Use of Systems Support Mapping to Guide Patient-Driven Self-Management in Rural and Urban Cancer Survivors

Wake Forest Baptist Comprehensive Cancer Center (WFBCCC)

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ABSTRACT

Approximately 66% of those diagnosed with colorectal cancer who will survive for at least 5 years post diagnosis need to take a more active role in their care to optimize their health outcomes. Standard care includes providing survivorship care plans that initially focused on information delivery alone, which has demonstrated limited efficacy for improving health outcomes. An increased emphasis on the process of patient engagement and support of non-pharmacologic self-management (SM; symptom management, medication adherence, screening, healthy behaviors) is needed to improve care plans. Holistic consideration of individual-level contextual factors such as values or tradeoffs with existing behaviors, could more sustainably integrate SM into survivors' life context. Facilitating SM with consideration of context is consistent with systems thinking. System Support Mapping (MAP) is a systems thinking activity that involves creating a visual diagram of how SM occurs within cancer survivors' life context that facilitates self-awareness and patient-driven engagement in SM. We propose to conduct a one-arm pilot study of MAP among 24 colorectal cancer survivors within one year of completing active treatment to describe study feasibility, intervention acceptability, and outcome variability. MAP can also be a powerful tool to reduce health disparities since it allows for simultaneous consideration of individual-level and multi-level contextual factors (i.e., geographic, social, institutional). Health disparities exist such that colorectal cancer survivors who are rural residents have higher cancer mortality than do urban cancer survivors. Furthermore, rural survivors are at increased risk for self-reported poorer health and engage in more health compromising behaviors compared to urban survivors. Therefore, we will also identify multi-level contextual factors influencing SM and examine how study results vary by rural-urban context to inform future studies. MAP is a novel approach that may generalize to improving care for other chronic illnesses such as cardiovascular disease.

1.0 Introduction and Background

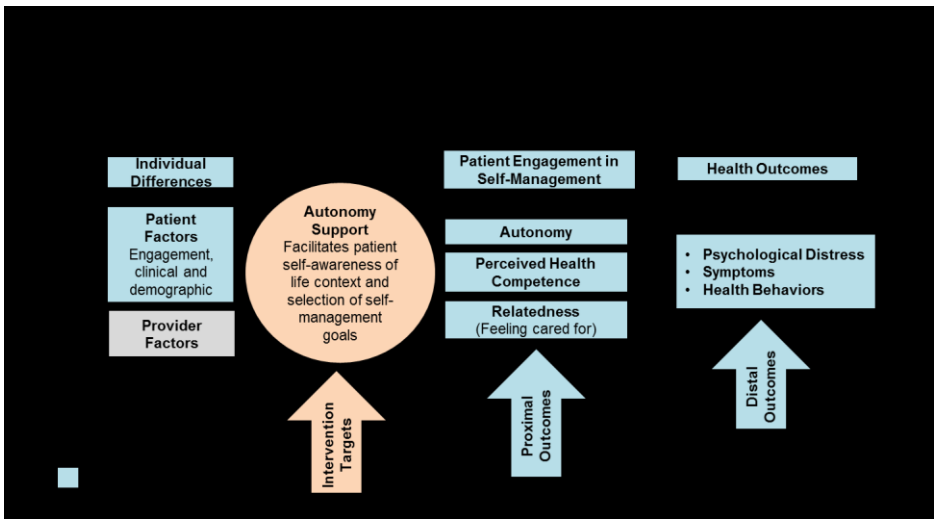
Cancer survivors need to engage in self-management (SM) to improve health outcomes. Approximately 66% of the 135,000 people diagnosed with colorectal cancer in the United States each year will survive for at least 5 years post diagnosis.[1] As cancer survivors are expected to live longer, there is a shift in perspective to viewing cancer as a chronic illness, which is accompanied by increased need for cancer survivors to partner with physicians and become more actively engaged in SM to optimize their own health outcomes.[2,3] The Institute of Medicine and others recommend that patients receive a comprehensive survivorship care plan when transitioning form active treatment to survivorship that provides a treatment summary and outlines follow-up care needs including multiple complex SM activities (e.g., psychosocial support, symptom management, health behaviors).[3,4] A *weakness* of initial research on survivorship care plans is that interventions have solely focused on information delivery and demonstrated limited efficacy for improving self-reported health outcomes.[4] Recommended future directions for improving upon information-focused survivorship care planning involve increasing the emphasis on the process of patient engagement and support of non-pharmacologic SM (e.g., health behaviors).[4–6] One particularly *strong* survivorship care planning intervention that improved self-reported health was designed to be patient-centered and focused on the process of engaging cancer survivors with one session that included goal setting, establishing a plan to improve health, and increasing the motivation, information, skills, and confidence necessary to engage in SM.[6] Yet, this intervention focused on survivors' cancer treatment narrative and did not holistically consider individual-level contextual factors such as values or tradeoffs with existing behaviors, which would more sustainably integrate SM into survivors' existing life context and ultimately facilitate translation of the intervention into practice.[7,8]

Self-awareness of contextual influences on behavior will engage survivors in sustainable SM. The conceptual framework for improving the quality of cancer care presented in an Institute of Medicine report starts with engaged patients.[9] This report defines patient engagement in cancer care as "A system that supports all patients in making informed medical decisions consistent with their needs, values, and preferences in consultation with their clinicians who have expertise in patient-centered communication and shared decision making." Self-determination Theory also emphasizes that supporting patients' partnership in healthcare decisions will enhance patients' engagement in SM and ultimately lead to more sustainable improvement in health outcomes.[10] According to Self-determination Theory, self-awareness is a necessary first step in facilitating patients' patient-driven (i.e., autonomous) motivation for engaging in SM.[11] Patient-driven goals are more likely to be achieved than goals that are extrinsically motivated.[12] This point is illustrated by an intervention to facilitate the SM in other chronic diseases that provided participants with the opportunity to self-select their goals rather than prescribing specific behavior changes.[13] Results showed that this process of patient-driven goal setting successfully changed health behaviors and reduced hospitalizations.[13] Yet, patients may need guidance to facilitate self-awareness and identify what they need to engage in multiple recommended SM activities with consideration of their broader life context.

Systems Support Mapping (MAP) facilitates self-awareness of contextual factors. Systems thinking unpacks complex behaviors (e.g., SM), while exploring how individual patient choices are facilitated and constrained by broader contextual systems.[14] System Support Mapping (MAP) is a structured systems thinking activity to facilitate survivors' creation of a visual diagram to tangibly illustrate and create self-awareness for how a SM behavior relates to the broader context of tradeoffs with other behaviors and achieving most-valued outcomes. MAP facilitates self-awareness of the complex broader system and the ability for patients to clearly identify any discrepancies or intervention targets for SM. Highlighting discrepancies between current and desired states is used as a technique to generate patient-driven motivation for behavior change.[15,16] Tying individual SM behaviors to broader life values

may also increase the perceived importance of SM goals and thus patient engagement. Similarly, identifying how changing SM holistically affects broader contextual systems will more sustainably integrate SM. Having patients select patient-driven goals for SM with a consideration of their life context will set the stage for engaging in patient-driven SM. MAP has primarily been applied to systems in the community setting with the exception of Dr. Befus' (Co-Investigator) work in collaboration with Dr. Lich (Consultant) that took an individual-focused approach to understanding SM and health equity in women with migraine occupying lower social locations.[17] Thus, it is novel to apply an individual-focused MAP to guide patient engagement in SM with a focus on non-pharmacologic approaches during the transition from active cancer treatment to survivorship.

MAP can be a powerful tool to reduce health disparities since it allows for simultaneous consideration of (1) individual-level and (2) multi-level contextual factors.[14,18] Rural cancer survivors' are especially likely to benefit from guidance to facilitate self-awareness and select patient-driven goals due to their need to consider complex multi-level contextual factors (i.e., geographic, social, institutional).[18,19] For example, geographic context is associated with the ability to access to supportive care services (e.g., psychologist, religious leader).[19–21] Rural residents may share a social context such as the importance of self-reliance.[19] Furthermore, results from our research and others show that a large portion (30-40%) of cancer survivors seek methods for SM outside of conventional cancer care institutions through means such as use of complementary health approaches (CHA) at higher rates than the general public[22–24] and use of CHA is higher in rural communities.[25,26] Thus, interventions are needed that consider multi-level contextual factors in order to optimize SM and address rural-urban disparities in health outcomes.[27] Health disparities exist such that colorectal cancer survivors who are rural residents have higher cancer mortality than do urban cancer survivors.[28] Furthermore, rural survivors are generally at increased risk for self-reported poorer health (e.g., psychological distress, symptoms) and engage in more health compromising behaviors (e.g., smoking and physical inactivity) compared to urban survivors.[27] Such health compromising behaviors are associated with mortality.[29] MAP may improve individual-level SM, while also identifying how individual-level SM interacts with multi-level contextual factors associated with rural-urban disparities (e.g., education, travel barriers).[27] Additionally, MAP will identify key stakeholders and leverage points needed to inform future multi-level studies.[17] Figure 1 shows the proposed conceptual model, which places Self-Determination Theory in context of other factors influencing patient-centered care and health disparities.[9,18,30–32]



2.0 Objectives

We will conduct a one-arm pilot study of MAP among 24 colorectal cancer survivors within one year of completing active treatment. We will quantitatively and qualitatively describe recruitment and retention; intervention completion and acceptability; and variability and changes in proposed outcomes (i.e., measures of patient engagement, health outcomes) to guide future study planning. We will analyze collected maps, and describe factors and targets for intervention at multiple levels (individual/geographic/social/institutional).

