Recovery Support for Bladder Cancer Patients and Caregivers: A Multimodal Approach
NCT04055311
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Version Date: 7/11/2025

RESEARCH PROTOCOL

Protocol Title:	Recovery Support for Bladder CA Patients and Caregivers: A Multimodal Approach
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Guidelines for Preparing a Research Protocol

Instructions:

- You do not need to complete this document if you are submitting an *Application for Exemption* or *Application for a Chart Review*.
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1. PREVIOUS STUDY HISTORY

Has this study ever been reviewed and rejected/disapproved by another IRB prior to submission to this IRB?

☒ No ☐ Yes – if yes, please explain: [ ]

2. BRIEF SUMMARY OF RESEARCH

- *The summary should be written in language intelligible to a moderately educated, non-scientific layperson.*
- *It should contain a clear statement of the rationale and hypothesis of your study, a concise description of the methodology, with an emphasis on what will happen to the subjects, and a discussion of the results.*
- *This section should be ½ page*

Treatment for certain types of bladder cancer (BC) involves the removal of the bladder and construction of a new voiding system and is physically and psychologically profoundly challenging for patients and caregivers. Based on our published literature and extensive pilot data, patients and caregivers have extensive unmet informational, social, psychological, instrumental, and medical needs from the time of diagnosis, through treatment and recovery which are not adequately addressed by health care professionals.

We propose to address these unmet needs through the refinement and evaluation of a comprehensive, 2-part (in-person and web-based) intervention, geared towards the patient and caregiver. Specifically, during Aim 1, the formative phase, we propose to further refine our newly developed intervention components with the help of an established patient/caregiver advisory board. The intervention, Recovery Support for Bladder Cancer (RSBC), consists of a pre-treatment, in-person preparatory instructional session with a trained health care professional (Module 1) to equip patients and caregivers with the skills to adjust to the upcoming treatment and recovery period. This is followed by a post-treatment, interactive web-based program (Module 2) to provide further support for both patients and caregivers to enhance quality of life (QOL) and reduce infections and nurse/ER visits. The RSBC intervention will be evaluated in a 12-month randomized controlled trial (Aim 2) among patients and caregivers (N=287 participants; 238 final sample) against a time and attention comparison condition that incorporates modules focusing on wellness. Primary outcomes for both patients and caregivers will be improved QOL, which is hypothesized to be significantly higher among participants randomized into RSBC. Secondary outcomes will be fewer infections and nurse-ER visits for patients randomized into RSBC. Aim 3 proposes moderator (i.e., age, gender, surgical diversion type) and mediator (i.e., patient activation, distress) analyses of intervention efficacy. We hypothesize that RSBC will be significantly more successful among (a) older, (b) female participants, and (c) patients with a conduit diversion type. Elevated levels of patient activation (i.e., higher self-care knowledge, self-efficacy, lower distress) will mediate the intervention effects. Exploratory Aim 4 will examine the costs and potential savings

associated with developing and implementing the RSBC intervention. We hypothesize that initial development and implementation costs of RSBC will be offset by reduced nurse/ER visits.

The scientific premise is strong and supported by an established theoretical framework, extensive pilot data and a rigorous application of clinical research methods. The proposed study is highly innovative, as it comprehensively addresses unmet needs of both patients and caregivers from pre- and (immediate) post-treatment to recovery. This is achieved through an innovative combination of in-person preparation and skill-building and web-based technology. If successful, RSBC has the potential to significantly change clinical care for patients and caregivers with BC.

