Document Coversheet

Study Title: **Problem Solving Skills Training in Adult Cancer Survivors: Bright IDEAS-AC**

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PROTOCOL TITLE:

Problem Solving Skills Training in Adult Cancer Survivors: Bright IDEAS-AC

PROTOCOL NUMBER:

I 65518

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Confidentiality Statement

Table of Contents

1.0 Objectives

1.1

The aim of this 2-year study will assess the acceptability and feasibility of offering Problem Solving Skills Therapy (PSST) to cancer survivors and their caregivers focusing on the highest risk patients with distress. We will recruit 50 adults with non-terminal colorectal (CRC), breast, bladder or prostate cancer who are about to complete their adjuvant therapy or who had a survivorship care appointment and discussion about their SCP, and who scored 2 or higher on the NCCN Distress scale. We will use stratified randomization to assign them to "care as usual" (CAU) vs. a 3-month PSST intervention. We will evaluate the feasibility of including caregivers in the program by encouraging patients to bring their caregivers/significant others to their appointments. We will determine the number/proportion of patients who identify and bring a caregiver and describe the patients' willingness and ability to do so. This study's specific aims (SA) and hypotheses (H) are:

SA1: To adapt the previously validated PSST to adult cancer patients and their caregivers, Bright IDEAS-AC. Following the NCI Guidelines for Choosing and Adapting Research-Tested Intervention Programs (RTIPs),[1,2] we will revise the program materials and training protocol and pilot the adapted products and processes with 5 adult cancer survivors and/or their caregivers.

SA2: Using established framework for future implementation, determine acceptability of PSST in cancer survivors. The 4 acceptability objectives of the Bright IDEAS-AC Study are: (1) minimize burden of patient-reported data collection; (2) maximize compliance with 8-session SCP-specific PSST intervention; (3) minimize barriers to consistent participation of supportive others (SO) in PSST; and (4) estimate recruitment rates for a future trial. We will collect patient self-reported data about problem solving skills (SPSI-R), physical health (pain, fatigue, bowel and bladder function (FACT-C, B, BI or P)), and behavioral health (depression and anxiety). We will also assess patient utilization of health services such as hospital and ED admissions.

SA3: Determine a) feasibility and b) sustainability of Bright IDEAS as a clinically adopted intervention for adult cancer survivors using the PRISM framework, and feasibility of recruiting adult cancer survivors' caregivers for inclusion in the Bright IDEAS intervention.

1.2

H1: At least 70% of contacted patients will enroll in the study.

H2: At least 80% of patients will complete 80% of PSST sessions after randomization.

H3: At least 50% of patients will identify the burden of PSST training as < 3 on a 5-item Likert scale.

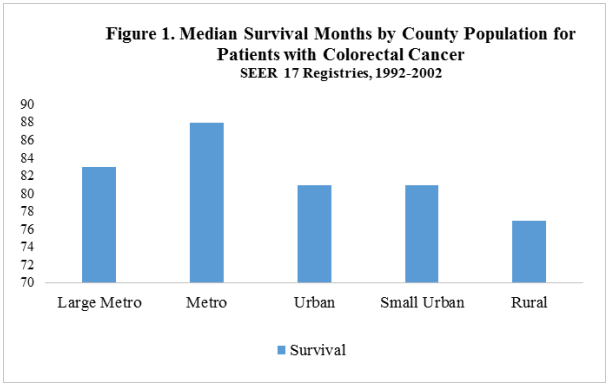
H4: At least 50% of patients with cancer will identify a significant other to join them in PSST training.

H5: Strategies associated with higher levels of institutional feasibility and sustainability of Bright IDEAS-AC affect provider burden and teamwork and institutional resources and workflow.

2.0 Background

A. Patient Role in the Implementation of Survivorship Care Guidelines. According to the National Cancer Institute's definition, "An individual is considered a cancer survivor from the time of diagnosis through the balance of his/her life."[3] Using this definition, the population of survivors approaches 15.5 million people nationally (2016) and is expected to reach 18 million by the end of the decade.[4] According to the current clinical guidelines from the Institute of Medicine and the American Society of Clinical Oncology,[5] all cancer patients should receive individual cancer survivorship care plans (SCPs) from their medical oncologists (Appendix 1). The SCP is a document detailing patient-specific risk factors for cancer recurrence and side effects (physical, psychosocial, socioeconomic), a follow-up care schedule, available resources, and health management considerations and should be administered by the patient's primary care provider, treating medical oncologist, or both, with support from a multidisciplinary survivorship care team. Lack of reliable evidence of SCP effectiveness is often cited as a reason why clinicians rarely discuss the potential usefulness of adhering to their SCP with patients.[5-7] At the same time, recent publications[8-11] have clearly demonstrated that studies evaluating SCP effectiveness have suffered from significant implementation errors[12] and omitted analysis of critically important components of SCPs such as patient role in SCP implementation, follow-up care, and care coordination, as well as mode and frequency of SCP presentation. Each of these elements could independently affect SCP use and patient outcomes, and several of these elements need to be implemented in concert to achieve optimal outcomes. *Our study is the first step in developing a patient-level intervention (PSST: problem-solving skills therapy) to improve patient ability to utilize SCP. Our target will be patients who have greater than average distress and so are more likely to benefit from the PSST intervention and ultimately, from their SCP.*

B. Patient Barriers to Survivorship Care Use. The reasons for limited implementation of SCP are multifactorial and include lack of patient self-management skills and accurate information about available options and their trade-offs, patient emotional and financial distress, and lack of care coordination among others.[8,10,13] Recent evidence demonstrates[4,14,15] that *cancer survivors are often distressed and overwhelmed by the burden of decision making* and prioritizing among family obligations and self-care, employment and disability-related issues, coordination of primary care and specialist services, transportation to appointments, insurance coverage and other costs. Other co-occurring factors that also compromise patient decision-making abilities are treatment-related fatigue and cognitive problems, anxiety about potential cancer recurrence and body image, and other life-altering consequences of cancer diagnosis.[4,14-19] *Strong evidence indicates that living in a rural area or a long distance from a cancer center and limited availability of cancer specialists (which is typical for many rural areas in the US) exacerbate the burden of patient decision making and represent a barrier to survivorship care.*[20,21] According to the American Society of Clinical Oncology's (ASCO) recent workforce analysis, only 3% of medical oncologists practice in rural areas, whereas 20% of the US population resides in rural areas, and over 70% of counties in the United States do not have medical oncologists.[22] An Iowa study found that of all



cancer patients diagnosed in Iowa between 2004 and 2010, 63% resided in a hospital service area (HSA) with a local oncologist, 29% resided in an HSA with a visiting oncologist, and 8% resided in an HSA with no oncologist; those in areas with no local oncologist traveled an average of 58 minutes to receive chemotherapy.[23] Impending physician retirements and financial pressures on small community oncology practices may exacerbate access issues in rural areas in the coming years.[24]

Effect of Distress on Cancer Patients Self-Management Ability and Treatment Adherence. The National Comprehensive Cancer Network (NCCN) defines distress in cancer as a "multifactorial unpleasant emotional experience of a psychological (cognitive, behavioral, emotional), social and/or spiritual nature that may interfere with the ability to cope effectively with cancer, its physical symptoms and its treatment."[25,26] Cancer patients report a wide range of distress symptoms from feelings of vulnerability to problems that disrupt their daily living.[27] Twenty-nine to forty-three percent of cancer patients experience significant psychosocial distress.[28] Cancer survivors have the highest levels of distress in times of care transition including, but not limited to, time of diagnosis, waiting for the start of treatment and after the completion of definitive treatment ("feeling abandoned by their oncologist").[28-30] Evidence demonstrates that negative affectivity and poor problem-solving skills are associated with poor treatment adherence in patients with cancer as well as poor quality of life, low physical and social functioning and poor prognosis.[16-19] *There have been no studies to date, however, examining whether improvement in problem-solving skills and alleviation of behavioral issues translates into better survivorship care,* e.g., better patient self-management of late effects of cancer therapy, better adherence to the SCP, and lower overall and out-of-pocket associated costs.

Table 1: Top clinical problem list for cancer survivors [31]

	Clinical Problems		Social Problems & Concerns
	Chemo induced Peripheral Neuropathy		Transportation
	Cognitive impairment (chemo brain)		Care coordination between multiple provider offices
	Fatigue		Disability and sick time from work
	Body image (Breast reconstruction, ostomy care, and bowel and bladder problems)		Billing and reimbursement issues
	Depression, worry, fear, distress		Provider communication/shared decision making

Focus on Colorectal, Breast, Bladder and Prostate Cancers. As of January 1, 2019, it is estimated that colorectal, breast, prostate and bladder survivors comprise more than a third (36% for men and 44% for women) of 16 million cancer survivors alive in the US.[7] Potential long-term and late physical effects affecting cancer survivors are substantial and include chronic peripheral neuropathy, infertility, secondary cancers, bowel, and bladder dysfunction (Table 1). Survivors also experience psychosocial issues such as distress, depression, anxiety, body image, sexual dysfunction and intimacy concerns that may vary depending on patient sex, as well as financial issues resulting from workforce displacement and/or costs of treatment[31]. Focusing on these 4 cancer types allows us to work with high risk clinically diverse and gender balanced population and to assess the feasibility of recruiting and providing therapy to both male and female patients as well as caregivers of both genders (addressing SEX AS BIOLOGICAL VARIABLE).