2.1 Primary Objective

2.1.1 To evaluate the feasibility of the MAP intervention in colorectal cancer survivors, as characterized by enrollment, intervention adherence, and retention rates.

We hypothesize >50% of eligible patients will enroll and that >70% of participants will complete the intervention and be retained in the study.

2.2 Secondary Objectives

2.2.1 To evaluate intervention acceptability as characterized by participant ratings.

2.2.2 To describe outcome variability to inform future studies.

2.2.3 To identify multi-level contextual factors influencing SM.

2.2.4 To qualitatively assess feasibility, acceptability using semi-structured interviews.

2.2.5 To examine how study results vary by rural-urban context.

3.0 Patient Selection

We will enroll 24 participants with equal numbers of patients from urban and rural communities over 10 months. To identify potential patients, programming with Epic will be used to provide automated reports identifying patients within one year of completing active treatment for colorectal cancer. We will also post the study on Be Involved. The Project Manager will screen the report and communicate with attending physicians, physician assistants, clinic nurses and/or the patient navigator regarding patients' potential eligibility for the study. Research staff will approach patients either in person or remotely (e.g., telephone, myWakeHealth, mail) regarding their interest in study participation. Ways to contact the study team if they wish to opt out of the study will be included. A study team member will then follow up with all patients who respond to the letter with an interest in participation. Of the patients who do not decline, the study coordinator will approach at their next clinic visit or by phone to provide study information and answer questions to determine willingness to participate. The consent will be signed remotely or in person. If signed remotely, patients will be asked to send the form back to us by a secure means (e.g., REDCap, mail). In the case that the patient is consented remotely, either a hard copy or email attachment of the informed consent document will be provided to the participant. We will compensate participants $50.

We will document recruitment in a Screening Log including reasons for ineligibility, eligible patients approached, number who declined participation, and number successfully recruited. After making sure

the patient clearly understands the study procedures and agrees to follow them, the patient will be asked to sign the informed consent form. A copy of the consent form will be given to the participant, and the original copy will be kept in the participant's file.

3.1 Inclusion Criteria

3.1.1 Adults ≥18 years of age

3.1.2 Diagnosed with stage I-III colorectal cancer

3.1.3 Within 2 years of completing active treatment for colorectal cancer

3.1.4 Cognitively able to complete interviews as judged by the study team

3.1.5 Able to understand, read and write English

Children under the age of 18 with colorectal cancer will be excluded due to the rarity of colorectal cancer in this population according to the National Cancer Institute (incidence rate ≤ 0.6) and because they are likely to have distinct needs and experiences if diagnosed this young. Further, it is unlikely that the study would recruit sufficient numbers in this subset of the cancer survivor population to gain meaningful results. Results from this research may inform future studies in children with cancer under 18 who are generally different from adults and should be researched separately.

3.2 Exclusion Criteria

3.2.1 Declined participation in the study

3.3 Inclusion of Women and Minorities

The target population for this study is adult men and women who have completed active treatment for colorectal cancer. We expect that women and minorities will be represented as is consistent with the proportion seen in the past five years at the Wake Forest Baptist Comprehensive Cancer Center. For this pilot study, non-English speaking patients will be excluded because the intervention will be implemented in English. Pending results of the pilot, a future study to determine the efficacy of translating the intervention will be proposed. Experts at Wake Forest Baptist Comprehensive Cancer Center's Office for Cancer Health Equity will review our protocol and suggest additional strategies to enhance the ability to recruit a representative sample. The OCHE includes a Hispanic Clinical Trial Patient Navigator who provides guidance to Hispanic participants throughout the research process and will be involved in educating any potential Hispanic study participants on clinical trials prior to in-person interaction with the Project Manager. The intervention is designed to reduce barriers to recruitment and to be presented in a manner that will be culturally sensitive with the aim of reaching all patients.

4.0 Registration Procedures

All patients entered on any WFBCCC trial, whether treatment, companion, or cancer control trial, must be linked to the study in EPIC within 24 hours of Informed Consent. Patients must be registered prior to the initiation of treatment.

You must perform the following steps in order to ensure prompt registration of your patient:

1. Complete the Eligibility Checklist (Appendix A)
2. Complete the Protocol Registration Form (Appendix B)
3. Alert the Cancer Center registrar by phone, *and then* send the signed Informed Consent Form, Eligibility Checklist and Protocol Registration Form to the registrar, either by fax or e-mail.

   *Protocol Registration is open from 8:30 AM - 4:00 PM, Monday-Friday.

4. Fax/e-mail ALL eligibility source documents with registration. Patients will not be registered without all required supporting documents.

Note: If labs were performed at an outside institution, provide a printout of the results. Ensure that the most recent lab values are sent.

To complete the registration process, the Registrar will:

- assign a patient study number
- register the patient on the study

5.0 Study Outcomes and Study Measures

We will collect data at two different levels, the individual-level (feasibility, outcome measures), and multi-level contextual factors (MAP data). We will collect self-reported data either remotely or in person at baseline and two weeks after MAP.

5.1 Primary Outcome (Feasibility)

Enrollment rate will be calculated as the percent of eligible participants approached who agree to participate.

Participation rate will be calculated as the percent of participants who complete the study intervention among those enrolled.

Retention rate will be calculated as the number of participants who complete the study measures among those enrolled.

5.2 Secondary Outcomes

5.2.1 Self-reported ratings of intervention acceptability

5.2.2 Proximal outcomes

5.2.2.1 Measures of autonomy [Index of Autonomous Functioning][33]

5.2.2.2 Self-efficacy for managing cancer [Self-efficacy to Manage Chronic Disease Scale and PROMIS self-efficacy for managing symptoms short form][34–36]

5.2.2.3 Relatedness [HEAL Patient-Provider Connection],[37] only assessed at follow-up because this construct is assessing the experience with the MAP facilitator.

5.2.3 Health outcomes
5.2.3.1 Psychological stress [Perceived Stress Scale, 4-item][38]
5.2.3.2 Symptoms [PROMIS Profile 29][39]
5.2.3.3 Health behaviors [items on tobacco use, physical activity, use of CHA][22]

5.2.4 Qualitative assessment of feasibility, acceptability and changes in outcomes with semi-structured interviews

5.2.5 Qualitative analysis of systems support maps

5.2.6 Demographic (age, rural-urban residence [classified by the Federal Office of Rural Health Policy definition of rural],[40] race/ethnicity, marital status, education level, health literacy,[41] financial toxicity[42])

5.2.7 Clinical factors (cancer type, disease stage, recurrence status, type of treatment) factors will be abstracted from medical charts or self-reported.

6.0 Study-Related Activities

6.1 Overview of Study-Related Activities

	Pre-Study[a]	Baseline	MAP[b] Intervention[c]	Follow-up (2-week)[d]
Recruitment	X			
Informed consent	X			
Demographic and Clinical Factors		X		
Patient-Reported Outcomes		X		X
Intervention Completion			X	
Acceptability Ratings				X
Semi-structured Interview				X
Adverse event evaluation			X	X

[a] Pre-study requirements listed in table must be completed within 30 days prior to registration.
[b] MAP = Systems Support Mapping
[c] Intervention may be coordinated with future clinic visit; must be completed within 6 months of registration
[d] Follow-up visit to be completed 14 - 28 days after intervention

6.2 Intervention Description

Systems Support Mapping (MAP) Intervention. The intervention will be implemented individually to outpatients. Trained facilitators will guide participants to create a visual diagram of their SM activities within their broader life context (MAP). MAP helps participants tangibly see complex SM activities on paper, which makes them more actionable. MAP was acceptable to participants in our preliminary work, which included social and economically marginalized women.[17] Each participant will be provided with a piece of poster-sized paper with five concentric circles on it and six pads of differently-colored sticky notes used to represent different rings. Participants will begin by identifying the most important aspects

of life that having cancer is preventing them from experiencing. Each resulting MAP will describe participants' most bothersome life impacts of cancer, SM activities with a focus on non-pharmacologic approaches, facilitators and needs for SM, and outcomes and tradeoffs of SM. We will ask participants to reflect aloud, discuss any discrepancies between current and desired outcomes of SM, and brainstorm about what they need to reconcile them. We will then have participants identify one goal that is important and achievable in the next two weeks and set action steps.[43] Dr. Befus (Co-Investigator) will train study staff who have experience with conducting qualitative research (Q-PRO staff) to facilitate MAPs. MAP will take 60-90 minutes, be digitally recorded, and transcribed to ensure treatment fidelity and facilitate analysis. Participants will be *off-treatment* upon completion of this one session.

