommended primary and preventive care, and patient-reported outcome measures will serve as secondary endpoints.

Participants in the RCT will have been treated for breast, prostate, or colorectal cancer. This RCT will be conducted in four oncology clinics in two medical systems. We will enroll survivors of Stage I-III breast, prostate, or colorectal cancer who are completing treatment and transitioning to long-term survivorship, and use a stratified randomization to assign participants to one of three study conditions (Arms A, B or C). This study will focus specifically on the period following completion of acute treatment (e.g., surgery, radiation, and chemotherapy); patients receiving long-term adjuvant endocrine/antibody therapies will also be eligible.

The proposed trial will be conducted at Johns Hopkins Medical Institution (JHMI) and Peninsula Regional Medical Center (PRMC) oncology program practices. JHMI is a large, academic medical center in an urban setting with distinct treatment programs based on disease site. At JHMI, we will recruit from the Breast Cancer Program, the Genitourinary Cancer Program (prostate cancer), and Gastrointestinal Cancer Program (colorectal cancer). These programs operate across disciplines (e.g., medical, radiation, and surgical oncology) but separately from each other, enabling evaluation of three separate clinical settings within JHMI. In addition, the trial will include the PRMC Richard A. Henson Cancer Institute, a community cancer program located in the rural area of Maryland's eastern shore. At PRMC, the oncology program practices include medical and radiation oncology services with surgical and urological oncology care provided within local private practices with medical staff privileges. The four programs differ in the extent to which survivorship care planning is already a part of routine care. As yet, none of the clinics in this study has a consistent format for the delivery of SCP universally at the completion of acute treatment. Our study design (cancer types, clinical systems and SCP models) is intended to enable the development of real-world best practices for the implementation of SCPs and assess whether these are consistent or vary across a wide range of clinical contexts and survivor characteristics.

b. Study duration and number of study visits required of research participants.

Each participant will be followed for 18 months, with the number of visits dependent on the randomization arm (described below). We will abstract 18 months of follow-up data for enrolled patients from medical

records, as well as from patient reports of health service use; data will be collected at months 6, 12, and 18. We will obtain and abstract medical records guided by the information in the summary document (see Health Services Use Summary included as a supplemental study document) and from the patient using provided tracking tools of providers they have seen, tests they have undergone, etc. (see Tip Sheet in supplemental study documents). Patient-reported outcomes will be collected at baseline, 6, 12, and 18 months primarily via a REDCap form, with telephone, mail, or in-person data collection as a back-up when needed (See Pro Data Collection form in supplemental study documents).

**ARM A (SCP document delivered to the patient & Primary Care Provider [PCP]):**
Patient participants randomized to Arm A will be sent a copy of the SCP within approximately 3 months of completion of treatment and a copy will be added to their medical record. A copy of the SCP will also be sent to the PCP on record. The SCP will be completed by a nurse, nurse practitioner, or physician assistant. The SCP will be accompanied by a cover letter that will be signed by a member of the clinical team.

**ARM B (SCP document provided to the patient in an in-person survivorship visit and copy sent to PCP):**
Patient participants randomized to Arm B will receive a copy of the SCP during an in-person 'stethoscope free' visit with a nurse, nurse practitioner, or physician assistant. A copy of the SCP will be added to the medical record and a copy will be sent to the primary care provider on record. The visit will be scheduled after consent is signed and will occur within approximately 3 months after treatment completion. The visit will focus on review of the SCP content and offer an opportunity for patients to ask questions about any aspect of the plan or associated treatment and survivorship issues.