3.0 Inclusion and Exclusion Criteria

The survivorship program coordinator (WCI - patients at all locations) and clinic nurse manager (Roswell Park patients) together with the study RAs will identify adult cancer patients who have completed treatment for stage I-III CRC, B, BI or P cancers and who are eligible for survivorship consultation using the clinic scheduling system and EHR and consulting with oncology team as needed. Each survivor will be asked to identify and bring along a personal caregiver/supportive other (SO). We will determine the number/proportion of patients who identify and bring a caregiver and describe characteristics of the caregiver group. No inclusion/exclusion criteria are proposed for the caregivers/SOs

Inclusion Criteria

To be included in this study, subjects must meet the following criteria:

1. Stage I-III CRC, B, BI and P.
2. Meet the screening criteria for psychological distress (NCCN Distress >2, PROMIS Anxiety >50 or any other clinical measure of mild distress).
3. Be able to speak English.
4. Have a 5-year survival rate of 50% or greater as deemed by their oncologist, surgeon, or other relevant attending physician (suggesting a reasonable rate of cure or prolonged medical survival with state-of-the-art medical care).
5. Be willing to provide written informed consent to participate in the study which includes several clinical evaluations, provide access to medical records/PCP, and allow all interviews and PSST therapy sessions to be audiotaped.
6. Among patients treated in the urban centers, we will specifically target patients who live more than 40 miles away from the clinic as they are more likely to experience problems with access to care.
7. Age 21 or older.

Exclusion Criteria

Participants will be excluded from the study for the following:

1. A diagnosis of mental retardation, and/or
2. Acute suicidal behavior.

Inclusion of Women and Minorities

Both men and women and members of all races and ethnic groups are eligible for this study.

Special Populations

The following special populations are excluded from this study:

- Cognitively impaired adults/adults with impaired decision-making capacity
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners

INVESTIGATOR STUDY ELIGIBILITY VERIFICATION FORM: INCLUSION CRITERIA

Participant Name: (Multi-site use participant initials): _____

Medical Record No.: (Multi-site use participant ID): _____

Title: Problem Solving Skills Training in Adult Cancer Survivors: Bright IDEAS-AC

INCLUSION CRITERIA				
Yes	**No**	**N/A**	**All answers must be "Yes" or "N/A" for participant enrollment.**	**Date**
☐	☐	☐	1. Stage I-III CRC, B, BI and P.	
☐	☐	☐	2. Meet the screening criteria for psychological distress (NCCN Distress >2, PROMIS Anxiety >50 or any other clinical measure of mild distress).	
☐	☐	☐	3. Be able to speak English.	
☐	☐	☐	4. Have a 5-year survival rate of 50% or greater as deemed by their oncologist, surgeon, or other relevant attending physician (suggesting a reasonable rate of cure or prolonged medical survival with state-of-the-art medical care).	
☐	☐	☐	5. Be willing to provide written informed consent to participate in the study which includes several clinical evaluations, provide access to medical records/PCP, and allow all interviews and PSST therapy sessions to be audiotaped.	
☐	☐	☐	6. Among patients treated in the urban centers, we will specifically target patients who live more than 40 miles away from the clinic as they are more likely to experience problems with access to care.	
☐	☐	☐	7. Age 21 or older.	

Investigator Signature: _____ **Date:** _____

Printed Name of Investigator: _____

INVESTIGATOR STUDY ELIGIBILITY VERIFICATION FORM: EXCLUSION CRITERIA

Participant Name: (Multi-site use participant initials): _____

Medical Record No.: (Multi-site use participant ID): _____

Title: Problem Solving Skills Training in Adult Cancer Survivors: Bright IDEAS-AC

EXCLUSION CRITERIA				
Yes	**No**	**N/A**	**All answers must be "No" or "N/A" for participant enrollment.**	**Date**
☐	☐	☐	1. A diagnosis of mental retardation or severe cognitive problems.	
☐	☐	☐	2. Acute suicidal behavior.	

Participant meets all entry criteria: ☐ **Yes** ☐ **No**
If "NO", do not enroll participant in study.

Investigator Signature: _____ **Date:** _____

Printed Name of Investigator: _____

4.0 Local and Study-Wide Number of Subjects

4.1

Based on the participating sites enrollment history, we expect an average enrollment rate of 3 new survivors a month at Wilmot Cancer Institute (WCI), 2 from RPCI (up to 20), and 1 new survivor every other month at Noyes Memorial Hospital (NMH), an offsite Wilmot Cancer Institute location, for 10 months. We will stop enrollments once we achieve 50 participants. We plan to recruit 50 patients and as many caregivers as possible.

4.2

One of the study goals is to estimate attrition rate for this protocol.

5.0 Local and Study-Wide Recruitment Methods

Response: The study recruitment will start in Month 7 and continue for 10 months with last patient completing the follow-up by Month 23 (Figure 2). To ensure that men and women are adequately represented in the study sample, study randomization will be stratified by sex. In this study, we will pay close attention to the impact of patient sex and gender on their unmet needs and self-reported issues (for instance, female CRC survivors may be less comfortable discussing their bowel issues and body image with their male partners and prefer to use a sister or a female friend as a caregiver). Based on the results of the study, we may develop a differential recruitment and/or training strategy for the future multisite study. For instance, if we find out that male cancer survivors are more likely to drop out of therapy or prefer face-to-face therapy (vs. over the phone), we will take that into account when designing the intervention for the larger pragmatic study. The survivorship program coordinator (WCI - patients at all locations) colorectal clinic nurse manager (RPCI patients) together with RAs will identify adult cancer patients who have completed adjuvant treatment for stage I-III cancer and who are eligible for survivorship consultation. Two weeks before the scheduled survivorship appointment, the survivorship nurse/clinic nurse manager will send the patient a study letter followed by a phone call, telling them about the study goals and procedures (e.g., duration of assessment and frequency of follow-up) and inviting them to participate. Patients who express interest will meet with the study RA in the location of their choice (hospital, clinic or patient home). To determine patient eligibility, patients will be screened for cancer-related distress using the NCCN Distress Thermometer (Appendix 2). Patients who are experiencing psychological distress (NCCN Distress >2 cut-off has 100% sensitivity, PROMIS Anxiety >50 or any other clinical measure of mild distress), and who meet the study's other inclusion and exclusion criteria (see below) will be invited to participate (patient with the distress level 4 or greater will be referred to additional behavioral therapy). If a person is willing to continue the screening process by providing written informed consent, he or she will then be asked to complete their baseline evaluation consisting of a battery of self-report measures (Table 2). The cancer patient will also be asked to identify a Supportive Other (SO) who might serve as a problem-solving partner.

We budget $100 incentive for each patient in the form of VISA gift cards to facilitate patient recruitment, completion and return of the study evaluation forms and data collection. Patients will receive $25 for completing the baseline assessment, another $25 for completing 3-month assessment and $50 for completing the close-out assessment at about 6 months (including semi-

structured interviews). Each supportive other will receive $25 gift card for each returned evaluation form.

6.0 Multi-Site Research

6.1

Drs. Sahler (Wilmot Cancer Institute) and Noyes (UB/RPCI) will serve as Principal Investigators on the proposed study, with Dr. Noyes serving as the Contact PI. Their complementary skills and research interests will ensure successful completion of the stated aims. Importantly, both investigators contributed significantly to the intellectual conceptualization of the proposed study that arose from several years of their collaborative work on the Wilmot Cancer Institute (WCI) Multidisciplinary Survivorship team.

The roles and responsibilities of the two PIs are relatively discrete with Dr. Sahler leading the development/revision of all intervention materials and the training and supervision of the RAs in the delivery of the intervention. Dr. Noyes will oversee patient recruitment, data collection and analysis. Any areas of potential dispute will be resolved by consensus with input from the entire team.

All three sites will use the same recruitment materials and protocol. The Roswell Park IRB will serve as the IRB of record for all study sites. The proper IRB Authorization Agreements has been obtained for each site.

- All sites have the most current version of the protocol, consent document, and HIPAA authorization.
- All modifications have been communicated to sites, and approved before the modification is implemented.
- All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies.
- All local site investigators will conduct the study in accordance with applicable federal regulations and local laws.
- All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.