3. INTRODUCTION/BACKGROUND MATERIAL/PRELIMINARY STUDIES AND SIGNIFICANCE

- *Describe and provide the results of previous work by yourself or others, including animal studies, laboratory studies, pilot studies, pre-clinical and/or clinical studies involving the compound or device to be studied.*
- *Include information as to why you are conducting the study and how the study differs from what has been previously researched, including what the knowledge gaps are.*
- *Describe the importance of the knowledge expected to result*

More than 70,000 Americans will be diagnosed with bladder cancer (BC) in 2017, leading to more than 16,000 deaths. BC is most likely to develop in older, White men and individuals with a history of smoking.[1] Because BC tumors are asymptomatic in the beginning stages of development, diagnosis is usually delayed until more advanced stages of the disease have developed. Standard of care for muscle invasive bladder cancer (MIBC) and certain cases of non-muscle invasive bladder cancer (NMIBC), involves the surgical removal of the bladder with or without neoadjuvant chemotherapy. As part of the bladder removal, the surgical team constructs a new diversion method and urinary reservoir. Depending on clinical factors and patient preferences, there are three possible urinary diversion methods: (a) ileal conduit, which involves the construction of a stoma from intestinal tissue and the placement of an external bag to hold urine; (b) Indiana pouch, which involves the construction of a stoma and internal reservoir from intestinal tissue that is emptied through self-catheterization; and (c) neobladder, in which an artificial bladder is fashioned from intestinal tissue. A majority of patients experience significantly elevated rates of depression and anxiety and significant declines in quality of life (QOL) following treatment.[2,3] QOL is generally compromised with patients reporting significant declines in the areas of physical, social, and emotional well-being.[4,5] Elevated levels of psychological distress (i.e., anxiety, depression) have been reported by as many as 70% of survivors and have been associated with frequent urinary incontinence as well as leakage, odors, and difficulties with standard activities of daily living (e.g., sleeping, dressing, socializing, traveling). Inconvenient stoma location and ineffectual self-care (e.g., care for one's stoma, in-ability to self-catheterize or empty one's neobladder) have

also been associated with elevated distress and severely compromised QOL.[6,7] Throughout the treatment and recovery period, patients and caregivers need to be involved in crucial aspects of patient care.[8-10] For example, prior to surgery, patients need to be consulted on optimal stoma placement by a stoma nurse and be informed about the surgical procedure and the immediate post-surgical recovery demands. Post-surgery, patients will need to learn how to live with an artificial exit, and the use and care of stoma appliances. Caregivers play a crucial role in supporting the patients in these self-care tasks.[11] In addition, patients who receive a neobladder need to learn to void with the Valsalva maneuver—a skill that is not mastered by every patient. Patients that do not master the Valsalva maneuver need to learn to self-catheterize to empty the bladder. Patients with a neobladder also frequently encounter nightly episodes of incontinence, thus further impacting patients and caregivers. Virtually all bladder cancer survivors and their caregivers need to cope with the prospect of a slow recovery, a diminished social life, reduced mobility, a changed body image and fears of recurrence.[4,5,12,13] Yet, few studies have addressed the needs of this underserved cancer population.

The literature suggests that family caregivers face a variety of burdens and unmet needs along each stage of the patient's treatment. Specifically, caregivers face burdens regarding access to care services and knowing when to contact the care team, dealing with emotional and psychological stress, managing normal daily activities (e.g., finances), communicating with the patient, knowledge on caregiver roles and illness expectations, and maintaining spirituality (e.g., hope for the future).[14] In addition, post-surgery care service visits (e.g., rehabilitation, visiting nurse appointments) are often coordinated by the caregiver.[13] Psychologically, caregivers must manage their own emotional distress often buffering their feelings as not to upset the patient. The unmet emotional caregiver burden is a strong predictor of poor mental health across all phases of survivorship.[15] Many caregivers face significant disruptions to their daily life when caring for their loved one. The majority of caregivers spend an average of 21 hours per week caring for the patient, which is the equivalent of adding a half-time job to their schedule.[16] Post-treatment training and education for BC caregivers is nonexistent, which means that post-operative care techniques are often learned by trial and error. The literature suggests that a caregiver-targeted intervention to provide support and education is essential to minimize caregiver burden and ultimately maximize patient QOL.[16-18] The goal of the proposed research is to fill this void in the literature by addressing the biopsychosocial consequences of BC surgical treatment in a patient- and caregiver-centered approach through the careful preparation of patients and their caregivers before treatment, as well as through post-treatment support. Our prior work (see D.2.)[4,13] has demonstrated that lack of time and hospital staffing constraints lead to less than optimal patient preparation. Pre-operative visits, conducted by the surgical staff, mainly focus on the upcoming surgical procedure, with less attention given to the complex psychosocial demands of recovery. Ideally, pre-operative care includes instruction from a stoma nurse to discuss stoma placement with patients based on their body type, clothing, and lifestyle preferences. However, this pre-operative counseling is not regularly performed, leaving the surgeon to make the decision about stoma placement without patient