Reported adverse events and potential risks are described in Section 7.

6.3 General Concomitant Medication and Supportive Care Guidelines

This behavioral intervention will not affect usual care.

6.4 Duration of Follow Up

Patients will be followed for two weeks after this minimal-risk behavioral intervention is administered for adverse events monitoring. Follow-up for serious adverse events and mortality after the intervention is implemented will take place during the routine clinic visits that the patient will have during the 2 follow-up window (also referenced in Appendix D). If no visit occurs during this window, a phone call confirmation should be made to the patient to determine vital status and whether any adverse events and in particular, Grade 4 unexpected and Grade 5 adverse events occurred during that window of time and recorded on Appendix E.

6.5 Criteria for Removal from Study

There are no additional criteria for removal from the study.

7.0 Adverse Events List and Reporting Requirements

Expected adverse experiences for the study intervention are as follows:

- Emotional distress (i.e., mild anxiety or mild depressive symptoms)

Each interventionist will monitor and note any adverse events experienced during the MAP session (e.g., patients' expression of emotional distress, request to discontinue the session). The study team will only document adverse events during the two-week period following the intervention.

7.1 Adverse Event Characteristics

- CTCAE term (AE description) and grade: The descriptions and grading scales found in the revised NCI Common Terminology Criteria for Adverse Events (CTCAE) version 4.0 will be utilized for AE reporting. All appropriate treatment areas should have access to a copy of the CTCAE version 4.0. A copy of the CTCAE version 4.0 can be downloaded from the CTEP web site (http://ctep.cancer.gov).

- 'Expectedness': AEs can be 'Unexpected' or 'Expected' (see Section 7.1 above) for expedited reporting purposes only.

- Attribution of the AE:

- Definite – The AE is clearly related to the study treatment.
- Probable – The AE is likely related to the study treatment.
- Possible – The AE may be related to the study treatment.
- Unlikely – The AE is doubtfully related to the study treatment.
- Unrelated – The AE is clearly NOT related to the study treatment.

7.2 STRC SAE Reporting Requirements

The Safety and Toxicity Reporting Committee (STRC) is responsible for reviewing SAEs for WFBCCC Institutional studies as outlined in Appendix D. STRC currently requires that all unexpected 4 and all grade 5 SAEs on these trials be reported to them for review. All WFBCCC Clinical Research Management (CRM) staff members assisting a Principal Investigator in investigating, documenting and reporting an SAE qualifying for STRC reporting are responsible for informing a clinical member of the STRC as well as the entire committee via the email notification procedure of the occurrence of an SAE.

7.3 WFUHS IRB AE Reporting Requirements

Any unanticipated problems involving risks to subjects or others and adverse events shall be promptly reported to the IRB, according to institutional policy. Reporting to the IRB is required regardless of the funding source, study sponsor, or whether the event involves an investigational or marketed drug, biologic or device. Reportable events are not limited to physical injury, but include psychological, economic and social harm. Reportable events may arise as a result of drugs, biological agents, devices, procedures or other interventions, or as a result of questionnaires, surveys, observations or other interactions with research subjects.

All members of the research team are responsible for the appropriate reporting to the IRB and other applicable parties of unanticipated problems involving risk to subjects or others. The Principal Investigator, however, is ultimately responsible for ensuring the prompt reporting of unanticipated problems involving risk to subjects or others to the IRB. The Principal Investigator is also responsible for ensuring that all reported unanticipated risks to subjects and others which they receive are reviewed to determine whether the report represents a change in the risks and/or benefits to study participants, and whether any changes in the informed consent, protocol or other study-related documents are required.

Any unanticipated problems involving risks to subjects or others occurring at a site where the study has been approved by the WFUHS IRB (internal events) must be reported to the WFUHS IRB within 7 calendar days of the investigator or other members of the study team becoming aware of the event.

Any unanticipated problems involving risks to subjects or others occurring at another site conducting the same study that has been approved by the WFUHS IRB (external events) must be reported to the WFUHS IRB within 7 calendar days of the investigator or other members of the study team becoming aware of the event.
Any event, incident, experience, or outcome that alters the risk versus potential benefit of the research and as a result warrants a substantive change in the research protocol or informed consent process/document in order to insure the safety, rights or welfare of research subjects.

7.4 Sponsor Reporting Requirements

There are no additional sponsor reporting requirements.

8.0 Data Management

Informed consent document	EPIC
Decline Forms	REDCap
Screening Log	File on a Secure Server
Protocol Registration Form	WISER/OnCore
Demographic and Clinical Factors	REDCap
Patient-reported Outcomes	REDCap
Intervention Completion Form	REDCap
Intervention MAP	Files on a Secure Server
Semi-structured Interview	Files on a Secure Server
Adverse Events Log	WISER/OnCore

9.0 Statistical Considerations

9.1 Analysis of Primary Objective

9.1.1 We will use one-sample tests of negative binomial probabilities and binomial proportions to compare rates of feasibility to hypothesized values. Rates will be summarized using point estimates and 95% confidence intervals. In exploratory analyses, we will compare participants' intervention completion and retention by baseline characteristics using chi-square tests and t-tests.

9.2 Analysis of Secondary Objectives

To meet Objective 2.2.1, we will use descriptive statistics to summarize participant ratings of acceptability.

Descriptive statistics (means, standard deviations, 95% confidence intervals) will be used to summarize proximal outcomes and change in health outcomes by assessment measure to meet Objective 2.2.2. The primary interest will be in estimating the variance for use in planning future studies.

For Objective 2.2.3, the internal study team will work with external collaborators through an iterative process to facilitate a qualitative content analysis[44] of the large quantity of textual MAP data. Specifically, we will first enter text data from the completed paper maps into a software program co-developed by Steve Chall (external Senior Programmer, University of North Carolina-Chapel Hill Renaissance Computing Institute) and Dr. Lich (Consultant) using the *ssm* function to create a digital map.[17,45] Steve Chall will translate the text MAP data into lists that can be sorted by the study team (using the *sort* program). The *sort* program will allow us to group and code similar terms or concepts. Next, we will send our sort files back to Steve Chall and he will use Python programming language to help aggregate the large amounts of textual

data into formats we can manipulate (Python Software Foundation, 2017). These matrices will be saved in the form of Excel (.csv) files, which are compatible with other statistical software. We will ultimately present resulting counts and descriptive statistics of findings alongside descriptive categories and themes.

To meet Objective 2.2.4, we will also conduct a qualitative content analysis.[44] Qualitative data will be sent to an external vendor to be transcribed. Two internal study team members will double-code at least 10% of coding of transcripts from the semi-structured interviews and resolve any disagreements to ensure that we achieve robust and unbiased results. We will evaluate qualitative and quantitative analyses in a mixed-methods framework for consistency and discrepancies across all analyses to refine the protocol.

To meet Objective 2.2.5, we will examine all quantitative and qualitative analyses by urban-rural status as classified using the Federal Office of Rural Health Policy definition of rural.[40] For quantitative measures, we will compute descriptive statistics by urban-rural status and will use Fisher's exact tests and Wilcoxon rank sum tests to compare urban and rural participants. Qualitative results will be summarized by urban-rural status. We will also compare MAP results by rural-urban status.

9.3 Power and Sample Size

The target sample size is based on estimating rates of feasibility measures to inform the design of an efficacy trial. If the recruitment rate is below 50% and intervention completion and retention rates are below 70%, a larger study may not be feasible. Assuming a negative binomial distribution and true rate of 50%, the probability that we would have to approach 61 or more people to recruit 24 is <0.05. Therefore, if we approach ≥61 participants to enroll 24, it is unlikely the true probability is above 50%, and we will conclude the study may not be feasible. Out of the 24 participants, if the true rate of intervention completion and study retention is 70%, we expect 13 or more will participate/be retained, so if 12 or fewer do not participate/are not retained the study may not be feasible; we have 80% power to test that the hypothesis that the rate is 70% compared to the alternative that is 46% or less. The number of participants interviewed will be determined when theoretical saturation is reached. We estimate that we will need 8-12 participants in each group (rural-urban).[46]

9.4 Estimated Accrual Rate

We will enroll 24 participants over 10 months at a rate of 3 participants per month. We expect this rate to be feasible since the Wake Forest Baptist Comprehensive Cancer Center (WFBCCC) sees approximately 60 patients with colorectal cancer who initiate chemotherapy each year and thus approximately the same number will be within a year of completing treatment when the study begins (plus a potential 5 per month after that who complete treatment and become eligible). Our study team (i.e., Dr. Sohl, Dr. Tooze, and Meg O'Mara) has experience working together to recruit patients diagnosed with colorectal cancer and conducting behavioral intervention research. Over 75% of patients approached have agreed to participate in our current behavioral intervention study in colorectal cancer patients initiating active treatment (K01 AT008219; PI: Sohl). The proposed research is less time sensitive and intensive for participants than the current study, so we expect to have similar success.