6.2

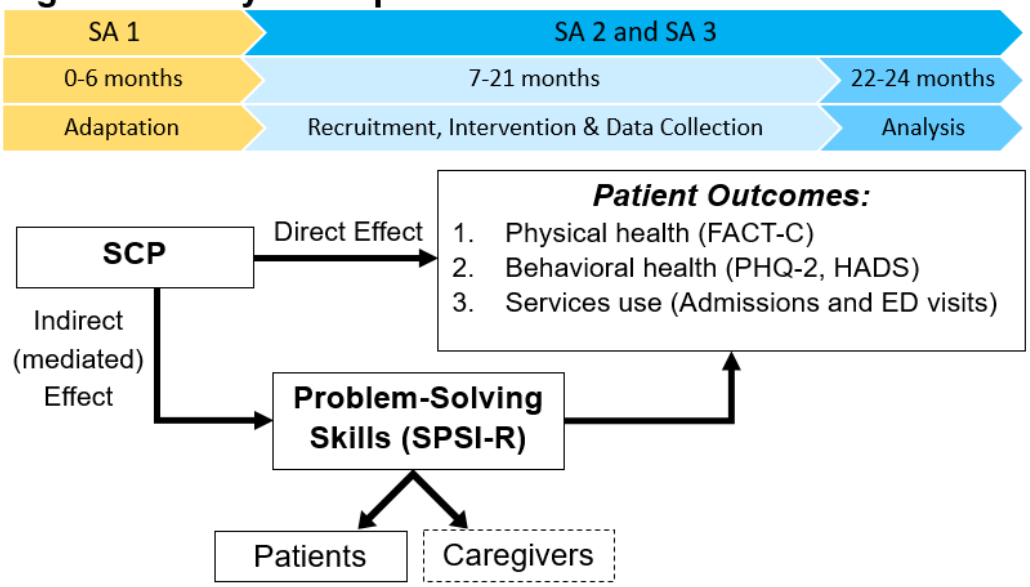
The MPIs will discuss study progress on an as-needed basis but no less frequently than weekly. Dr. Sahler will also serve as de-facto a site lead for the Rochester team and Dr. Noyes will be responsible for the Buffalo and Dansville teams including weekly meetings and communication. A joint (all-project) conference call will be held monthly.

7.0 Study Timelines

7.1

The study recruitment will start in Month 7 and continue for 10 months with last patient completing the follow-up by Month 23.

Figure 2. Study conceptual model



8.0 Study Endpoints

8.1

We will collect data to help quantify the burden of enrollment process including duration of the initial meeting between the patient and study coordinator and informal consent, number, duration and content of subsequent meetings and phone calls before and after patient/SO enrollment. At every stage, we will capture patient feedback and reasons for refusal to participate.

Table 2: Study self-reported instruments and questionnaires administered at T0, T1, and T2*

Instrument	***Short title***	***Number of items***	***Total score***	***Description***
Social Problem-Solving Inventory-Revised[32,33] (Appendix 5)	SPSI-R	52	0-20	±Problem Orientation, Rational Problem Solving, Impulsivity/ Carelessness Style, Avoidance Style
Patient Health Questionnaire-2[34] (Appendix 6)	PHQ-2	2	0-6	scoring each answer as 0 ("not at all") to 3 ("nearly every day")
Hospital Anxiety and Depression Scale[35,36](Appendix 7)	HADS	7+7	0-21	Depression/anxiety symptoms over the last week; scores >11 considered abnormal
The Functional Assessment of Cancer Therapy–disease specific[37](Appendix 8)	FACT-C FACT-B FACT-BI FACT-P	36	0-136	Δ5-8 ~clinically significant Reported based on the past 7 days

****For each metric, we will test for internal consistency ratings across the three assessment time points (T0, T1, and T2).***

Healthcare utilization. All patients in the intervention and control arms at the time of T0, T1, and T2 assessments will be asked about their healthcare utilization since the last assessment including primary care, specialist and ED visits and any hospital stays. This information will be validated with the patient SO and medical record/PCP. We will also ask about reasons for the visits to further distinguish utilization into avoidable (consequence of poor quality of care or insufficient self-management skills) and unavoidable (true healthcare emergency).

9.0 Design

Bright IDEAS-AC is a PSST intervention for adult colorectal cancer survivors and their caregivers designed to improve patient ability to participate in and benefit from SCP (Figure 2) This study will take place at three different settings, a hospital affiliated cancer center (Wilmot Cancer Institute (WCI), Rochester, NY), a free- standing NCI-designated cancer center (Roswell Park Cancer Institute (RPCI), Buffalo, NY) and a rural community oncology clinic (Myers Cancer Center, Dansville, NY) affiliated with WCI.

Bright IDEAS Adult Cancer (Bright IDEAS-AC) will be delivered in the most patient-friendly way. Sessions 1 and 8 (S1, S8) will be face-to-face at the location of patient choice (hospital, clinic, or participant's home). The rest of the sessions (S2-7) will be delivered over the phone by research assistants (RAs) who have received training in PSST skills building and supervision. Before enrollment, each participating cancer survivor will receive a description of the Bright IDEAS-AC

intervention, associated goals, and the randomization procedure in an informed consent document. Upon completion of the baseline assessment (Time 0) (Table 2), subjects will be randomized to the intervention or control arm in a 1:1 fashion using a stratified permuted block randomization scheme with stratification variables by patient sex and study site, using small blocks of size 2. The randomization lists will be generated by the study biostatistician (GW). All participants will undergo another self-assessment 3 months after enrollment (Time 1, by which time patients in the active treatment arm should have completed their PSST training) and at 6 months (Time 2). Participants will receive a modest stipend after each returned evaluation to compensate them for their time. The materials for the baseline (T0) assessment will be given to the patients during the baseline face-to-face meeting (S1). The RA will phone the patient reminding him/her about the upcoming follow-up assessment and will confirm the best way of delivering the self-assessment instruments (in clinic, online, email, or postal mail).

The PSST intervention will consist of eight one-hour individual weekly sessions conducted according to the previously published comprehensive protocol as summarized below. Problem solving is presented as a general coping skill applicable to a range of challenging circumstances commonly encountered by cancer survivors (Table 1). To promote patient engagement, the patients will be encouraged to identify specific problems particularly relevant to them and to their family's situation (instead of providing them with standardized examples) to be discussed and "solved" during the PSST sessions. The eight sessions of PSST will be organized in a systematized, therapeutic manner. Session 1 will be face-to-face and devoted to rapport building and understanding relevant social and medical information. The therapist (RA) will introduce PSST and the Bright IDEAS paradigm, present worksheets to guide PSST homework assignments, and give an overview of subsequent sessions. Starting at Session 2, participants will continue training over the phone, with the same general structure and format. In Sessions 2–7, the therapist and patient, with a supportive other (SO) if available, will review the patient's identified problems and work on application of problem-solving strategies and skills learned earlier.

For patients who struggle to define a problem, we will offer a choice from a list of typical CRC survivor problems developed by the research team with input from the clinical teams (Table 1). Session 8 will be conducted face-to-face and dedicated to a review of PSST training and relapse prevention, emphasizing persistence and learned optimism, and the process of termination. Note: Two RAs will be employed for this project. The RA not providing the intervention to a given patient will schedule the T1 assessment after Session 8 for the intervention arm and at 3 months post-randomization for the CAU patients and the T2 assessment 3 months later. Process notes will be recorded in a systematized format across both intervention arms at all data collection sites and kept in each participant's study file and entered electronically into REDCap.

Treatment Integrity (TI): We believe integrity of treatment implementation (i.e., assurance that interventions are conducted as intended by a competent therapist) is a critical feature of well-controlled outcomes research. Although the use of manuals does much to address this issue, systematic assessment of integrity must be conducted to draw firm conclusions about differential treatment effects, if any. Tests of TI are also important when interventions are conducted at multiple sites by different providers to identify any confounding site/personality effects. To assure TI, every session will be audiotaped, identified only by subject code, and uploaded to a secure site maintained by the project coordinator and MPIs. Twenty percent of the PSST tapes (0.2 * (25 subjects *8 sessions) = 40 tapes) will be chosen at random for review by Dr. Sahler according to

a checklist of content items and personal responses that have been used for prior projects. Feedback about any TI concerns will be delivered during supervision sessions with the study RAs.

10.0 Treatment

Bright IDEAS Adult Cancer (Bright IDEAS-AC): The PSST intervention will be delivered in the most patient-friendly way. Sessions 1 and 8 (S1, S8) will be face-to-face at the location of patient choice (hospital, clinic, or participant's home). The rest of the sessions (S2-7) will be delivered over the phone by research assistants (RAs) who have received training in PSST skills building and supervision. Before enrollment, each participating cancer survivor will receive a description of the Bright IDEAS-AC intervention, associated goals, and the randomization procedure in an informed consent document. All sessions will be audiotaped for quality assurance

Care As Usual Group (CAU): Participants randomized to the CAU group will be observed under naturalistic conditions. Both PSST and CAU participants and their clinicians (PCP and oncology providers) will be allowed to use any clinically appropriate medical and behavioral care without restriction (e.g., care management, rehabilitation, behavioral therapy, palliative care) or refer patients to social and community services (e.g., peer support, county cancer services program or aging services). The CAU participants will undergo the same evaluation protocol as the PSST group. After study completion, the CAU participants will be offered the PSST training manuals.