**ARM C (SCP document provided to the patient in an in-person survivorship visit with an additional follow-up visit and copy of the document sent to PCP):**
Patient participants randomized to Arm C will receive a copy of the SCP during an in-person 'stethoscope free' visit with a nurse, nurse practitioner, or physician assistant. A copy of the SCP will be added to the medical record and a copy will be sent to the primary care provider on record. The visit will be scheduled after consent is signed and will occur within approximately 3 months after treatment completion. The initial visit will focus on review of the SCP content and offer an opportunity for patients to ask questions about any aspect of the plan or associated treatment and survivorship issues. In addition, patients randomized to Arm C will receive a follow up survivorship visit approximately 6 months after the initial in-person 'stethoscope free' visit. The follow-up visit will focus on a review and refresher of the SCP and offer patients the opportunity to ask about any persistent or emerging issues.

c. Blinding, including justification for blinding or not blinding the trial, if applicable.

Given the nature of the interventions, it is not possible to blind patients or providers to the randomization arm.

d. Justification of why participants will not receive routine care or will have current therapy stopped.

All patients will receive routine care and there is no impact on current therapy. This study is evaluating three different approaches for survivorship care planning, each of which is standard of care.

e. Justification for inclusion of a placebo or non-treatment group.

Because of the Commission on Cancer Accreditation requirement that all cancer patients completing acute treatment receive a survivorship care plan, a no intervention arm is not appropriate. Rather, this study will

evaluate different approaches for conducting survivorship care planning in the simplest way that is still effective in helping survivors receive appropriate follow-up care.

f. Definition of treatment failure or participant removal criteria.

We will follow participants for 18 months or until cancer recurrence, at which point they would not receive any further survivorship care planning visits, and no additional health service use or patient reported outcomes data would be collected. Treatment failure is not relevant to this study, and we will not remove participants unless they explicitly withdraw consent. Even if patients do not complete the follow-up surveys, we can still collect their health resource use from their medical records (unless they have withdrawn consent).

g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.

Not applicable as no therapy is included in this study.

RECRUITMENT PROCESS: Clinic and study staff trained in research ethics and HIPAA requirements will coordinate identification and recruitment of potential participants. Specifically, potential participants will be identified during chart review in advance of a routine clinic visit or during a routine clinic visit with a provider. The research team will be searching medical records for patients who have completed, or will soon be completing, treatment. Searching for patients with active treatment appointments is one, but not the only, way we may identify eligible patients. The clinical teams have agreed to provide us with insights on the best ways to identify patients potentially eligible for the study based on their medical records. Potential participants will be approached by a member of clinic staff to determine willingness to learn more about a study for which they may be eligible.

Clinic staff will always get permission from the patient for the research staff to make contact with the patient before any contact is made by the research staff. If a patient expresses interest in learning about the study then clinic staff will refer them to research staff. The research team will attempt to recruit participants in the clinic (face to face) unless scheduling does not permit or the patient requests to be contacted by email or telephone. Discussions regarding study participation will take place privately and individuals will be provided with the IRB approved consent form. In addition, potential participants may contact the study team directly using contact information as provided on the IRB approved consent form and the IRB approved handout. Potential participants will be given as much time as is needed to consider study participation. For individuals who choose to take part, informed consent will happen as per the consent process.

CONSENT PROCESS: Potentially eligible patients will be notified about the nature of the survivorship care planning trial and associated study procedures by a member of the research staff. Eligibility information will be retained on all potential participants who come into contact with the research team.

Potential participants will be informed that not participating in this study will not affect the care that they receive other than the SCP delivery mechanism that is being studied in the trial.

The consent process will be conducted by a member of the research team (principal investigator, co-investigators, study staff). The researcher will ask whether the potential participant has any questions and will provide an opportunity to review the form together, discuss any issues, questions or concerns before the document is signed.

Signed consent will be required for inclusion in the trial. With their permission, we will track the number and basic demographics of any potential participants who decline to participate (e.g., age, sex, cancer type, reason for declining) in order to capture characteristics of patients approached who declined.

Those members of the research team (principal investigator, co-investigators, study staff) who consent patients have been trained in informed consent procedures, are familiar with the protocol, and are listed as a consenter in the application document. Patients are given adequate time and privacy to consider the research study. Before the patient signs the consent, the consenter must be satisfied that the participant understands the information provided, has had an opportunity to discuss the information and ask questions, and is aware that he/she may withdraw from the study at any time. We will not be enrolling Non-English speaking participants to this study.