9.5 Estimated Study Length

We expect the study to be completed in approximately one year (by April, 2019).

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Appendix A – Eligibility Checklist

IRB Protocol No. 00048866	WFBCCC Protocol No. 99118
Study Title: Use of Systems Support Mapping to Guide Patient-Driven Self-Management in Rural and Urban Cancer Survivors	
Principal Investigator: Stephanie Jean Sohl, PhD	

Inclusion Criteria (as outlined in study protocol)	Criteria is met	Criteria is NOT met	Source Used to Confirm * (Please document dates and lab results)
Adults ≥18 years of age	☐	☐	
Diagnosed with stage I-III colorectal cancer	☐	☐	
Within 2 years of completing active treatment for colorectal cancer	☐	☐	
Cognitively able to complete interviews as judged by the study team	☐	☐	
Able to understand, read and write English	☐	☐	
Exclusion Criteria (as outlined in study protocol)	Criteria NOT present	Criteria is present	Source Used to Confirm * (Please document dates and lab results)
Declined study participation	☐	☐	

This subject is ☐ eligible / ☐ ineligible for participation in this study.

OnCore Assigned PID: ___ ___ ___ ___ ___ ___ ___ ___

Signature of research professional confirming eligibility: _____

Date: ___ ___ / ___ ___ / ___ ___

* Examples of source documents include clinic note, pathology report, laboratory results, etc. When listing the source, specifically state which document in the medical record was used to assess eligibility. Also include the date on the document. Example: “Pathology report, 01/01/14” or “Clinic note, 01/01/14”

Appendix B – Reduced Review** Registration Form

DEMOGRAPHICS

Patient: Last Name: _____ First Name: _____

MRN: ___ ___ ___ ___ ___ ___ ___ ___ ZIPCODE: ___ ___ ___ ___ ___

*SEX: ☐ Male ☐ Female

*Ethnicity (choose one): ☐ Hispanic ☐Non-Hispanic

*Race (choose all that apply): ☐ WHITE ☐African American ☐ ASIAN ☐ PACIFIC ISLANDER ☐ NATIVE AMERICAN (Alaskan)

*Diagnosis: _____

DOB (mm/dd/yy): ___ ___ / ___ ___ / ___ ___ (include if no MRN is provided)

*MD Name (Last, First) : _____, _____

*Date Consent Signed: ___ ___ / ___ ___ / ___ ___

Date of Registration: (if different than consent signing) ___ ___ / ___ ___ / ___ ___

PID # (OnCore): ___ ___ ___ ___ ___ ___ ___ ___ (to be completed by registrar)

Comprehensive Cancer Center requires that all registrations be sent to the CCCWFU Centralized Registrar the day the patient is consented; if this is not possible we require that all registration be communicated to the Centralized Registrar within 72 hours by the CRM registrar.

***Reduced Review means eligibility and other review are not performed by CRM registrar.*

For questions, the Protocol Registrar can be contact between 8:30 AM and 4:00 PM, Monday – Friday.

Completed Eligibility Checklist and Protocol Registration Form must be hand delivered, faxed or e-mailed to the registrar

**** if not using the full wakehealth.edu outlook client (full outlook, not web outlook) save this file and attach to an email.*

Appendix C - Race & Ethnicity Verification Form

Thank you so much for helping us to verify your race and ethnicity to ensure the quality of our information. As a brief reminder, the information you provide today will be kept confidential.

1. Are you:
   - ☐ Hispanic or Latino/a
   - ☐ Not Hispanic or Latino/a

2. What is your race? One or more categories may be selected.
   - ☐ White or Caucasian
   - ☐ Black or African American
   - ☐ American Indian or Alaskan Native
   - ☐ Asian
   - ☐ Native Hawaiian or Other Pacific Islander
   - ☐ Other, Please Specify: _____

Internal use only:

Name: _____ MRN#: _____

Was the self-reported race and ethnicity of the participant verified at the time of consent?
☐ Yes ☐ No

Was a discrepancy found? Yes ☐ No ☐
If yes, please provide what is currently indicated in the EMR:
Ethnicity: _____ Race: _____

Additional comments: _____
_____
_____

Appendix D – Mandatory STRC SAE Reporting Guidelines

Safety and Toxicity Review Committee (STRC; previously known as CROC) Serious Adverse Event (SAE) Notification SOP	Date: 2/2/2018

Mandatory STRC SAE Reporting Requirements in WISER

All AEs and SAEs that occur on any CCCWFU Institutional Interventional trial must be entered into the WISER system. Once these AEs and SAEs are entered, the following document describes how to initiate STRC reporting using the SAE form in WISER that is submitted for unexpected grade 4 and any grade 5 (death during protocol intervention) SAEs on CCCWFU Institutional interventional trial patients. There are multiple entities that require reporting of SAEs. Each entity has different rules for what is reported, and how it is reported.
Rules used by other entities (Institutional Review Board (IRB), AdEERS, MedWatch, etc.) should NOT be used to evaluate whether an event should be reported to STRC. Only the rules for reporting described in this document should be considered.

As defined in the NCI Data Table 4 reporting guidelines, CCCWFU Institutional Interventional studies covered by these reporting requirements are defined as: In-house, internally reviewed trials, including those collaborative studies conducted with industry sponsorship in which the center is a primary contributor to the design, implementation, and monitoring of the trial, or participation in a multi-site trial initiated by an institutional investigator at another center. Institutional trials are almost always authored by a researcher here at CCCWFU. Cooperative group protocols are not considered Institutional, but Research Base trials are classified as Institutional.

The STRC is responsible for reviewing SAEs for CCCWFU Institutional Interventional studies, as defined above. STRC currently requires that unexpected grade 4 and all grade 5 SAEs on these trials be reported to the STRC for review. All staff members assisting a PI in documenting and reporting an SAE that qualifies for STRC reporting are responsible for informing a clinical member of the STRC by phone (or in-person), followed by informing the entire committee via the required email notification.

THESE REPORTING REQUIREMENTS APPLY TO any faculty or staff member on the study team for a CCCWFU Institutional Interventional trial. Ultimately, the protocol PI has the primary responsibility for AE identification, documentation, grading and assignment of attribution to the investigational agent/intervention. However, when an SAE event as described below is observed, it is the responsibility of the person who observed the event to be sure that it is reported to the STRC.

What is considered an SAE under this mandatory procedure?
Any unexpected grade 4 event and all grade 5 events (death during protocol intervention) should be reported. These events should be reported if they occur while a patient is on study treatment or if they occur within 30 days of last study treatment (even if patient begins a new treatment during the 30 days). This window of 30 days should be the standard window to be used in all protocols unless a specific scientific rationale is presented to suggest that a shorter window can be used to identify events. In addition, if it is not clear whether the Grade 4 is unexpected it should be reported.

Table 1: Summary of STRC Reporting Requirements for Institutional Pilot, Phase 1, Phase 2 and Phase 3 Interventional Trials

STRC reporting may not be appropriate for specific expected adverse events for protocols. In those situations the adverse events that will not require STRC reporting must be specified in the text of the approved protocol.

	ADVERSE EVENT					
	Grade 1, Grade 2, Grade 3		Grade 4		Grade 5	
	Unexpected	Expected	Unexpected	Expected	Unexpected	Expected
Unrelated	Not Required	Not Required	REPORT TO STRC	Not Required	REPORT TO STRC	REPORT TO STRC
Unlikely	Not Required	Not Required	REPORT TO STRC	Not Required	REPORT TO STRC	REPORT TO STRC
Possible	Not Required	Not Required	REPORT TO STRC	Not Required	REPORT TO STRC	REPORT TO STRC
Probable	Not Required	Not Required	REPORT TO STRC	Not Required	REPORT TO STRC	REPORT TO STRC
Definite	Not Required	Not Required	REPORT TO STRC	Not Required	REPORT TO STRC	REPORT TO STRC

STRC notification responsibilities of the person (e.g., nurse) handling the reporting/documenting of the SAE in WISER:

1. Make a phone call (or speak in person) to the appropriate clinical member of the STRC as listed below (page if necessary)—see note 2 below
2. Enter a new SAE into the SAE module that is located in the Subject>> CRA Console in WISER WITHIN 24 HOURS of first knowledge of the event. Information can be entered and saved, but the STRC members will not be notified until a date is entered into the STRC Notification Date Field. This will ensure that all persons that need to be made aware of the event (i.e., study team members and STRC members) will be notified; remember to file a copy of your confirmation.
3. Ensure that you document that the appropriate person(s) on the STRC has been contacted. Indicate the name of the STRC clinician that was contacted in the comments field in the SAE console of the particular subject.
4. In addition, it is very important to enter whether or not the protocol should be suspended based on the discussion with the STRC clinician. This is the major function of the email notification. This should also be entered in the comments field in the SAE console of the subject.
5. Follow up/update the clinical member(s) of STRC regarding any new developments or information obtained during the course of the SAE investigation and reporting process.