11.0 Procedures Involved

The Months 1-6 of the project is the adaptation phase. Using the NCI Guidelines for Choosing and Adapting RTIPs[1,2] and RE-AIM framework for implementation and dissemination, we will start by revising the program materials and training protocol to adapt them for the needs of cancer survivors and their caregivers. While the basic principles and approaches of PSST are generalized to a wide range of health and non-health related situations (e.g., providing at home care-giving to a disabled spouse, waiting for a refugee status after being displaced from your home county during a civil war crisis), using relevant examples will accelerate learning and improve information retention and new skills development. Based on the analysis of CRC survivorship literature and qualitative interviews with community oncology providers (VROC preliminary data), we have identified five most common clinical problems that affect cancer survivors and five social issues that all cancer survivors have a hard time dealing with (Table 1). Working together, the project team will review the Bright IDEAS materials to identify areas (processes, timing or examples) that are unique for mothers of pediatric cancer patients but not relevant for adult cancer survivors and their caregivers (ex., prioritizing between the care for the sick child and the needs of his healthy siblings). Using the experience and expertise of the project team, we will adapt these materials to reflect specific challenges that cancer survivors are likely to experience and/or have difficulty addressing. Once all revisions are completed, the updated manuals and materials will be piloted with 5 adult cancer survivors and their caregivers. Their feedback will be reviewed by the study team and incorporated in the study documents. The revised materials will be then pilot-tested with 5 adult cancer survivors and caregivers from WCI. The study team will review the results of the pilot test and make any necessary changes to the study approach.

The study recruitment will start in Month 7 and continue for 10 months with last patient completing the follow-up by Month 23 (Figure 2). To ensure that men and women are adequately represented in the study sample, study randomization will be stratified by sex. In this study, we will pay close attention to the impact of patient sex and gender on their unmet needs and self-reported issues (for

instance, female cancer survivors may be less comfortable discussing their bowel issues and body image with their male partners and prefer to use a sister or a female friend as a caregiver). Based on the results of the study, we may develop a differential recruitment and/or training strategy for the future multisite study. For instance, if we find out that male cancer survivors are more likely to drop out of therapy or prefer face-to-face therapy (vs. over the phone), we will take that into account when designing the intervention for the larger pragmatic study.

The survivorship program coordinator (WCI - patients at all locations) and colorectal clinic nurse manager (RPCI patients) together with RAs will identify adult cancer patients who have completed adjuvant treatment for stage I-III cancer and who are eligible for survivorship consultation. Two weeks before the scheduled survivorship appointment, the survivorship nurse/CRC nurse manager will send the patient a study letter followed by a phone call, telling them about the study goals and procedures (e.g., duration of assessment and frequency of follow-up) and inviting them to participate. Patients who express interest will meet with the study RA in the location of their choice (hospital, clinic or patient home).

To determine patient eligibility, patients will be screened for cancer-related distress using the NCCN Distress Thermometer (Appendix 2). Patients who are experiencing psychological distress (NCCN Distress >2 cut-off has 100% sensitivity),[62] and who meet the study's other inclusion and exclusion criteria (see below) will be invited to participate (patient with the distress level 4 or greater will be referred to therapy). If a person is willing to continue the screening process by providing written informed consent, he or she will then be asked to complete their baseline evaluation consisting of a battery of self-report measures (Table 2). The cancer patient will also be asked to identify a Supportive Other (SO) who might serve as a problem-solving partner. Inclusion and exclusion criteria: To be eligible to participate in this study, individuals will need to (a) meet the screening criteria for psychological distress (NCCN Distress >2, PROMIS Anxiety >50 or any other clinical measure of mild distress); (b) be able to speak English; (c) have a 5-year survival rate of 50% or greater as deemed by their oncologist, surgeon, or other relevant attending physician (suggesting a reasonable rate of cure or prolonged medical survival with state-of-the-art medical care); and (d) be willing to provide written informed consent to participate in the study which includes several clinical evaluations, provide access to medical records/PCP, and allow all interviews and PSST therapy sessions to be audiotaped. Exclusion criteria include the presence of (a) a diagnosis of mental retardation, and/or (b) acute suicidal behavior. Among patients treated in the urban centers, we will specifically target patients who live more than 40 miles away from the clinic as they are more likely to experience problems with access to care. All study procedures and materials will be reviewed and approved by the Institutional Review Board to ensure maximum protection of patient privacy and confidentiality, HIPAA compliance, and appropriate data handling (see Data and Safety Monitoring Plan). Sample size justification: Based on the participating sites enrollment history, we expect an average enrollment rate of 3 new cancer survivors a month at WCI, 2 from RPCI, and 1 new cancer survivor every other month at NMH for 10 months (Figure 2). We will stop enrollments once we achieve 50 participants.

The RAs will collect patient self-reported demographic, clinical, and socio-economic information at the baseline (age, gender, race/ethnicity, employment status, education, health insurance, place of residence, living arrangements, diagnosis, SCP or treatment history and time since diagnosis and end of treatment) as well as the information about the SO (age, sex, education level, religion/ethnicity, racial background, cancer history and relationship to the patient). We will collect data to help quantify the burden of enrollment process including duration of the initial

meeting between the patient and study coordinator and informal consent, number, duration and content of subsequent meetings and phone calls before and after patient/SO enrollment. At every stage, we will capture patient feedback and reasons for refusal to participate.

Caregivers are asked to play their usual supportive role and invited to participate in the therapy sessions and exercises, talk with patients about their problems, offer solutions and emotional support. They are also invited to participate in evaluations and qualitative interviews.

All patients in the intervention and control arms, as well as any participating caregivers, at the time of T0, T1, and T2 assessments will be asked about their healthcare utilization since the last assessment including primary care, specialist and ED visits and any hospital stays. This information will be validated with the patient SO and medical record/Primary Care Provider (PCP) office staff. For RPCI patients, information about number and timing of care visits will be requested electronically. For external patients, the RA will call the PCP office staff and confirm all patient-reported clinic visits after the medical record release form is signed. We will also ask about reasons for the visits to further distinguish utilization into avoidable (consequence of poor quality of care or insufficient self-management skills) and unavoidable (true healthcare emergency).

Using in-depth semi structured interview approach, we will explore the viewpoints of participating stakeholders in diverse clinical and social settings (including patients from various family and religious backgrounds, caregivers, clinic staff and administration for each clinical setting) regarding how the intervention design, the external environment and infrastructure may influence Bright IDEAS-AC adoption and sustainability. We will ask stakeholders about the time they spent on the intervention-related activities, how optimistic they were about the impact of the intervention, and their confidence in the intervention (Appendix 7). We plan to conduct five 1-hour interviews each year, which will be professionally transcribed and analyzed by the study implementation scientist. We strategically selected an outside consultant (DM) who has no personal ties to the study organizations to minimize subjective validation bias and promote open communication with the stakeholders. The results of the SA3 analysis will be shared with the study team to inform any changes to the study approach and planning of subsequent multisite trial.

At any point during the study, a participant, caregiver, or clinical staff may receive a phone call from the study consultant Dr. Demetria McNeal from the University of Colorado at Denver. Dr. McNeal will randomly select up to 10 patients and up to 5 supportive others to ask them about how participation in this study may affect their lives and clinical care. The participation is voluntarily; the phone call should take about an hour. A written letter will be sent to selected participants to make them aware that Dr. McNeal will be contacting them.

12.0 Withdrawal of Subjects

As long as the subjects are willing and able to participate in the study, they will be kept in the study and followed as planned.

13.0 Risks to Subjects

We are unaware of any potential risks from participation and have seen no reports of adverse effects during the prior PSST projects (total n=900 subjects). All records will be kept strictly confidential as required by the policies and procedures of the participating institutions. Should a subject become distressed while completing a questionnaire or participating in an intervention

session to an extent that exceeds the research assistant's clinical experience, the issue will be discussed with the site PI or the subject will be referred to a mental health professional as appropriate. Provision of 1 hour of supervision for each four hours of subject contact and review of a sample of audiotapes from therapy sessions by Dr. Sahler, experienced licensed health professional, adds another layer of monitoring to ensure subject safety.

14.0 Potential Benefits to Subjects

Subjects will receive immediate benefit from participating in the study in the form of improved problem-solving skills, reduction in emotional distress, improvement in confidence and affect. Compared with mothers of children diagnosed with cancer who received usual care, PSST mothers reported significantly enhanced problem-solving skills (SPSI-R score12.55 vs. 11.46, p=0.003) and significantly decreased negative affectivity,[38] even after the active PSST had stopped.[38-41]

15.0 Data and Specimen Banking

Returned subject questionnaires will be kept in the PI's office in locked storage cabinets.

Electronic data will be stored on password protected HIPAA-compliant shared drive accessible to the qualified study personnel only.

Address:

School of Public Health and Health Professions

University of Buffalo

270C Farber Hall

Buffalo, NY

Department: Division of Health Services Policy and Practice

Department of Epidemiology and Environmental Health

16.0 Measurement of Effect

Using study self-reported instruments and questionnaires administered at T0, T1, and T2, we will track changes in-patient problem-solving skills, depression, anxiety, and GI functioning (see Section 8.1 Table 2). While this feasibility study is not powered to detected statistically significant changes in the tracked metrics, we will use GEE approach to perform trend analysis and controlling for multiple observation per person over time.