STUDY IMPLEMENTATION: We will use stratified randomization to assign enrolled patients 1:1:1 to the 3 study arms using a random number generator with the condition concealed until randomization. Patients and their clinicians will be informed of the condition to which the patient was assigned after randomization. The SCP template will be completed via EPIC or in paper format. The EPIC templates have been developed and created in EPIC with the guidance of the clinical co-investigators and the clinic staff. Currently, we are working with clinic staff to test the EPIC templates and then to work with the EPIC programming team make necessary modifications for staff and patient utility. The SCP that has been built into EPIC is based on the template developed by the American Society of Clinical Oncology (ASCO) via a multi-stakeholder process. This ASCO template has been revised and refined in consultation with the clinical co-investigators and advisors to improve functionality and processes in the clinics involved in the trial (e.g., through drop-down menus) (See supplementary study documents for mock-ups of each of the 3 EPIC templates). A member of the clinical staff (and not research staff) will be in charge of the creation of the SCP. The specific follow-up care recommended will be informed by ASCO and other relevant guidelines, as well as standards of care in each clinic. The general recommendations will be based on the guidelines as outlined in Table 1, but the clinician completing the form can tailor the specific recommendations based on clinical judgement. As described above, the SCP will either sent to the patient (Arm A) or delivered in an in-person visit conducted by a nurse, nurse practitioner, or physician assistant (Arms B & C).

**Table 1: Recommended Follow-up Care and Outcome Measures**

<table>
<tr><th colspan="5">Outcome Measures<br>(Based on NCCN 2013 and ASCO Guidelines)</th></tr>
<tr><td colspan="2">TUMOR TYPE</td><td>BREAST</td><td>COLORECTAL</td><td>PROSTATE</td><td rowspan="2">Data Collection<br>Timing and Approach</td></tr>
<tr><td colspan="2">Stage</td><td>Stage I-III</td><td>Stage I-III</td><td>Stage I-III</td></tr>
<tr><td rowspan="3">HEALTH SERVICE USE</td><td>Recommended Surveillance</td><td>Every 3-6 months:<br>H&P exam<br>Annually:<br>Mammography (excluding women with bilateral mastectomy)</td><td>Every 3-6 months:<br>H&P exam<br>CEA<br>Annually:<br>CT scan chest, abdomen, and pelvis<br>Colonoscopy (ok to do first at year 3 if preoperative full colonoscopy normal)</td><td>Every 6-12 months:<br>H&P exam<br>PSA</td><td rowspan="3">Patient reports assessed at:<br>Baseline & Months 6, 12, 18<br><br>Medical records abstracted at:<br>Month 18<br><br>All health service use variables will be based on medical record abstractions, guided by patient tracking tools. During the study contacts, we will obtain patients' reports of providers they have seen, tests they have undergone, etc. At Month 18, we will obtain & abstract all relevant medical records.</td></tr>
<tr><td>Not Recommended Surveillance (assumes normal H&P and normal recommended surveillance)</td><td>Imaging<br>Breast MRI<br>FDG PET/CT<br>CT chest, abdomen, pelvis<br>Liver ultrasound<br>Bone scan<br>Blood tests<br>Tumor marker CEA, CA15-3, or CA27-29</td><td>Imaging<br>Chest X-ray<br>FDG PET/CT</td><td>Imaging<br>FDG PET/CT<br>Bone scan<br><br>.</td></tr>
<tr><td>Recommended Preventive Care Measures</td><td colspan="3">Visit with primary care provider<br>Annual influenza immunization</td></tr>
</table>

The general recommendations will be based on Table 1, but the clinician completing the form can tailor the specific recommendations based on clinical judgement. As described above, the SCP will either be sent to the patient (Arm A) or delivered in an in-person visit conducted by a nurse, nurse practitioner, or physician assistant (Arms B & C).