Elements to complete the SAE form in the Subject Console in WISER:

1. Event Date
2. Reported Date
3. Reported by

4. If Grade 5, enter Death Date
5. Death occurred: within 30 days
6. Event Narrative: Brief description (include brief clinical history relevant to this event, including therapies believed related to event).
7. Treating Physician comments
8. PI comments if available
9. Protocol Attribution after discussion with STRC clinician
10. Outcome
11. Consent form Change Required? Y/N
12. SAE Classification *This is required in order for the email notification to be sent*
13. Adverse Event Details – Enter all details for each AE associated with the SAE.
    a. Course start date
    b. Category
    c. AE Detail
    d. Comments
        i. STRC clinician name and comments
        ii. Date of last dose before the event
        iii. Is suspension of the protocol needed?
    e. Grade/Severity
    f. Unexpected Y/N
    g. DLT Y/N
    h. Attributions
    i. Action
    j. Therapy.
14. Enter Date Notified STRC -- *This is required for the email notification to be sent*

The Clinical Members of STRC to Notify by Phone or Page:

Bayard Powell, MD – Director-at-Large, CCCWFU; Section Head, Hematology/Oncology
Glenn Lesser, MD – Hematology Oncology
Stefan Grant, MD, JD-Hematology Oncology
Jimmy Ruiz, MD-Hematology Oncology
Kathryn Greven, MD – Vice Chair–Radiation Oncology
Marissa Howard-McNatt, MD – General Surgery
Mercedes Porosnicu, MD- Hematology Oncology

Definition of Unavailable:

As a general guideline if the first clinician that is contacted does not respond to the phone call or page within 30 minutes, then initiate contact with their backup. Allow up to 30 minutes for the backup to respond to a phone call or page before contacting another member. These times (30 minutes) are a general guideline. You must use your best judgment as a clinical research professional given the time of day, severity of the SAE, and other circumstances as to when it is appropriate to contact backup clinicians. If the event occurs near the end of day, then leave messages (voice or email) as appropriate and proceed with submitting your STRC notification form. It is important that you have taken reasonable steps and documented that you have initiated some type of contact to one or more of the clinical members of STRC.

STRC CLINICAN RESPONSIBILITY:

It is the responsibility of the STRC clinician to review all reported events, evaluate the events as they are reported; and communicate a response to the Investigator, event reporter and the members of STRC. The review will include but not be limited to the information reported; there may be times when additional information is needed in order for an assessment to be made and further communication directly with the investigator may be warranted. STRC reserves the right to agree with the investigator's assessment if STRC does not agree with the investigator. STRC reserves the right to suspend the trial pending further investigation. If there is any immediate danger or harm that could be present for a future patient based on the information provided in the STRC report then an immediate suspension of enrollment should be considered.

AMENDMENTS TO PREVIOUS REPORTS

If you are not able to supply all pertinent information with the initial submission, once the additional information is available do not submit a new report. Go to the original email that was received by STRC and others "reply to all" and entitle your email "Amendment for (list date of event and patient ID)" this will avoid duplications of the same event. List the additional information which you are reporting. This information needs to be entered into WISER as well. To do this, go to the Subject console and click SAEs on the left column. Click on the appropriate SAE number that needs updating. Then click update. This will allow you to add additional information.

Acronyms

STRC-Safety and Toxicity Review Committee
SAE-Serious Adverse Event
IRB-Institutional Review Board
CCCWFU-Comprehensive Cancer Center Wake Forest University
NCI-National Cancer Institute
CPDM-Clinical Protocol and Data Management
WISER –Wake Integrated Solution for Enterprise Research

Appendix E – Adverse Event Log

WFBCCC Adverse Event (AE) Log

PI: _____ PID: _____ MRN: _____

Cycle Start Date: _____ Cycle End Date: _____ Cycle #: _____

Adverse Event CTC Term	Value (-5 if non-numeric)	Grade (0-5) per CTC	Start Date	Attribution 1=Related 2=Probably 3=Possible 4=Unlikely 5=Unrelated	Treating MD Initials/Date	End Date	Expected 1=Yes 0=No	*Serious Adverse Event (SAE) 1=Yes 0=No	Dose Limiting Toxicity (DLT) 1=Yes 0=No	Action Taken 1=None 2=Tx withheld 3=Tx D/C 4=Tx adjusted 5=Other	Reportable? 1=IRB 2=STRC 3=FDA 4=Sponsor

*Serious Adverse Event: Hospitalization; Disability; Birth Defect; Life-threatening; Death.

CTCAE Version 4 - http://evs.nci.nih.gov/ftp1/CTCAE/CTCAE_4.03_2010-06-14_QuickReference_8.5x11.pdf

Appendix F – Study Questionnaires

Mapping to Guide Self-Management in Cancer Survivors

Baseline Questionnaire

Study ID: _____
Date: _____

Name of Facilitator: _____

Please answer each of the following questions to the best of your ability. We ask that you try not to skip any questions or write in any answers that are not given as choices for that particular question. There are no "right" or "wrong" answers for any of the questions, so please be honest in answering all questions. We encourage you not to spend too much time on any single question. Please go with your first instinct in answering most of the questions, as many of the questions ask you to state your opinion. Thank you again for your time. All responses will be kept completely confidential.

A. The next few questions about your background are important to help describe, *in general terms*, people who are part of this study.

A1. What is your date of birth? ___ ___ / ___ ___ / ___ ___ ___ ___
Month *Day* *Year*

A2. What is your current age? ___ ___
Age

A3. Are you… (check one)
- ☐ Currently married
- ☐ Currently living with partner
- ☐ Separated
- ☐ Divorced
- ☐ Widowed
- ☐ Single, never married
- ☐ Prefer not to answer

A4. What was the highest grade of school that you completed?
- ☐ Less than 8th grade
- ☐ 8th to 11th grades
- ☐ High school graduate or equivalent (GED)
- ☐ Technical or vocational school
- ☐ Some college
- ☐ College graduate
- ☐ Post-graduate degree
- ☐ Prefer not to answer

A5. How difficult is it for you (and your family) to pay your monthly bills?
- ☐ Very difficult
- ☐ Somewhat difficult
- ☐ Not very difficult
- ☐ Not at all difficult

A6. How many minutes did it take you to get to travel to the clinic? _____minutes

A7. Do you use the internet or email, at least occasionally?

- ☐ No
- ☐ Yes

A8. How confident are you filling out medical forms by yourself?

- ☐ Extremely
- ☐ Quite a bit
- ☐ Somewhat
- ☐ A little bit
- ☐ Not at all

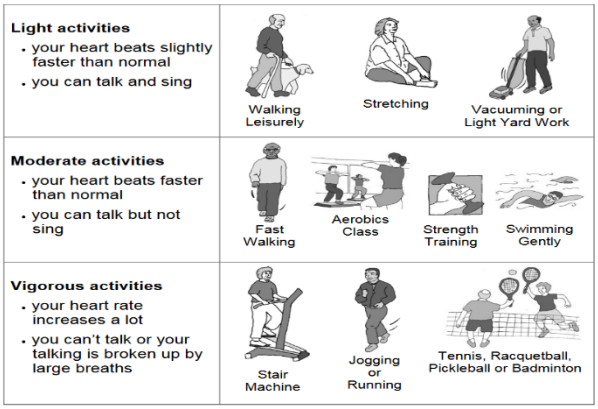
A9. How many times have you received income from AFDC, TANF, Work First, WIC or food stamps as an adult?

- ☐ Never
- ☐ Once
- ☐ Twice
- ☐ Three times
- ☐ Four times
- ☐ More than four times

B. The next section will ask you some questions about your health behaviors.

Physical activities are activities where you move and increase your heart rate above its resting rate, whether you do it for pleasure, work or transportation. The following questions ask about the amount and intensity of physical activity you usually do. The intensity of an activity is related to the amount of energy you use to do these activities.

Examples of physical activity intensity levels:



B1. How physically active are you? (check one answer on each line)

	Does this accurately describe you?	
a) I rarely or never do any physical activities.	Yes ☐	No ☐
b) I do some **light** or **moderate** physical activities, but not every week.	Yes ☐	No ☐
c) I do some **light** physical activity every week.	Yes ☐	No ☐
d) I do **moderate** physical activities every week, but less than 30 minutes a day or 5 days a week.	Yes ☐	No ☐
e) I do **vigorous** physical activities every week, but less than 20 minutes a day or 3 days a week.	Yes ☐	No ☐
f) I do 30 minutes or more a day of **moderate** physical activities, 5 or more days a week.	Yes ☐	No ☐
g) I do 20 minutes or more a day of **vigorous** physical activities, 3 or more days a week.	Yes ☐	No ☐

This section will ask you some questions about smoking. For the questions below, please try to select a single number.