17.0 Safety Evaluation

N/A

18.0 Data Management and Confidentiality

18.1 *Waiver of HIPPA Authorization*

Using random number generator, each subject will be randomized to either intervention or care as usual arm. Two RAs will be employed for this project. The RA not providing the intervention to a given patient will schedule the T1 assessment after session 8 for the intervention arm and at 3 months post-randomization for the CAU patients and the T2 assessment 3 months later. The

RAs will collect all evaluation forms and electronically input data into REDCap database using subject Study ID for identification. The crosslink between the Study ID and subject person-identifiable information will be stored separately and not available to the study analyst, to minimize any bias. The research database available for analysis will contain no person identifiable information (e.g., name or address). All individuals who will have access to data have completed all the necessary training for working with PHI data, institutional and federal regulations compliance, conflict of interest and good clinical practice training. The department administrator maintains the records of certification and issues reminders when re-certification is due.

All collected data will stored in accordance with the Roswell Park and UB data security policies. The respondent database will be maintained on a secure, network encrypted shared drive that is password protected, in a locked research office. The database will be maintained for a period of 5 years, after which time it will be destroyed.

The data will be accessed only from a UB or Roswell Park secure password protected computer by pre-identified and appropriately trained faculty and staff. All faculty and staff have private locked offices.

19.0 Statistical Plan

We will compare characteristics of patients who enrolled and did not enroll in the study including characteristics of the settings where the initial contact took place (e.g., doctor's office, waiting room, or other). We will calculate proportion of recruited and retained cancer patients and their SOs for the PSST training, proportion of completed and returned 3- and 6 month evaluations, recruitment rates for various sites, and patient personal time spent on the intervention-related activities (H1, 2, and 4). To evaluate acceptability, we will assess patients' perceptions of the intervention burden immediately after Sessions 1, 4, and 8 (or the last session in the case of early mastery or termination) (H3). Healthcare utilization will be compared between the study arm using count data models (Poisson and negative binomial for trend analysis only). All statistical analyses will be carried out using SAS version 9.4 (or higher) statistical software (Cary, NC).

20.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

N/A

21.0 Vulnerable Populations

N/A

22.0 Community-Based Participatory Research

The design of this feasibility study was informed by our findings from a prior project, Virtual Rural Oncology Community (V-ROC). V-ROC is a PCORI-funded study (Eugene Washington PCORI Engagement Award Contract # 2481- Rochester) that aims to engage all stakeholders involved with rural cancer care in an effective and transparent process of decision making to achieve better outcomes for this hard-to-reach population. The stakeholders include rural cancer patients, their caregivers, county public health departments, community organizations and services, and a wide spectrum of healthcare providers. Prior work on this project provided preliminary data on feasibility of recruitment of rural cancer survivors and informed our understanding of unmet needs and barriers to survivorship care in rural cancer survivors. For instance, a large proportion of

elderly rural patients have limited experience using the internet and electronic devices and are also uncomfortable using technology in healthcare. Based on this evidence, we decided against using a PDA or an online PSST modality and made the first PSST session face-to-face, to be delivered by the research assistant at the hospital or clinic or patient's home.

23.0 Sharing of Results with Subjects

Only aggregate results (enrollment and drop-out rate, average time to recruit a subject and to complete study evaluation) from this study will be shared with participating providers to appreciate their time and effort, assist with data interpretation, to ensure data validity and build partnership to facilitate enrollment in the subsequent multicenter pragmatic RCT study.

24.0 Setting

This study will take place at three different settings, a hospital affiliated cancer center (Wilmot Cancer Institute (WCI), Rochester, NY), a free standing NCI-designated cancer center (Roswell Park Cancer Institute (RPCI), Buffalo, NY) and a rural community oncology clinic (Myers Cancer Center, Dansville, NY) affiliated with WCI. The survivorship program coordinator (WCI - patients at all locations) and clinic nurse manager (RPCI patients) together with RAs will identify adult cancer patients who have completed adjuvant treatment for stage I-III cancer and who are eligible for survivorship consultation. Two weeks before the scheduled survivorship appointment, the survivorship nurse/clinic nurse manager will send the patient a study letter followed by a phone call, telling them about the study goals and procedures (e.g., duration of assessment and frequency of follow-up) and inviting them to participate. Patients who express interest will meet with the study RA in the location of their choice (hospital, clinic or patient home).

25.0 Provisions to Protect the Privacy Interests of Subjects

Only study coordinators and RAs will know the identity of the patients. Once the data are collected (from patient EHR and study instruments) and inputted into REDCap database, each patients will be refereed to only by their study ID. The study participation can be discontinued at any time and patients may decline to answer any questions they find upsetting.

The subjects will be initially approached by their clinic staff to inform them about the study. Only subjects who expressed interest in the study will be then contacted by the study team. All members of the subject's clinical team will receive information about the study and will be qualified to discuss with the study subjects their questions/concerns. The study participation can be discontinued at any time and patients may decline to answer any questions they find upsetting. The study RAs are certified therapists and are qualified to handle patient distress or refer them to mental health providers as appropriate.

Only study coordinators and RAs will be allowed to access information about the subjects in the EHR system for the purpose of confirming subject eligibility, abstracting their medical history and scheduling the first meeting with the therapist. The de-identified study data will be accessed only from a UB or Roswell Park secure password protected computer by pre-identified and appropriately trained faculty and staff.

26.0 Resources Available

Ekaterina (Katia) Noyes, PhD, MPH, Contact MPI

Katia Noyes, PhD, MPH is Professor and Director, Division of Health Services Policy and Practice, Department of Epidemiology and Environmental Health, at the School of Public Health and Health Professions of The State University of New York at Buffalo (UB). She is also Adjunct Professor of Oncology at Roswell Park Cancer Institute (RPCI) in Buffalo, NY.

DUTIES FOR THIS PROJECT: Dr. Noyes will serve as the contact MPI on this project. In this capacity she will be responsible for general administration of the project and for overseeing all aspects of data collection, including development, completion and integrity of the REDCap database, personnel management, team meetings and communication, coding development, data analysis and findings dissemination. Dr. Noyes has collaborated extensively with all investigators and personnel on this project.

BACKGROUND and EXPERIENCE: Dr. Noyes is a health services researcher with expertise in outcomes and comparative effectiveness research, economic assessment in healthcare and quality of care evaluation. The breadth of her scholarly productivity attests to her capacity to work in interdisciplinary teams and collaborate with researchers from diverse backgrounds. She has received funding from the National Institute of Health, Robert Wood Johnson Foundation, Agency for Healthcare Research and Quality, Patient Centered Outcomes Research Institute (PCORI), National Multiple Sclerosis Society and a variety of other public and private sources. Dr. Noyes has been involved in and led studies on evaluation of quality of life, cost and quality of long-term interventions, including outcomes and cost-effectiveness of treatment for colorectal, bladder and breast cancers, use of colonoscopy in Medicare patients living in rural areas, effect of frailty on Medicare costs, among others. She has conducted several studies using the SEER registry, National Surgical Quality Improvement Project (NSQIP) database, NYS hospital discharge abstract data (SPARCS), and Medicare administrative data. She is also familiar with methodological advances and limitations associated with using these data for research. She recently has spent 6 months in the UK, Canada and the leading US surgical outcomes and quality assessment centers learning state-of-the-art strategies and approaches for multidisciplinary oncology care.

Since 2012, the core of this project team has performed an extensive analysis of cancer patient medical records, hospital discharge summaries, tumor registries and insurance claims data, and cancer stakeholders' focus groups and interviews. The team has demonstrated that rural patients and minorities experience significant deficiencies in cancer care provided in rural communities (including poor adherence to national cancer care guidelines, lack of high-quality providers and higher medical costs). The team works closely with the URMC Regional Telemedicine Group and ECHO (Extension for Community Healthcare Outcomes) consortium and has extensive experience conducting tele- and video conferences and training for cancer patients, caregivers, and providers. PCORI funding (Eugene Washington PCORI Engagement Award Contract # 2481- Rochester) was used to develop a region-wide stakeholder network, "Virtual Rural Oncology Community" (V-ROC), led by Dr. Noyes, to facilitate stakeholder involvement in patient-centered outcomes, comparative effectiveness and health services research which could ultimately promote better decisions about regional cancer care delivery, improve the quality of regional cancer care, and reduce health inequalities between rural and urban communities. This experience guided the plan for patient recruitment strategy and choice of study design and outcomes.

Gregory Wilding, PhD, Co-Investigator, Biostatistics

Dr. Wilding is the recently named Chair of the Department of Biostatistics at UB, after having served as the Interim Chair for over a year. He is also Director of the Epidemiology and Research Design Core of the Buffalo Clinical and Translational Research Center, and Professor of Oncology in the Department of Biostatistics and Bioinformatics, at Roswell Park Cancer Institute. He is skilled in a vast array of statistical analysis techniques and computer programming languages. His bio statistical interests are in the areas of clinical trials, computationally intensive methods, and tests for and measures of independence.