input.[19] Furthermore, crucial post-operative recovery and management information is given to the patient shortly before discharge, a time when information processing is compromised by multiple discharge tasks, lack of privacy, and pain medication. Despite caregivers' crucial role in patient recovery, they are typically not included during discharge instructions.[4,13]

In addition, preparation mainly focuses on post-treatment-related medical issues and the clinical mechanics of recovery, paying less attention to the psychosocial aspects of BC and recovery. Finally, information processing is impacted by patient psychological and emotional factors (e.g., concerns and worries about fatigue, pain, future QOL), undermining the understanding and execution of necessary health promotion tasks, as suggested by the literature[20] and our prior work (see D.2.). Our pilot data[4,13] demonstrate the important role caregivers play in the recovery of patients, thus it is crucial that caregivers are included in all patient-directed communications and educational processes. In sum, the inclusion of caregivers in the provision of survivorship-related techniques and information is essential and should be accomplished prior to surgery treatment.

In the current application we are using two modes of information delivery: (a) a pre-treatment preparatory module (Module 1) conducted by a trained health care provider that focuses on preparing for post-surgical tasks and (b) a post-treatment web-based education and support program (Module 2) that provides information and support for patients and caregivers in the post-treatment phase. Our own research has shown that family caregivers provided a large majority of stoma support[30,31]. However, caregivers are often unprepared for this role, leading to increased patient complications as well as patient and caregiver distress. Routinely, patients are referred to a visiting nurse service to provide basic medical support during the immediate post-operative period. Our research found inconsistent and uneven support for bladder cancer patients after receiving a cystectomy, and no support for caregivers. Overall, patients perceive the support from visiting nurses as suboptimal; nurses lack sufficient knowledge of bladder cancer and its stoma appliances and were largely unavailable because of busy schedules. Thus, there is a clear need for timely on-demand information and support addressing critical areas of recovery (e.g., medical, psychosocial) at the convenience of the patient and their caregiver. Our combined in-person and web-based program, focusing on the patient and the caregiver, addresses this significant unmet need of this underserved population. Americans have become accustomed to receiving health information from the Internet. Most Internet users (72%) have looked online for health information within the past year.[21] Though many websites provide health information, such information is often inaccurate, sensational [e.g., "ten tips to improve (insert health problem here)"], and not tailored or targeted to specific conditions or populations. Yet, there are many advantages to developing and providing web-based solutions: (a) patients can consume the information at their own schedule, in a private place, and as often as they desire; (b) information sharing with caregivers; (c) information can be transmitted through multiple channels (personal computer, tablet, or phone); (d) content can be augmented through videos, graphics, testimonials, and interactive activities; (e) content can be

tailored to specific time-points in the recovery trajectory, treatment approaches, and targeted to specific groups; (f) access transcends geographical barriers; (g) patient recovery progress and trajectory can be tracked in real-time, allowing for immediate feedback. Overall, web-based patient education has been shown to be effective in increasing disease-related knowledge and improving health behaviors and self-management skills.[22-29] Based on that data and our experience in developing web-based software tools for health education (see D.2.d), we will augment our in-person instructions and preparations delivered in Module 1 with a web-based program in Module 2 and optimized for tablet delivery that will be available to patients and caregivers who are randomized to the intervention group. Patients and caregivers in the control group will receive the "Facing Forward" brochure from the National Cancer Institute as part of Module 2. This time and attention comparison module will be provided to subjects in a printed or electronic format. There are 2 versions of the brochure- one for patients and one for caregivers. The proposed application has a strong scientific premise in that the study will comprehensively address the identified gaps through a novel intervention for both patients and caregivers. Significant gaps in supportive care persist in the treatment of patients diagnosed with MIBC.[30,31] These gaps include: (a) insufficient pre-treatment patient preparation and information from physicians and nursing staff and insufficient psychosocial support; (b) inadequate post-treatment discharge instructions and skills building for post-treatment recovery; (c) insufficient support for caregivers, leaving caregivers with inadequate skills and psychosocial support; and (d) lack of interventions targeting MIBC patients and caregivers. The premise is further strengthened through our preliminary data demonstrating the synergistic effects of in-person support (see D.2.c.) combined with on-demand web-based information and support (see D.2.d), as well as an established literature on web-based supportive interventions, for cancer patients and caregivers.[25-27,29]