B2. Have you smoked at least 100 cigarettes (5 packs=100 cigarettes) in your entire life?

- □ Yes
- □ No ➡ Go to Question B6.
- □ Don't know / Not sure ➡ Go to Question B6.

B3. How many total years have you smoked (or did you smoke) cigarettes? Do not count any time you may have stayed off cigarettes.

_____ Years *If you smoked less than one year, write "1."*

B4. On average when you have smoked, about how many cigarettes do you (or did you) smoke a day?

A pack usually has 20 cigarettes in it.

_____ Number of cigarettes per day

B5. How long has it been since you last smoked a cigarette (even one or two puffs)? *First check which one of the following choices applies to you. Then, if applicable, write a number on the line for how many days, weeks, months, or years it has been since your last cigarette.*

- □ I smoked a cigarette today (at least one puff).
- □ 1-7 days. ➡ Number of days since last cigarette: _____
- □ Less than 1 month. ➡ Number of weeks since last cigarette: _____
- □ Less than 1 year. ➡ Number of months since last cigarette: _____
- □ More than 1 year. ➡ Number of years since last cigarette: _____
- □ Don't know / Don't remember.

B6. Which of the following phrases best characterizes you at this time? *(Please mark only one response.)*

- □ Normal, no complaints, no symptoms of disease
- □ Able to carry on normal activity, minor symptoms of disease
- □ Normal activity with effort, some symptoms of disease
- □ Care for self, unable to carry on normal activity or to do active work
- □ Require occasional assistance but able to care for most of personal needs
- □ Require considerable assistance for personal care
- □ Disabled, require special care and assistance
- □ Severely disabled, require continuous nursing care

B7. How many times have you fallen in the last 6 months? ____ times

B8. **At any time** since you were first diagnosed with cancer, have you used any of the following complementary and alternative therapies?

		No	Yes		Have you used them in the past year?	
a.	Special diets such as mostly vegetarian or low fat	0☐	1☐	➔	0☐ No	1☐ Yes
b.	Movement or physical therapies such as yoga, tai chi, massage, chiropractic, or electromagnetic therapy	0☐	1☐	➔	0☐ No	1☐ Yes
c.	High dose or mega vitamins (DO NOT include 1-a-day multivitamins), nutritional supplements, or herbal remedies	0☐	1☐	➔	0☐ No	1☐ Yes
d.	Homeopathy (small doses of drugs that in a healthy person would produce symptoms like those of the disease)	0☐	1☐	➔	0☐ No	1☐ Yes
e.	Mind/body therapies such as guided imagery/visualization, biofeedback, meditation, relaxation techniques, hypnosis/hypnotherapy, energy healing, therapeutic touch, or music therapy	0☐	1☐	➔	0☐ No	1☐ Yes
f.	Oriental therapies such as acupuncture, acupressure, Qigong, or Shiatsu	0☐	1☐	➔	0☐ No	1☐ Yes
g.	Self-help or support groups (either face-to-face or on the Internet)	0☐	1☐	➔	0☐ No	1☐ Yes
h.	Psychological therapy or counseling from a psychologist, psychiatrist, social worker, or any other mental health professional	0☐	1☐	➔	0☐ No	1☐ Yes
i.	Faith healing, laying on of hands, or any other spiritual or religious group experience	0☐	1☐	➔	0☐ No	1☐ Yes
j.	Personal prayer or personal spiritual healing	0☐	1☐	➔	0☐ No	1☐ Yes
k.	Other, please specify: _____	0☐	1☐	➔	0☐ No	1☐ Yes

Study ID: _____ Date: _____

Index of Autonomous Functioning (Authorship/Self-Congruance Subscale):

Below is a collection of statements about your general experiences. Please indicate how true each statement is of your experiences on the whole. Remember that there are no right or wrong answers. Please answer according to what really reflects your experience rather than what you think your experience should be.

1. My decisions represent my most important values and feelings

1	2	3	4	5
Not at all true	*a bit true*	*somewhat true*	*mostly true*	*completely true*

2. I strongly identify with the things that I do

1	2	3	4	5
not at all true	*a bit true*	*somewhat true*	*mostly true*	*completely true*

3. My actions are congruent with who I really am

1	2	3	4	5
not at all true	*a bit true*	*somewhat true*	*mostly true*	*completely true*

4. My whole self stands behind the important decisions I make

1	2	3	4	5
not at all true	*a bit true*	*somewhat true*	*mostly true*	*completely true*

5. My decisions are steadily informed by things I want or care about

1	2	3	4	5
not at all true	*a bit true*	*somewhat true*	*mostly true*	*completely true*

Study ID: _____ Date: _____

The Self Efficacy for Managing Chronic Disease Scale (SEMCD):

For each of the following questions, please ***circle*** the number that corresponds with your **confidence** that you can do the tasks regularly at the present time

How confident are you that you can...

1.	Keep the fatigue caused by your disease from interfering with the things you want to do?	not at all confident	| | | | | | | | | | 1 2 3 4 5 6 7 8 9 10	totally confident
2.	Keep the physical discomfort or pain of your disease from interfering with the things you want to do?	not at all confident	| | | | | | | | | | 1 2 3 4 5 6 7 8 9 10	totally confident
3.	Keep the emotional distress caused by your disease from interfering with the things you want to do?	not at all confident	| | | | | | | | | | 1 2 3 4 5 6 7 8 9 10	totally confident
4.	Keep any other symptoms or health problems you have from interfering with the things you want to do?	not at all confident	| | | | | | | | | | 1 2 3 4 5 6 7 8 9 10	totally confident
5.	Do the different tasks and activities needed to manage your health condition so as to reduce your need to see a doctor?	not at all confident	| | | | | | | | | | 1 2 3 4 5 6 7 8 9 10	totally confident
6.	Do things other than just taking medication to reduce how much your illness affects your everyday life?	not at all confident	| | | | | | | | | | 1 2 3 4 5 6 7 8 9 10	totally confident

Study ID: _____ Date: _____

Self-Efficacy for Managing Symptoms – Short Form 4a

Please respond to each question or statement by marking one box per row.

	CURRENT level of confidence…	I am not at all confident	I am a little confident	I am somewhat confident	I am quite confident	I am very confident
SEMSX010	I can manage my symptoms during my daily activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX014	I can keep my symptoms from interfering with relationships with friends and family	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX009	I can manage my symptoms in a public place	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX011	I can work with my doctor to manage my symptoms	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Perceived Stress Scale

Instructions: The questions in this scale ask you about your feelings and thoughts during the past 7 days. In each case, please indicate with a check how often you felt or thought a certain way.

1. In the past 7 days, how often have you felt that you were unable to control the important things in your life?

___0=never
___1=almost never
___2=sometimes
___3=fairly often
___4=very often

2. In the past 7 days, how often have you felt confident about your ability to handle your personal problems?

___0=never
___1=almost never
___2=sometimes
___3=fairly often
___4=very often

3. In the past 7 days, how often have you felt that things were going your way?

___0=never
___1=almost never
___2=sometimes
___3=fairly often
___4=very often

4. In the past 7 days, how often have you felt difficulties were piling up so high that you could not overcome them?

___0=never
___1=almost never
___2=sometimes
___3=fairly often
___4=very often

Study ID: _____ Date: _____

PROMIS-29:

Please respond to each question or statement by marking one box per row.