For all arms, participants will be followed for 18 months, or until cancer recurrence. The participants will be contacted approximately 6, 12, and 18 months after the end of treatment to provide data on health service use and patient-reported outcomes.

Health service use will be collected from patient-report via telephone or in-person at 6, 12, and 18 months after completion of treatment, as well as from medical records. Patients will be supplied with a calendar and asked to note office visits, hospitalizations, emergency department visits, prescriptions, tests, and other health resource use. We will also provide participants with a tip sheet for tracking providers visited, care received, tests done, and prescriptions obtained. The tip sheet template has been adapted from the Medical Expenditure Panel Survey, courtesy of the Agency for Healthcare Research & Quality (see study supplemental documents) (Cohen, et al., 1996). At each data collection point, patients will use these resources to report what health services they have received during the past 6 months.

We will also request and abstract the medical record of each participant for the 18-month study period. The abstraction will focus specifically on surveillance and preventive care. We will also collect all health service use during the study period (outpatient visits, tests, imaging studies, hospitalizations, emergency department visits, medication list). These data will allow us to explore receipt of other preventive and screening services that may be age-based and/or not required on an annual basis (e.g., cholesterol screening, cervical cancer screening), as well as overall health service use (see supplemental study documents for Health Services Use document) .

Patient-reported outcomes will be collected at baseline, 6, 12, and 18 months. The default mechanism for these contacts will be via a REDcap form, with a link sent to the participants via email (see supplemental study documents for Pro Data Collection form). Where this is not possible, the research staff will collect data on the telephone, by mail or in-person.

SAFETY AND MONITORING: Dr. Smith (PI) is responsible for internally monitoring the study and establishing additional external data & safety monitoring oversight, as required. Dr. Smith will also monitor the progress of the trial, review safety reports, and confirm that the safety outcomes and response assessments favor continuation of the study. CROQA will perform risk-based auditing, depending on rate of accrual and relevant review findings. Review reporting will assessed annually by the SKCCC Safety Monitoring Committee (SMC); requested source documentation, including SKCCC-required AE & Deviation Logs, must be continually updated per GCP and provided annually to assure validity of data and safety of subjects for peer-review. Dr. Smith will also monitor the progress of the trial, review safety reports, and clinical trial efficacy endpoints and to confirm that the safety outcomes favor continuation of the study. Dr. Smith is also responsible for internally monitoring the study and establishing additional external data & safety monitoring oversight (MEC, DSMB, etc) as required per protocol.

DATA SAFETY AND MONITORING: All electronic data will be stored on password protected space on JHBox. Only members of the study team who are listed on the IRB protocol will have access to the data. Data (both electronic and hard copies) will have a unique identifier and no additional identifying information will be included with data. The file linking the unique identifier and name and contact information for all participants will be kept in a locked cabinet in a private study office, separate from the data themselves. All hard copies of data will be kept in locked filing cabinets in a private study office in Hampton House (624 N. Broadway). Data will be collected via REDCap and by study staff over the

telephone. Data collected via REDCap will not require any delivery between staff at PRMC and Johns Hopkins. Data collected on paper over the telephone or by mail by PRMC staff will be entered into REDCap by the research staff.

## 5. Inclusion/Exclusion Criteria

PARTICIPANTS: We will enroll survivors of Stage I-III breast, prostate, or colorectal cancer who are completing acute cancer treatment and transitioning to long-term survivorship. This study will focus specifically on the period following completion of acute treatment (e.g., surgery, radiation, and chemotherapy); patients receiving long-term adjuvant endocrine/antibody therapies will also be eligible. To be eligible for this study, JHMI or PRMC oncology program practices have to be considered "responsible" for the patient's survivorship (e.g., patients who only received part of their treatment at a recruiting site but who are being followed elsewhere would not be eligible). This study focuses on adult survivors of adult cancers; no children will be included.