DUTIES FOR THIS PROJECT: Dr. Wilding will oversee the direct randomization as well as the work of the data analyst and work closely with the study PI and the RAs to develop the REDCap data collection forms as well as the optimal risk-adjusted approach for data analysis given the limited power of the pilot study. Dr. Wilding will also be the project's liaison with the Department of Biostatistics and RPCI.

Other Personnel:

Jing Nie, PhD, Programmer/Data Analyst

Dr. Nie is Research Assistant Professor in the Department of Epidemiology and Environmental Health at UB and has worked in this capacity for eleven years. He has expertise in data management, programming and epidemiologic studies, and has been involved with data management and analysis from a diverse portfolio of research studies (e.g., New York State Angler Cohort Study, Alcohol studies, Western New York Exposures and Breast Cancer (WEB) Study, Atherosclerosis Risk in Communities (ARIC) Study, and Women's Health Initiative (WHI)). He has advanced training in epidemiologic methods, statistics and statistical programming using SAS.

DUTIES FOR THIS PROJECT: Dr. Nie will work closely with Drs. Noyes and Wilding and the RAs to oversee data quality and management, create and manage data entry screens, and conduct analyses for the outlined specific aims, and any subsequent presentations and publications.

Consultants:

Demetria McNeal, PhD, Dissemination Scientist Consultant

Dr. McNeal is a dissemination science expert who has worked extensively with Dr. Sahler on R25 CA183725 (Sahler & Noll, MPI) evaluating the reach of a project to train psychosocial oncology health care professionals in the use of the Bright IDEAS paradigm of problem-solving skills training (PSST) in clinical practice. The R25 project represents an intermediate step in the dissemination of Bright IDEAS and will serve as the template for evaluating the dissemination potential of Bright IDEAS for adult cancer survivors, especially in rural settings.

DUTIES FOR THIS PROJECT: During the time of the study recruitment, intervention and patient self-assessment, Dr. McNeal will conduct in-depth semi-structured interviews to explore the viewpoints of participating stakeholders in diverse clinical settings (including patients, caregivers, clinic staff and administration) regarding how the intervention design, the external environment and infrastructure influence program adoption. She will conduct five 1-hour interviews each year, which will be professionally transcribed (60 minutes/interview x 5 interviews x $0.02/min = $600/year, Years 01 and 02). Together with the rest of the study team, Dr. McNeal will analyze the interview data to inform any changes to the study design or planning of subsequent multisite trial.

Steven Nurkin, MD, MS, FACS, Consultant

Dr. Nurkin is a fellowship-trained surgical oncologist who specializes in gastrointestinal precancerous conditions and cancers of the entire GI tract, with a focus in colon, appendix, rectum, and anus. His clinical research interests focus on improving the outcomes and quality of care in patients with cancer. He is a Quality Leader at Roswell Park Cancer Institute and spearheaded the implementation of Enhance Recovery After Surgery (ERAS) at RPCI. Dr. Nurkin is a panel member for the National Comprehensive Cancer Network and helps develop national guidelines for the management of these diseases.

DUTIES FOR THIS PROJECT: Dr. Nurkin will serve as the clinical expert on colorectal cancer, and as a liaison to the local, regional, and national CRC resources and expertise, including late treatment effect and surgical side effect management. Together with his clinical staff, they will recruit 2 patients per month over the 10-month recruitment period. They will introduce the study and link interested patients to the project RAs.

Tessa Flores, MD, Consultant

Dr. Flores is a fellowship-trained staff physician in Medical Oncology at Roswell Park Cancer Institute (RPCI) in Buffalo, NY, who specializes in breast cancers. Her clinical research interests focus on improving the outcomes and quality of care in patients with cancer. She is the Medical Director of the RPCI Screening and Survivorship Clinic.

DUTIES FOR THIS PROJECT: Dr. Flores will serve as the clinical expert on breast cancer, and as a liaison to the local, regional, and national CRC resources and expertise, including late treatment effect and surgical side effect management.

SUBAWARD: The State University at Buffalo will establish a subaward agreement with the University of Rochester (UR), a domestic institution, which will include both personnel and other direct costs. Dr. OJ Sahler at UR will serve as MPI and will be the lead investigator in revising Bright IDEAS training materials for the particular population of colorectal cancer survivors and their supportive others, training the research assistants in providing the intervention, supervising the research assistants on a weekly basis, and performing treatment integrity audits on a random sample of audiotapes, which will be obtained for every intervention session. The following personnel will appear in the UR subaward:

- Olle Jane Z. Sahler, MD (MPI)
- Patricia Bellohusen, RN (Co-Investigator)
- Louis Constine, MD (Co-Investigator)
- Fergal Fleming, MD (Co-Investigator)
- Barbara Schuman (Project Assistant)
- TBN Research Assistants (2)

Olle Jane Sahler, MD (Multiple PI and Subaward PI)

Dr. Sahler is Professor of Pediatrics, Psychiatry, Medical Humanities, and Oncology at the University of Rochester.

DUTIES FOR THIS PROJECT: (A) Adaptation of the Bright IDEAS intervention materials for use in the colorectal cancer survivor population (B) Research assistant training in the intervention: The Bright IDEAS PSST intervention will be delivered by specially trained research assistants (RAs) with background in nursing, behavioral health, or social work (see letter of support from

Warner School of Education). Dr. Sahler will use a training protocol she previously developed for her earlier studies (NCI R01 CA 159013: Online problem-solving skills training for mothers of childhood cancer patients; R25CA183725: Problem-solving skills training for clinicians providing psychosocial care in pediatric oncology). The protocol includes a 1.5 day training and follow-up case supervision in Problem Solving Skills Training (PSST). We will update the previously developed Bright IDEAS training materials and manuals to reflect the unique needs and problems of the study population (patients with colorectal cancer). Dr. Sahler will facilitate role playing exercises for RAs which will be conducted as a means of training and provide feedback on the RAs training and counseling skills. (C) Treatment Integrity Oversight: To assure treatment integrity (TI), every session will be audiotaped, identified only by subject code, and uploaded to a secure site maintained by the data management center. 20% of the PSST tapes (40 tapes) will be chosen at random for review by Dr. Sahler according to a checklist of content items and personal responses that have been used for prior projects. Feedback about any TI concerns will be delivered during supervision sessions with the study RAs. (D) Participate in developing the assessment battery of onco-behavioral outcomes. (E) Participate in data analysis, interpretation, and presentation/publication. Dr. Sahler will work closely with the study team to develop tools to optimize assessment of psychosocial distress in cancer survivors and capture changes in their emotional state over time.

BACKGROUND and EXPERIENCE: Dr. Sahler is a Behavioral Pediatrician and has specialized in the care of chronically and terminally ill children and adolescents for more than 40 years, with special emphasis on children with cancer. She has been the Director of Pediatric Psychosocial Oncology Services and Research at Golisano Children's Hospital of Rochester for 20 years and medical director of the Childhood Cancer Long-Term Survivors Program for 11 years. Over the last 22 years, Dr. Sahler has been sole PI on 4 multisite NCI-funded RCT studies of the Bright IDEAS PSST intervention and contact Co-PI on 1 NCI funded R25 focused on the development, evaluation, implementation, and dissemination of Bright IDEAS --- including face-to-face, telephone-based, and web-based versions --- and training 200 healthcare professionals in delivering the intervention. These experiences and expertise uniquely qualify her for this proposed project

Louis S. Constine, MD, Co-Investigator

Dr. Constine is Professor of Radiation Oncology and Pediatrics and Vice Chair of the Department of Radiation Oncology, and was awarded fellowship in his professional society, The American Society of Radiation Oncology. His clinical and scientific expertise is in lymphomas, sarcomas, all pediatric malignancies, and the broad area of Survivorship that includes the acute and chronic effects of chemotherapy and radiation therapy on normal tissues. He is the Director of the Judy DiMarzo Survivorship Program at the Wilmot Cancer Institute. He is a member or a leader of the core committees for the Children's Oncology Group Survivorship Guidelines, the International Survivorship Harmonization Guidelines, the American Society of Clinical Oncology Survivorship Advisory Group, and the Pediatric Quantitative Analysis of Normal Tissue Effects in the Clinic ASTRO/AAPM initiative, among others. He is recipient of the NIH Merit Award in 2010. He has authored (co-authored) more than 50 book chapters, eight books and 175 original and invited reports.

DUTIES FOR THIS PROJECT: Dr. Constine will serve as the Clinical Survivorship Lead on this project to facilitate institutional and regional partnerships with clinicians and institutions providing

care for cancer survivors. He will also be involved in results interpretation and preparation of the future multi-site clinical trial.