	Physical Function	**Without any difficulty**	**With a little difficulty**	**With some difficulty**	**With much difficulty**	**Unable to do**
1	Are you able to do chores such as vacuuming or yard work?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
2	Are you able to go up and down stairs at a normal pace?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
3	Are you able to go for a walk of at least 15 minutes?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
4	Are you able to run errands and shop?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	Anxiety **In the past 7 days…**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
5	I felt fearful	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6	I found it hard to focus on anything other than my anxiety	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
7	My worries overwhelmed me	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8	I felt uneasy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Depression In the past 7 days...	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
9	I felt worthless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
10	I felt helpless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
11	I felt depressed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
12	I felt hopeless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Fatigue **During the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
13	I feel fatigued	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
14	I have trouble starting things because I am tired	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Fatigue **In the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
15	How run-down did you feel on average? ...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
16	How fatigued were you on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Sleep Disturbance **In the past 7 days…**	**Very poor**	**Poor**	**Fair**	**Good**	**Very good**
17	My sleep quality was	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
18	My sleep was refreshing.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
19	I had a problem with my sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
20	I had difficulty falling asleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Ability to Participate in Social Roles and Activities **In the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
21	I have trouble doing all of my regular leisure activities with others	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
22	I have trouble doing all of the family activities that I want to do	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
23	I have trouble doing all of my usual work (include work at home)	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
24	I have trouble doing all of the activities with friends that I want to do	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	Pain Interference **In the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
25	How much did pain interfere with your day to day activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
26	How much did pain interfere with work around the home?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
27	How much did pain interfere with your ability to participate in social activities? .	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
28	How much did pain interfere with your household chores?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Pain Intensity **In the past 7 days…**					
29	How would you rate your pain on average?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10
		No pain										**Worst imaginable pain**

Study ID: _____ Date: _____

Comprehensive Score for Financial Toxicity (COST):

Below is a list of statements that other people with your illness have said are important**. Please circle or mark one number per line to indicate your response as it applies to the past 7 days.**

		Not at all	A little bit	Somewhat	Quite a bit	Very much
1	I know that I have enough money in savings, retirement, or assets to cover the costs of my treatment.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
2	My out-of-pocket medical expenses are more than I thought they would be.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
3	I worry about the financial problems I will have in the future as a result of my illness or treatment.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
4	I feel I have no choice about the amount of money I spend on care.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
5	I am frustrated that I cannot work or contribute as much as I usually do.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
6	I am satisfied with my current financial situation.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
7	I am able to meet my monthly expenses.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
8	I feel financially stressed.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
9	I am concerned about keeping my job and income, including work at home.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
10	My cancer or treatment has reduced my satisfaction with my present financial situation.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
11	I feel in control of my financial situation.	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

Mapping to Guide Self-Management in Cancer Survivors

Follow-Up Questionnaire

Study ID: _____
Date: _____

Name of Facilitator: _____

Acceptability - Future Study Planning

1. How important is it for people to have support in determining their own health-related goals following cancer treatment?

1	2	3	4	5	6
Not at all	A little bit	Somewhat	Moderately	Quite a bit	Very much

2. How interested would you be in meeting with someone to follow-up up with you on the goals you chose during the study mapping exercise?

1	2	3	4	5	6
Not at all	A little bit	Somewhat	Moderately	Quite a bit	Very much

3. What person would you like to meet with to discuss those goals?

   a. A nurse
   b. Other healthcare provider
   c. A mental health provider
   d. A cancer survivor
   e. Any of the above people
   f. Other (please specify): _____

4. How often do you think it would be helpful to meet with someone to discuss your goals?

   a. Weekly
   b. Twice per month
   c. Monthly
   d. I do not think it would be helpful
   e. Other (please specify): _____

5. How would you like to meet with someone to discuss your goals?

   a. In person at the Cancer Center
   b. In person at my primary healthcare location
   c. On the telephone
   d. Over videoconferencing
   e. I would not like to meet with someone
   f. Other (please specify): _____

Study ID: _____ Date: _____

Acceptability - Satisfaction with the Mapping Exercise

Instructions: Please circle the number below that best describes your feelings about each statement.

	Not at All	A Little Bit	Somewhat	Quite a Bit	Very Much
I liked the study mapping exercise.	0	1	2	3	4
The study mapping exercise was helpful to me.	0	1	2	3	4
I plan to continue to use what I learned.	0	1	2	3	4
The interventionist who led the mapping was competent.	0	1	2	3	4
The interventionist who led the mapping was sensitive.	0	1	2	3	4

Acceptability - Overall Satisfaction

Instructions: Please rate the services you received from our facility in general. Circle the number that best describes your experience.

	Very Poor	Poor	Fair	Good	Very Good
1. Degree to which healthcare providers addressed your emotional needs	1	2	3	4	5
2. Likelihood of your recommending this medical center to others	1	2	3	4	5
3. Overall rating of care given at the medical center	1	2	3	4	5

Study ID: _____ Date: _____

HEAL - Patient-Provider Connection - Short Form:

Please respond to each item by marking one box per row.

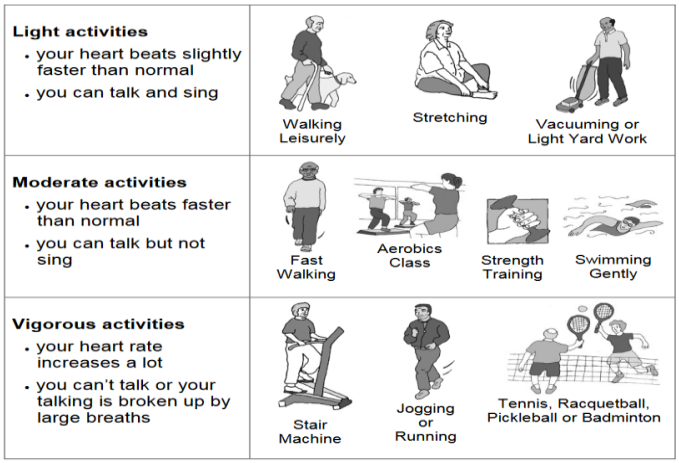
Think of the person who worked with you to create a map of your experience with cancer during this study as the "healthcare provider"…

	Not at all	A little bit	Somewhat	Quite a bit	Very much
I am satisfied with my healthcare provider.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I trust my healthcare provider.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
My healthcare provider pays attention to my individual needs.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
My healthcare provider gives me support and encouragement.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
My healthcare provider respects me.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I feel my healthcare provider understands me.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Never	**Rarely**	**Sometimes**	**Often**	**Almost Always**
My healthcare provider gives me enough information.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

The next section will ask you some questions about your health behaviors.

Physical activities are activities where you move and increase your heart rate above its resting rate, whether you do it for pleasure, work or transportation. The following questions ask about the amount and intensity of physical activity you usually do. The intensity of an activity is related to the amount of energy you use to do these activities.

Examples of physical activity intensity levels:



1. How physically active are you? (check one answer on each line)

	Does this accurately describe you?	
a) I rarely or never do any physical activities.	Yes ☐	No ☐
b) I do some **light** or **moderate** physical activities, but not every week.	Yes ☐	No ☐
c) I do some **light** physical activity every week.	Yes ☐	No ☐
d) I do **moderate** physical activities every week, but less than 30 minutes a day or 5 days a week.	Yes ☐	No ☐
e) I do **vigorous** physical activities every week, but less than 20 minutes a day or 3 days a week.	Yes ☐	No ☐
f) I do 30 minutes or more a day of **moderate** physical activities, 5 or more days a week.	Yes ☐	No ☐
g) I do 20 minutes or more a day of **vigorous** physical activities, 3 or more days a week.	Yes ☐	No ☐

This section will ask you some questions about smoking. For the questions below, please try to select a single number.

2. Have you smoked at least 100 cigarettes (5 packs=100 cigarettes) in your entire life?
   - □ Yes
   - □ No ➡ Go to Question B6.
   - □ Don't know / Not sure ➡ Go to Question B6.

3. How many total years have you smoked (or did you smoke) cigarettes? Do not count any time you may have stayed off cigarettes.
   _____ Years *If you smoked less than one year, write "1."*

4. On average when you have smoked, about how many cigarettes do you (or did you) smoke a day?
   A pack usually has 20 cigarettes in it.
   _____ Number of cigarettes per day

5. How long has it been since you last smoked a cigarette (even one or two puffs)?
First check which one of the following choices applies to you. Then, if applicable, write a number on the line for how many days, weeks, months, or years it has been since your last cigarette.
   - □ I smoked a cigarette today (at least one puff).
   - □ 1-7 days. ➡ Number of days since last cigarette: _____
   - □ Less than 1 month. ➡ Number of weeks since last cigarette: _____
   - □ Less than 1 year. ➡ Number of months since last cigarette: _____
   - □ More than 1 year. ➡ Number of years since last cigarette: _____
   - □ Don't know / Don't remember.

6. Which of the following phrases best characterizes you at this time? *(Please mark only one response.)*
   - □ Normal, no complaints, no symptoms of disease
   - □ Able to carry on normal activity, minor symptoms of disease
   - □ Normal activity with effort, some symptoms of disease
   - □ Care for self, unable to carry on normal activity or to do active work
   - □ Require occasional assistance but able to care for most of personal needs
   - □ Require considerable assistance for personal care
   - □ Disabled, require special care and assistance
   - □ Severely disabled, require continuous nursing care

7. How many times have you fallen in the last 6 months? ____ times

8. Have you used any of the following complementary and alternative therapies in the past 2 weeks?

	No	Yes
a. Special diets such as mostly vegetarian or low fat	0☐	1☐
b. Movement or physical therapies such as yoga, tai chi, massage, chiropractic, or electromagnetic therapy	0☐	1☐
c. High dose or mega vitamins (DO NOT include 1-a-day multivitamins), nutritional supplements, or herbal remedies	0☐	1☐
d. Homeopathy (small doses of drugs that in a healthy person would produce symptoms like those of the disease)	0☐	1☐
e. Mind/body therapies such as guided imagery/visualization, biofeedback, meditation, relaxation techniques, hypnosis/hypnotherapy, energy healing, therapeutic touch, or music therapy	0☐	1☐
f. Oriental therapies such as acupuncture, acupressure, Qigong, or Shiatsu	0☐	1☐
g. Self-help or support groups (either face-to-face or on the Internet)	0☐	1☐
h. Psychological therapy or counseling from a psychologist, psychiatrist, social worker, or any other mental health professional	0☐	1☐
i. Faith healing, laying on of hands, or any other spiritual or religious group experience	0☐	1☐
j. Personal prayer or personal spiritual healing	0☐	1☐
k. Other, please specify: _____	0☐	1☐

Study ID: _____ Date: _____

Index of Autonomous Functioning:

Below is a collection of statements about your general experiences. Please indicate how true each statement is of your experiences on the whole. Remember that there are no right or wrong answers. Please answer according to what really reflects your experience rather than what you think your experience should be.