We will obtain a HIPAA waiver for this study. The research team will review clinic appointment schedules and medical records to identify potentially eligible patients. The research team will track the number of patients approached, the number eligible, the number who consented, (with permission) basic demographic information on patients who declined, and reasons for declining.

We will be collecting identifying information from participants. We will collect participant names, addresses, and phone numbers (and email addresses if applicable) to use to contact participants throughout the study. We will also be accessing participants' medical records to abstract data on participants' health status and care received.

INCLUSION CRITERIA: Patient participants will be identified from both the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center and the Richard A. Henson Cancer Institute at Peninsula Regional Medical Center (PRMC). Patients will be selected based on the following inclusion criteria:

- Age 21 years or older;
- Diagnosed with breast, colorectal, or prostate cancer (stages I-III);
- Treated with intent to cure
- People who are on long-term (>1 year) chronic treatment are eligible;
- Able to complete the study data collection in English;
- Had their cancer care primarily managed by either JHMI or PRMC, with JHMI or PRMC oncology program practices primarily responsible for the patients' survivorship care; and
- Has private insurance, or covered by Medicare or Medicaid.

EXCLUSION CRITERIA: The specific exclusion criteria for patients are:

- Younger than 21 years of age;
- Diagnosed with in situ or metastatic breast, prostate or colorectal cancer (i.e. Stage 0 or IV);
- Not treated with intent to cure;
- Did not have cancer care primarily managed within one of the 4 participating clinics, or JHMI or PRMC oncology program practices are not primarily responsible for the patients' survivorship care;
- Does not have health insurance at screening; and
- Enrolled in a competing and/or conflicting research trial at the time of enrollment.

## 6. Drugs/ Substances/ Devices

Not applicable

## 7. Study Statistics

a. Primary outcome variable.

The primary endpoint of this study will be the proportion of patients who receive appropriate cancer-related follow-up care (based on the individual's SCP). The outcome will be operationalized as a dichotomous variable (received recommended care: yes/no). This endpoint will be used to determine the preferable delivery modality (study arm).

b. Secondary outcome variables.

Secondary outcomes of health service use include (1) receipt of appropriate primary and preventive care and (2) not receiving tests that are not recommended. These outcomes will also be operationalized as a dichotomous variable (received recommended primary/preventive care: yes/no; did not receive inappropriate care: yes/no). In addition to the dichotomous outcomes, we will also examine receipt of individual care services. For example, the primary dichotomous outcome for colorectal cancer patients may include receipt of colonoscopy and CEA testing; as a secondary outcome, we will also examine receipt of each of those services separately.

Patient-reported outcomes (PROs) are also important secondary outcomes. Participants will complete PRO measures assessing survivorship knowledge and confidence, worry, and information needs at baseline, 6-months, 12-months, and 18-months post treatment completion. Based on a review of the literature and consultation with the survivor members of our Stakeholder Advisory Board, the PRO assessment will include three instruments:

- Preparing for Life as a (New) Survivor (PLANS): The PLANS survey includes 11 knowledge items rated on a 4-point Likert scale from 1=strongly disagree to 4=strongly agree, as well as 5 confidence items rated on a 10-point scale from 1=not at all confident to 10=extremely confident, and an open-ended question. The PLANS was developed at the University of Michigan and was used by our team in a previous survivorship care planning evaluation (Dunn, R., Crowley, S., & Janz, N., 2011; Smith et al., 2016). The items are analyzed individually.
- Assessment of Survivor Concerns (ASC): The Assessment of Survivor Concerns is a 5-item questionnaire that assesses two subscales: cancer worry and general health worry. Each item is rated on a 4-point scale from 1=not at all to 4=very much. Subscale scores and an overall score are calculated by summing the relevant items. The ASC was developed by Gotay & Pagano and used in a previous study of survivorship care planning (Gotay, C. C., & Pagano, I. S., 2007; Hershman, D. L., et al., 2013).
- Follow-up Care Use among Survivors (FOCUS)-Information Needs Module: The FOCUS information needs questionnaire asks about the need for information regarding 12 topics (Kent, E. E., et al., 2012) Response options are "no," "yes," and "not sure." It was developed by the National Cancer Institute based on previously published information needs questionnaires (Beckjord, E. B., et al., 2008; Mallinger, et al., 2005; Nelson, et al., 2004). The FOCUS study included an evaluation of the impact of survivorship care plans on information needs.