Fergal J. Fleming, MB BCh BAO, MD, FRCS Co-Investigator

Dr. Fleming is a colorectal surgeon and an Assistant Professor of Surgery and Oncology with a research interest and expertise in the field of surgical outcomes research with over 50 peer reviewed publications in this arena. He is particularly interested in exploring factors associated with poor perioperative outcomes following colorectal cancer surgery. In addition to acting as the Quality Improvement (QI) liaison for the Division of Colorectal Surgery, he is also a project lead with Upstate New York Surgical Quality Improvement Program (UNYSQI). UNYSQI is a collaborative of 15 hospitals in Upstate New York engaged in QI projects for patients undergoing colorectal surgery. UNYSQI would offer a wonderful vehicle to test the efficacy of the intensive smoking cessation program, should the pilot program demonstrate it to be feasible.

DUTIES FOR THIS PROJECT: Dr. Fleming will serve as the clinical expert on colorectal cancer, and as a liaison to the local, regional, and national CRC resources and expertise, including late treatment effect and surgical side effect management. He is very excited about being a part of this study and exploring the possibility of improving patient adherence to survivorship care plans and improving their self-management skills by using PSST.

Thomas Frye, DO, Co-Investigator

Dr. Frye is Assistant Professor of Urology and a Urologic Oncologist who specializes in minimally invasive urologic oncology (robotic surgery of bladder, prostate, and kidney cancers), advanced open pelvic and retroperitoneal cancer surgery, and detection and management of localized prostate cancer with magnetic resonance imaging (MRI). Dr. Frye is one of only a few providers in the United States who offers High Intensity Focused Ultrasound (HIFU) - personalized treatment of prostate cancer. Dr. Frye is the Chair of GU tumor board at Wilmot Cancer Institute and is responsible for GU service line operations, including survivorship consultations and referrals.

DUTIES FOR THIS PROJECT: Dr. Frye will serve as the clinical expert on bladder and prostate cancers, and as a liaison to the local, regional, and national GI resources and expertise, including late treatment effect and surgical side effect management. He is committed to providing high quality of care to patients with GU malignancies and improving their self-management skills by using PSST.

Patricia Bellohusen, RN, Co-Investigator

Ms. Bellohusen is clinical nurse coordinator for the Judy DiMarzo Cancer Survivorship Program at Wilmot Cancer Institute. As the Survivorship Program Coordinator, Ms. Bellohusen collaborates with all the various disease clinics in the areas of cancer survivorship, institutionally and in the region. She provides leadership in the clinical management of survivors. She also assists in the development and implementation of educational resources for survivorship care. She has experience and expertise in many areas of oncology and survivorship care including clinical guidelines implementation, clinical pathway and documentation development, EHR, caregiver involvement, and patient reported outcomes.

DUTIES FOR THIS PROJECT: On this project, Ms. Bellohusen will work with the study PIs and RAs and serve as the Lead Liaison between cancer survivorship services, cancer service lines,

social services and community providers to help identify eligible patients and facilitate recruitment.

Other Personnel:

TBA, 2 Research Assistants

The RAs will be Master's level mental health professionals or doctoral candidates in psychology who have completed at least 2 years of study in a counseling-related field (e.g. clinical psychology or counseling) or have equivalent experience (see letter of support from Warner School of Education).

DUTIES FOR THIS PROJECT: The Research Assistants will be responsible for patient recruitment, training and evaluation. Their careful attention to detail and ability to constructively critique issues related to implementation of both forms of PSST will provide useful information about how PSST can eventually be delivered in real-life situations at centers with modest psychological resources. The RA training will occur at a 1-day workshop before the start of patient enrollment. We have conducted 4 similar workshops in support of previous PSST projects, resulting in standardized training and enhanced RA understanding of and commitment to the project. RAs will be supervised by Dr. Sahler in weekly 2-hour supervision sessions. The RAs will also distribute the study materials (training guide and evaluation forms) to the study participants, provide instructions, will be available to answer any questions the patients or caregivers may have, collect completed patient evaluation forms, and input data into the REDCap database. Together with the study PIs, the RAs will analyze qualitative data to identify trends of patient learning and problem-solving patterns in order to evaluate program effectiveness in meeting patient needs. For a given study participant, one RA will recruit, assess at time T0 and provide all instruction/support for the intervention. The opposite RA will be responsible for collecting T1 and T2 assessment materials. This procedure is designed to reduce respondent bias due to his/her relationship with the interventionist.

Barbara Schuman, Project Assistant

Ms. Schuman has provided project related clerical support for Bright IDEAS interventions for more than 10 years. She will develop and revise study related printed materials, prepare assessment batteries, design and order project-specific supplies, and process reports for publication and presentation.

FACILITIES

THE STATE UNIVERSITY OF NEW YORK (SUNY) AT BUFFALO is New York State's premier public center for graduate and professional education, as well as the State University of New York's (SUNY's) largest and most comprehensive public university. A member of the Association of American Universities (AAU), the University at Buffalo stands in the first rank among the nation's research-intensive public universities. With strengths in medicine, engineering and computer science, and public health, the university offers outstanding resources for multi-disciplinary research and education.

The history of the University at Buffalo's **School of Public Health and Health Professions** (SPHHP) dates back to Oct. 14, 1965, when the School of Health Related Professions (HRP) was created by order of the Trustees of the State University of New York. Albert C. Rekate, MD. The next year, UB recruited J. Warren Perry from the Vocational Rehabilitation Administration in Washington, D.C., where he had helped shape the 1966 Allied Health Professions Training Act.

Perry moved quickly to unify programs in physical therapy, occupational therapy and medical technology, all previously housed in the medical school. When HRP was formally dedicated in 1967, it was the first of its kind in New York and one of the first in the nation.

Since its beginning, SPHHP put a strong emphasis on multidisciplinary cross-institutional research and education on the crucial public health issues facing the United States and other countries. The SPHHP has full accreditation from the Council of Education for Public Health (CEPH). The school's goal is to create an environment in which researchers, educators, public health and other health professionals, and students can work together to explore problems and produce innovative solutions to address emerging health needs for populations and individuals. The school currently has five departments (Biostatistics, Health Behavior, Exercise and Nutrition Sciences, Rehabilitation Sciences and Epidemiology and Environmental Health) offering undergraduate and graduate degree programs.

The School occupies approximately 101,000 square feet of university space assigned to the Dean's office, its five departments and research centers. Currently, the majority of faculty offices are located in two buildings (Kimball Tower and Farber Hall) that are in close proximity to each other on the University at Buffalo's South Campus.

Department of Epidemiology & Environmental Health (EEH) has a long tradition of research focused on population health and cancer. UB courses in public health, hygiene, sanitation and disease prevention date back to the late 1800s. Our department was formally established in 1919 as the Department of Hygiene and Public Health. Over the years, the name changed to Preventive Medicine and Public Health in 1946, to Social and Preventive Medicine in 1967 and in 2014, the department became the Department of Epidemiology and Environmental Health. Many distinguished researchers contributed to the legacy of EEH, including the late Saxon Graham, PhD, one of the fathers of U.S. chronic disease epidemiology and among the first researchers to focus on links between diet and the etiology and prevention of cancer and James R. Marshall, PhD, senior vice president for cancer prevention and population sciences and chair of the Department of Cancer Prevention and Population Sciences at Roswell Park Cancer Institute.

Extensive facilities are available for all stages of epidemiologic and outcomes research: interviewee ascertainment, clinical space for the conducting of interviews and specimen collection, facilities for data entry and storage, data processing and for data analysis. Also available are a plotter for printing of posters for research presentations, color laser printer and multimedia projectors. All major software packages are supported either by the university or by the department including SAS®, SPSS®, SPlus, Sudaan®, ARCGIS, Epi-Info™, NCSS, STATA, StatExact, LogExact, MINITAB, and nQuery. Numerous data base management systems are also available including Access and dBase.

ROSWELL PARK CANCER INSTITUTE (RPCI): Founded in 1898, Roswell Park Cancer Institute was the first institution in the world to focus exclusively on cancer research. It grew from the vision of Dr. Roswell Park, an eminent surgeon who accurately predicted that cancer would become a leading cause of death both in the United States and worldwide. The RPCI campus, spread out in 15 separate buildings of approximately two million square feet, occupies 28 acres (11 ha) on the 100-acre (40 ha) Buffalo Niagara Medical Campus (BNMC) in downtown Buffalo, and includes 1,500,000 square feet (140,000 m^2) of space equally distributed between clinical programs and research/education functions. A separate hospital building, completed in 1998, houses a diagnostic and treatment center. The campus also includes a medical research complex

as well as research and education focused space. Research enterprise at RPCI encompasses more than 500 research studies that bring over $100 million in grant funding.

RPCI is ranked among the nation's top cancer hospitals by U.S. News & World Report, designated as Leapfrog Group Top Hospital, and received Quality Oncology Practice Initiative (QOPI) Certification from the American Society of Clinical Oncology (ASCO). RPCI has over 3,000 employees, including 308 faculty members and 606 nurses. RPCI hospital has 133 licensed inpatient beds, provides over 200,000 outpatient visits a year and more than 4,000 surgical procedures providing active care to more than 30,000 patients at any time.