1. My decisions represent my most important values and feelings

1	2	3	4	5
not at all true	*a bit true*	*somewhat true*	*mostly true*	*completely true*

2. I strongly identify with the things that I do

1	2	3	4	5
not at all true	*a bit true*	*somewhat true*	*mostly true*	*completely true*

3. My actions are congruent with who I really am

1	2	3	4	5
not at all true	*a bit true*	*somewhat true*	*mostly true*	*completely true*

4. My whole self stands behind the important decisions I make

1	2	3	4	5
not at all true	*a bit true*	*somewhat true*	*mostly true*	*completely true*

5. My decisions are steadily informed by things I want or care about

1	2	3	4	5
not at all true	*a bit true*	*somewhat true*	*mostly true*	*completely true*

Study ID: _____ Date: _____

The Self Efficacy for Managing Chronic Disease Scale (SEMCD):

For each of the following questions, please ***circle*** the number that corresponds with your **confidence** that you can do the tasks regularly at the present time

How confident are you that you can...

1.	Keep the fatigue caused by your disease from interfering with the things you want to do?	not at all confident	1 2 3 4 5 6 7 8 9 10 totally confident
2.	Keep the physical discomfort or pain of your disease from interfering with the things you want to do?	not at all confident	1 2 3 4 5 6 7 8 9 10 totally confident
3.	Keep the emotional distress caused by your disease from interfering with the things you want to do?	not at all confident	1 2 3 4 5 6 7 8 9 10 totally confident
4.	Keep any other symptoms or health problems you have from interfering with the things you want to do?	not at all confident	1 2 3 4 5 6 7 8 9 10 totally confident
5.	Do the different tasks and activities needed to manage your health condition so as to reduce your need to see a doctor?	not at all confident	1 2 3 4 5 6 7 8 9 10 totally confident
6.	Do things other than just taking medication to reduce how much your illness affects your everyday life?	not at all confident	1 2 3 4 5 6 7 8 9 10 totally confident

Study ID: _____ Date: _____

Self-Efficacy for Managing Symptoms – Short Form 4a

Please respond to each question or statement by marking one box per row.

	CURRENT level of confidence…	I am not at all confident	I am a little confident	I am somewhat confident	I am quite confident	I am very confident
SEMSX010	I can manage my symptoms during my daily activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX014	I can keep my symptoms from interfering with relationships with friends and family	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX009	I can manage my symptoms in a public place	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX011	I can work with my doctor to manage my symptoms	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Perceived Stress Scale

Instructions: The questions in this scale ask you about your feelings and thoughts during the past 7 days. In each case, please indicate with a check how often you felt or thought a certain way.

1. In the past 7 days, how often have you felt that you were unable to control the important things in your life?

___0=never
___1=almost never
___2=sometimes
___3=fairly often
___4=very often

2. In the past 7 days, how often have you felt confident about your ability to handle your personal problems?

___0=never
___1=almost never
___2=sometimes
___3=fairly often
___4=very often

4. In the past 7 days, how often have you felt that things were going your way?

___0=never
___1=almost never
___2=sometimes
___3=fairly often
___4=very often

4. In the past 7 days, how often have you felt difficulties were piling up so high that you could not overcome them?

___0=never
___1=almost never
___2=sometimes
___3=fairly often
___4=very often

Study ID: _____ Date: _____

PROMIS-29:

Please respond to each question or statement by marking one box per row.

	Physical Function	**Without any difficulty**	**With a little difficulty**	**With some difficulty**	**With much difficulty**	**Unable to do**
1	Are you able to do chores such as vacuuming or yard work?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
2	Are you able to go up and down stairs at a normal pace?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
3	Are you able to go for a walk of at least 15 minutes?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
4	Are you able to run errands and shop?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	Anxiety **In the past 7 days…**	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
5	I felt fearful	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6	I found it hard to focus on anything other than my anxiety	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
7	My worries overwhelmed me	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8	I felt uneasy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Depression In the past 7 days...	**Never**	**Rarely**	**Sometimes**	**Often**	**Always**
9	I felt worthless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
10	I felt helpless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
11	I felt depressed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
12	I felt hopeless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Fatigue **During the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
13	I feel fatigued	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
14	I have trouble starting things because I am tired	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Fatigue **In the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
15	How run-down did you feel on average? ...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
16	How fatigued were you on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Sleep Disturbance **In the past 7 days…**	**Very poor**	**Poor**	**Fair**	**Good**	**Very good**
17	My sleep quality was	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
18	My sleep was refreshing.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
19	I had a problem with my sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
20	I had difficulty falling asleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Ability to Participate in Social Roles and Activities **In the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
21	I have trouble doing all of my regular leisure activities with others	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
22	I have trouble doing all of the family activities that I want to do	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
23	I have trouble doing all of my usual work (include work at home)	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
24	I have trouble doing all of the activities with friends that I want to do	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
	Pain Interference **In the past 7 days…**	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
25	How much did pain interfere with your day to day activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
26	How much did pain interfere with work around the home?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
27	How much did pain interfere with your ability to participate in social activities? .	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
28	How much did pain interfere with your household chores?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	Pain Intensity **In the past 7 days…**					
29	How would you rate your pain on average?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
		No pain				

☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10	
					Worst imaginable pain	

Appendix G – Chart Review Data Collection Form

Mapping to Guide Self-Management in Cancer Survivors

Participant ID:_____

Date Abstraction Completed: ____ ____/____ ____/____ ____

Abstracter's Initials _____

BASELINE CLINICAL DATA

1. Weight: ___ ___ ___lbs.
2. Height: ___ ___in.
3. BMI: ___ ___
4. Date for BMI (mm/dd/yy): __ __/__ __/__ __

Primary Diagnosis

5. Date of initial colorectal cancer <u>pathological</u> diagnosis (mm/dd/yy): __ __/__ __/__ __

6. Primary Tumor Site (select one):

   ☐ Colon
   ☐ Rectum
   ☐ Other: _____
   ☐ Unknown Primary _____

7. AJCC overall staging at diagnosis:

   T ___ N____ M ____

   7a. Summary Stage:

☐ 0	☐ IIIA
☐ I	☐ IIIB
☐ IIA	☐ IIIC
☐ IIB	☐ IVA
☐ IIC	☐ IVB

8. Is this recurrent disease?
   - ☐ No
   - ☐ Yes

   If yes,

   8a. Date of Recurrence (mm/dd/yy): __ __/__ __/__ __

Prior Treatment Details:

9. History of any cancer-related surgical procedure(s):
   - ☐ No
   - ☐ Yes

   9a. Surgery Date (mm/dd/yy): __ __/__ __/__ __

   9b. Surgery Date (mm/dd/yy): __ __/__ __/__ __

10. History of Radiation Therapy
    - ☐ No
    - ☐ Yes:

      10a. Was radiation therapy given for colorectal cancer?
      - ☐ No
      - ☐ Yes

      10b. Date *most recent* treatment was completed (mm/dd/yy): __ __/__ __/__ __

11. History of Chemotherapy?
    - ☐ No
    - ☐ Yes

      11a. Was chemotherapy given for colorectal cancer?
      - ☐ No
      - ☐ Yes

      11b. Date *most recent* treatment was completed (mm/dd/yy): __ __/__ __/__ __

12. Other Cancer Treatments?
    - ☐ No
    - ☐ Yes (describe): _____

      12b. Date *most recent* treatment was completed (mm/dd/yy): __ __/__ __/__ __

13. Comorbidities:
    - ☐ Myocardial infarction
    - ☐ Congestive heart failure
    - ☐ Peripheral Vascular Disease
    - ☐ Cerebrovascular Disease (CVD)
    - ☐ Chronic obstructive pulmonary disease
    - ☐ Dementia
    - ☐ Paralysis (Hemiplegia or Paraplegia)
    - ☐ Diabetes or diabetes with complications
    - ☐ Renal disease
    - ☐ Any liver disease
    - ☐ Peptic ulcer disease
    - ☐ Rheumatologic disease
    - ☐ AIDS
    - ☐ Other cancer (describe): _____