The PROs will be collecting using REDCap (see supplemental study documents). Patients who do not complete the PROs electronically prior to the health-service use follow-up phone calls will have the opportunity to complete the PROs over the phone, by mail, or in-person.

c. Statistical plan including sample size justification and interim data analysis.

No interim analyses are planned.

SAMPLE SIZE: We will recruit 250 participants through JHMI and 125 participants at PRMC oncology program practices (see Table 2). This weighting of recruitment reflects the difference in the number of patients seen at each site, and the fact that we will be studying three separate clinical settings within a large academic center versus a rural based community cancer program. Based on 2011/2012 cancer registry data from each site, our desired sample size is feasible based on approximately 680 breast, 676 colorectal, and 1310 prostate cancer cases newly seen per year at JHMI, and approximately 187 breast, 96 colorectal, and 206 prostate cancer cases newly seen per year at PRMC. To ensure balanced randomization between the three arms, we will stratify by site (JHMI or PRMC) and by cancer type (breast, prostate, or colorectal).

**Table 2: Recruitment by Site**

| Sites | JHMI N=250 | | | PRMC Oncology Program Practices N=125 | | |
|---|---|---|---|---|---|---|
| Tumor Groups | Breast (n=100) | Colorectal (n=50) | Prostate (n=100) | Breast (n=50) | Colorectal (n=25) | Prostate (n=50) |
| Arm A | 34 | 17 | 33 | 17 | 8 | 17 |
| Arm B | 33 | 16 | 34 | 17 | 8 | 16 |
| Arm C | 33 | 17 | 33 | 16 | 9 | 17 |
| Total | 100 | 50 | 100 | 50 | 25 | 50 |

Previous studies show that patient adherence in the survivorship period is varied, depending on the cancer type and/or the particular health service being studied. We considered a range of adherence probabilities and varying differences between them among randomization arms. The operating characteristics of the design are shown in Table 3 below. Simulations (1,000) with varying values of the underlying probability of perfect adherence for each study arm provided the estimates in the table. For each simulation, responses for the primary endpoint were randomly drawn from a binomial distribution and compared between study arms with Fisher's exact test. Estimated power is the proportion of simulations that yielded a two-sided p value $\leq 0.05$. Table 3 shows that the study will have more than 80% power to detect differences ranging of about 5% and higher in the proportion of patients with perfect adherence among study arms. Table 3 also shows the power assuming 20% attrition, and even then, we have 80% power to detect differences of 10%-15% (and in some cases lower).

**Table 3: Power Calculations for Primary Outcome**

| Total Sample Size (A / B / C) | Probability of receipt of outcome | | | Difference between arms | Estimated Power with Type I error = 5% |
|---|---|---|---|---|---|
| | Arm A | Arm B | Arm C | | |
| 125 / 125 / 125 | 30% | 39.5%<br>37.5%<br>45% | 49%<br>52.5%<br>60% | 9.5%, 9.5%<br>7.5%, 15%<br>15%, 15% | 79.2%<br>93.2%<br>99.7% |
| | 50% | 55%<br>65%<br>65% | 70%<br>72.5%<br>80.0% | 5%, 15%<br>15%, 10%<br>15%, 15% | 88.1%<br>91.7%<br>99.7% |
| | 70% | 75%<br>77.5%<br>82.5% | 87.5%<br>90%<br>92.5% | 5%, 12.5%<br>7.5%, 12.5%<br>12.5%, 10% | 91.6%<br>96.8%<br>99.3% |
| **Total Sample** | **Probability of receipt of** | | | **Difference** | **Estimated** |