Interdisciplinary collaboration and education are essential parts of the experience of working and training at Roswell Park Cancer Institute. Both internal and external experts regularly present their latest research, opening up opportunities for learning and collaboration. A sample of these activities across the Institute include:

- Weekly Population Sciences, Medical and Surgical Grand Rounds presentations
- Tumor Immunology & Immunotherapy outside speaker series
- Cancer Genetics External Seminar Series
- Shashikant Lele Lectureship in Gynecologic Oncology
- Cancer Prevention and Control weekly Works-in-Progress and Journal Review Group meetings
- Disease Site Research Groups (DSRGs): Interdisciplinary groups dedicated to organ site-specific translational research, clinical research, and the promotion of team science. DSRGs include those dedicated to Breast, GI, STM/Dermatology, Thoracic, Gynecologic, Head & Neck, Genitourinary, Hem/Onc, and Bone Marrow/Hematopoietic Microenvironment.

The **Department of Cancer Prevention and Control**, chaired by Christine Ambrosone, PhD, includes research that spans the cancer continuum, from understanding the causes of cancer for prevention and targeting of high risk populations, to identification of markers for early detection and diagnosis, and to understand and prevent factors that impact morbidity and mortality associated with cancer diagnosis and treatment. Dr. Noyes is Adjunct Professor in this Department.

The **Department of Health Behavior** at Roswell Park Cancer Institute is focused on understanding all areas of tobacco control. This includes research into the components of tobacco products, documenting and understanding tobacco marketing, and influencing and assessing the impact of tobacco control policies regionally and nationally. Tobacco use remains the leading cause of preventable disease across all population groups, including cancer survivors. The Department of Health Behavior houses the Tobacco Cessation Services and Nicotine and Tobacco Product Assessment Resource (NicoTAR) which provides instrumentation and services to investigators requiring nicotine and tobacco product assessment for their research projects.

In January 2017, RPCI established the comprehensive multidisciplinary cancer Survivorship Program and the Supportive Care Clinical Center (Director: Mary Reid, PhD, Care Coordinator: Karen Larkin, NP). The center coordinates services provided by a multidisciplinary team of RPCI and community providers to improve quality of life and long-term outcomes of cancer survivors in the Buffalo region.

UNIVERSITY OF ROCHESTER MEDICAL CENTER (URMC): The URMC serves over 1,000,000 patients annually in Greater Rochester and surrounding communities through its Strong Memorial, Golisano Children's, and Highland Hospitals; James P. Wilmot Cancer Institute; Eastman Institute for Oral Health; Visiting Nurse Service of Rochester; regional affiliates; two long-term care facilities; and numerous primary care and specialty offices. This network is anchored by Strong—the University's 800-bed teaching hospital, which consistently ranks among "America's Best Hospitals" (US News & World Report). The URMC also houses the School of Medicine Dentistry (SMD), the School of Nursing, and the Aab Cardiovascular Research Institute. The excellence of these programs is reflected in their ability to attract substantial external funding. Over the past five years, the SMD has received almost $1.3 billion in research grants. The University is the Rochester area's largest employer and a primary economic driver for our region.

The URMC has a truly distinguished history of clinical innovation and community partnership with highest commitment to clinician education, patient- and family-centered care, and population health. This history dates back to Abraham Flexner's 1910 national report on medical schools, which proposed linking medical schools to universities and requiring stricter standards in the training of medical students. Those recommendations undergirded the mission of the UR School of Medicine when it opened in 1925 with crucial support from philanthropist George Eastman. The SMD quickly became a national leader in biomedical research and patient care under its first dean, Nobel laureate Dr. George Whipple.

Strong Memorial Hospital is an 800-bed tertiary care facility, which serves as the primary teaching hospital for the University. It is the only upstate New York hospital to be selected as one of the "100 Best Hospitals" in the US. Strong provides primary, secondary, and tertiary care to over 1 million people in the 16-county service area. In that same area, the University of Rochester Medical Center (URMC) has approximately 50% cancer market share and is the largest single provider. Moreover, in the largest population center of this region, Monroe County, URMC has 60 – 70% of all Cancer discharges. Highland Hospital is a fully affiliated community hospital, with focused strengths in geriatric oncology, sarcomas and bone oncology, gynecologic oncology, and breast cancer. Medical research initiatives, including clinical trials, are a cornerstone of the University of Rochester School of Medicine.

The URMC has always had a strong commitment to community health. When George Eastman pledged his financial support to the URMC in 1920, it was with the proviso that the URMC "make Rochester one of the healthiest communities in the world." Since then, our varied URMC departments and centers have independently integrated community health across their education, patient care, and research platforms. We are the birthplace of the biopsychosocial model of care, as of numerous other clinical, community, and provider training innovations - including in fields of general pediatrics, nursing education, school-based dentistry, patient-centered care, and many more. In 2004, in evidence of the URMC's commitment to community health, the Association of American Medical Colleges awarded the UR SMD its prestigious Outstanding Community Service Award. In 2006, the Center for Community Health was established to further advance the URMC's community health mission.

National, regional, and local philanthropy are critical in enabling the URMC to meet its mission for community health. Over the past decade, grants from the Greater Rochester Health Foundation have supported the launch and demonstration of novel community health programs, including projects for hypertension, depression, stroke, diabetic retinopathy, and other serious illnesses. These projects have significantly targeted underserved, low-income, and minority populations,

thereby expanding and enhancing the URMC's and our larger community's capacity to address and redress the problem of ongoing health disparities.

Aside from internal partnerships with URMC centers, the project team has established regional and international collaborations with community providers, including with the Upstate New York Surgical Quality Initiative (UNYSQI)—a network of 16 hospitals committed to improve the quality of care for upstate surgical patients through evidence-based, focused, and measurable best practice efforts. All UNYSQI members are part of the National Surgical Quality Improvement Project (NSQIP) supported by the American College of Surgeons (ACS). Additional information about the participating community primary care practices is provided in each practice's Letter of Collaboration.

27.0 Prior Approvals

N/A

28.0 Compensation for Research-Related Injury

N/A

29.0 Economic Burden to Subjects

We budget $100 incentive for each patient ($5,000 total) in the form of VISA gift cards to facilitate patient recruitment, completion and return of the study evaluation forms and data collection. Patients will receive $25 for completing the baseline assessment, another $25 for completing 3-month assessment and $50 for completing the close-out assessment at about 6 months (including semi-structured interviews). Each supportive other will receive $25 gift card for each returned evaluation form. Transportation/parking costs and cost of therapy will be covered by the study.

30.0 Consent Process

The survivorship program coordinator (WCI - patients at all locations) and colorectal clinic nurse manager (RPCI patients) together with the study RAs will identify adult cancer patients who have completed adjuvant treatment for stage I-III cancer and who are eligible for survivorship consultation. Two weeks before the scheduled survivorship appointment, the survivorship nurse/clinic nurse manager will send the patient a study letter followed by a phone call, telling them about the study goals and procedures (e.g., duration of assessment and frequency of follow-up) and inviting them to participate. Patients who express interest will meet with the study RA in the location of their choice (hospital, clinic or patient home). To determine patient eligibility, patients will be screened for cancer-related distress using the NCCN Distress Thermometer (Appendix 4). Patients who are experiencing psychological distress (NCCN Distress >2 cut-off has 100% sensitivity, PROMIS Anxiety >50 or any other clinical measure of mild distress),[42] and who meet the study's other inclusion and exclusion criteria (see below) will be invited to participate (*patient with the distress level 4 or greater will be referred to therapy*). If a person is willing to continue the screening process by providing written informed consent, he or she will then be asked to complete their baseline evaluation consisting of a battery of self-report measures (Table 2). The cancer patient will also be asked to identify a Supportive Other (SO) who might serve as a problem-solving partner and will undergo the same consent process. Caregivers will be

provided with an information sheet describing the research study and their involvement and verbal consent to participate will be sought.

Non-English-Speaking Subjects

Because of the budget constraints (this study is funded by NIH R21 mechanism with budget cap of $275K for 2 years) only English-speaking subjects will be eligible for this pilot study.

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

Since the study is focused on adults with distress and socio-economic disadvantage and this is a minimal risk study, we choose to use a short consent and study information format.

Subjects who are not yet adults (infants, children, teenagers)

N/A

Cognitively Impaired Adults

Because the intervention is a cognitive-behavior therapy, patients who have a prior diagnosis of cognitive problems (as documented in EHR) will be excluded from the study.

Adults Unable to Consent

Same as above

31.0 Process to Document Consent in Writing

Eligible patients will initially be contacted by the survivorship nurse/clinic nurse manager who will send the patient a study letter followed by a phone call, telling them about the study goals and procedures (e.g., duration of assessment and frequency of follow-up) and inviting them to participate. Patients who express interest will meet with the study RA in the location of their choice (hospital, clinic or patient home). The RA will introduce the study, provide a copy of the consent document and answer any questions. After signing the consent, patients will receive a copy of the document.

32.0 Drugs or Devices

32.1

Drugs will not be supplied by the study.

33.0 REFERENCES

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34.0 APPENDICES/SUPPLEMENTS