| Size (A / B / C) | outcome | | | between arms | Power with Type I error = 5% |
|---|---|---|---|---|---|
| | Arm A | Arm B | Arm C | | |
| 100 / 100 / 100 | 30% | 39.5%<br>37.5%<br>45% | 49%<br>52.5%<br>60% | 9.5%, 9.5%<br>7.5%, 15%<br>15%, 15% | 68.7%<br>84.2%<br>98.8% |
| | 50% | 55%<br>65%<br>65% | 70%<br>72.5%<br>80.0% | 5%, 15%<br>15%, 10%<br>15%, 15% | 78.7%<br>84.8%<br>98.5% |
| | 70% | 75%<br>77.5%<br>82.5% | 87.5%<br>90%<br>92.5% | 5%, 12.5%<br>7.5%, 12.5%<br>12.5%, 10% | 82.2%<br>91.6%<br>97.7% |

Although it is not the primary outcome of this study, the PROs are important secondary outcomes in survivorship care planning. Therefore, we have also calculated the power our sample size has to detect meaningful differences in the PROs across the study arms. PROs will be compared among study arms using linear regression and ANOVA. PRO values at follow-up visits will be modeled as a function of study arm while adjusting for the baseline value and other patient characteristics. Because patients are randomized, there should be no difference in PRO scores or other characteristics between patients at baseline. Given that we will be using a range of different PRO questionnaires and the evidence that differences of one-half a standard deviation are meaningful (Norman et al, Medical Care 2003), these power calculations were conducted to estimate the power to detect differences in standard deviations. For each power calculation, outcomes were simulated from a random normal distribution using the mean (SD) specified in the table for each study arm. Values were compared between arms using ANOVA, and power was calculated as the proportion of simulations that yielded a $p < 0.05$. For each scenario, 1000 simulations were run. As shown in Table 4, we have >80% power to detect meaningful differences in PROs given the sample size planned for the primary analysis of health service outcomes.

**Table 4: Power Calculations for Patient-Reported Outcomes**

| Total Sample Size (A / B / C) | | | | Difference between arms, in standard deviations | Estimated Power |
|---|---|---|---|---|---|
| | Arm A | Arm B | Arm C | | |
| 125 / 125 / 125 | 0 | 0.10<br>0.15<br>0.4<br>0.25 | 0.45<br>0.45<br>0.4<br>0.45 | 0.10, 0.45<br>0.15, 0.45<br>0.4, 0.4<br>0.25, 0.45 | 85.7%<br>81.6%<br>82.8%<br>82.9% |

DATA ANALYSIS: Comparing the three models of SCPs, we will examine whether there are differences between intervention arms in receipt of care as recommended on the SCP, regardless of whether the SCP was received ('intention to treat'), and also whether receipt of an SCP leads to appropriate care receipt, comparing those who received a SCP to those who did not. In both cases, the endpoint is the proportion of patients who receive all cancer-related follow up care. We will also examine each component of appropriate care individually (e.g., proportion receiving mammogram). Analysis will be by Fisher's exact test for differences between groups. To help quantitatively describe the differences between groups, we will also use binary or categorical logistic regression models as appropriate to estimate odds ratios with 95% confidence intervals. To account for the stratified randomization, we will also include a regression model that estimates the main SCP-type effect while adjusting for cancer type and recruitment site. Planned

subgroup analyses include examining differential outcomes by patient cancer type and recruitment site using interaction analyses. P-values for determining statistical significance of these interaction tests will be corrected for multiple comparisons using a Bonferroni approach.

Receipt of primary/preventive care, avoidance of non-recommended care, and PROs are secondary endpoints, and the analyses are descriptive. The analysis for receipt of primary/preventive care is similar to that for cancer-related follow-up. The endpoint for the avoidance of non-recommended care will be the proportion of patients who do not receive tests that are not recommended in the year following completion of acute treatment. This will be evaluated as a dichotomous variable (did not receive inappropriate care: yes vs. no). For the patient-reported outcomes, we will report the PRO scores by intervention arm at baseline, 6-month, 12-months, and 18-months. The main PRO analysis will be a comparison of the follow-up scores at 12-months by intervention arm adjusting for baseline. We will also compare the PROs at 6 months for Arms B&C vs. Arm A to evaluate the effective of the in-person transition visit vs. just sending the SCP. For the PLANS, we will report mean (SD) scores at the individual item level. For the ASC, we will primarily report the mean (SD) on the two subscale scores, but will also report the individual items and total score. For the FOCUS Information Needs, we will primarily report total number of health information needs (i.e., number of items endorsed "yes"), but will also report individual needs endorsed (dichotomous). For all of the PROs, we will also explore changes longitudinally using appropriate methods (GEE, random effects) and examine any differences in the trends over time between patient subgroups using interaction tests as needed.

d. Early stopping rules.

Early stopping rules are not applicable to this study.

**8. Risks**

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.

There is a risk of participants feeling tired, bored, or uncomfortable when answering questions about health and health care.

b. Steps taken to minimize the risks.

Participants do not have to answer any question they do not want to answer.

c. Plan for reporting unanticipated problems or study deviations.

The study will undergo review and approval by the IRB at the Johns Hopkins School of Medicine. All JHCRN sites have agreed to use the review of the Johns Hopkins IRB. The IRB requirements are in full compliance with Federal Regulations regarding the protection of human subjects. All appropriate HIPAA procedures will be followed. Any participant concerns and/or complaints or study deviations will be reported to the IRB immediately.

d. Legal risks such as the risks that would be associated with breach of confidentiality.

There is a risk that patient information will be seen by someone who is not a member of the research team. We take precautions to keep information we collect safe, secure, and confidential. Information will be encrypted and grouped with other participants' information without any personal identifiers and will only be used for this study. Documents with any identifying information will be kept in a locked location that is only accessible to study team members. Electronic information will be protected by log-on identification and password protected computer procedures. All data will be presented in a grouped manner in reports

and publications so that no one participant can be identified. PHI will be retained to justify screen failures, and will be stored under the same secure conditions as all study-related data for the length of the trial.

e. Financial risks to the participants.

Participants randomized to either Arms B or C, will have one or two visits. These visits will be billed to their insurance, but the participant will be responsible for any out-of-pocket costs such as copays. The visits are billable to insurance because the study is comparing three standard-of-care approaches. In current practice, insurance is billed for patients who have these visits.

**9. Benefits**

a. Description of the probable benefits for the participant and for society.

There are no direct benefits from participation in this study; however, issues that are discussed may aid participants' understanding and experience of survivorship care. Also, this research may serve to help future adult cancer survivors receive quality survivorship care.

**10. Payment and Remuneration**

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

Participants will be paid up to $125 for their time spent participating in this study (See Table 5). The table below shows the study activities for which they will be compensated and the dollar amount of compensation per activity. Compensation will be mailed shortly after each study activity, or provided in person, depending on the type of activity.

**Table 5: Participant Compensation Schedule**

| **Study Activity** | **Compensation for Time** |
|---|---|
| Baseline – shortly following enrollment<br>Providing information 6 months after end of treatment<br>Providing information 12 months after end of treatment<br>Providing information 18 months after end of treatment<br>Incentive for completing all 4 data points | $25<br>$25<br>$25<br>$25<br>$25 |
| **TOTAL COMPENSATION AFTER COMPLETING ENTIRE STUDY** | **$125** |

**11. Costs**

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.

Participants randomized to either Arms B or C, will have one or two visits. These visits will be billed to their insurance, but the participant will be responsible for any out-of-pocket costs such as copays.

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