4. OBJECTIVE(S)/SPECIFIC AIMS AND HYPOTHESES

- *A concise statement of the goal(s) of the current study.*
- *The rationale for and specific objectives of the study.*
- *The goals and the hypothesis to be tested should be stated.*

Bladder cancer (BC) is a severe but psychosocially unaddressed disease that involves highly invasive surgical procedures. Most commonly, patients undergo the surgical removal of the bladder, prostate, and infected lymph nodes, followed by the construction of a new voiding system [i.e., either an ileal conduit (a stoma with external bag), stoma with internal reservoir, or neobladder]. The treatment and recovery period is physically and psychologically extremely challenging for patients and their spouse/partners (henceforth defined as caregivers). Based on our published literature and pilot data, patients and caregivers have persistent and dramatic unmet needs from the time of diagnosis, through treatment and during recovery. These needs in the areas of informational, social, psychological, instrumental, and medical domains are not adequately addressed by health professionals. Specifically, within the medical domain patients have to cope with a

lengthy surgical intervention, significant clinical complications, high re-hospitalization rates, and a long recovery period. Lack of adequate support and self-care information contribute to a difficult post treatment adjustment period. Psychosocial distress is fueled by concerns over an altered body image, feelings of isolation through restrictions in social activities and fears of recurrence (reflected by a ~46-57% 5-year recurrence rate). Caregivers have to learn and adjust to sensitive and potentially difficult caregiving tasks, such as stoma care. Not surprisingly, the complex care regimens and high recurrence rates are associated with high levels of distress among patients and caregivers. The scientific premise of this application is based on a strong conceptual model, data analyses from our previously developed survivorship interventions and our pilot studies, which include extensive qualitative assessments of unmet needs of BC patients and caregivers, and development and testing of intervention components. Our pilot work point to the necessity for support across the disease and recovery spectrum. In particular, we have identified three understudied needs that require novel interventions to better support patients and caregivers: (1) pre-treatment preparation, (2) post-treatment/discharge self-care challenges, and (3) long-term adjustment. To address these needs, we will refine and evaluate a comprehensive, synergistic in-person (Module 1) and web-based program (Module 2) geared to the patient and caregiver [*Recovery Support for Bladder Cancer* (RSBC)]. The **overall purpose** of the proposed project is to improve patient and caregiver quality of life (QOL), reduce infections and nurse/ER visits, and reduce costs by enhancing self-care knowledge and self-efficacy.

Specific Aim 1 (Formative work): To further refine our newly designed intervention components for patients with BC and caregivers. Our prior work suggests an in-person preparatory visit before treatment combined with a post-treatment web-based intervention targeting patients and caregivers. The components will be further refined through usability testing with the involvement of our patient/caregiver and physician advisory board.

Specific Aim 2: Conduct a rigorous 12-month randomized controlled trial with BC patients and their caregivers at three diverse hospital systems. Patient and caregivers (N=287 participants) will be randomized into the (a) RSBC intervention or (b) time and attention comparison condition that incorporates appropriate health promotion adapted from our prior work (final N= 238 participants). Patients and caregivers in the intervention group compared to the comparison group will experience improved QOL (**primary outcome**) both in the short- (6 mo post-op) and long-term (12 mo post-op; H1), and will experience fewer infections and nurse/ER visits (patients only, **secondary outcomes**; H2).

Specific Aim 3: Conduct moderator and mediator analyses. 3a: To examine the impact of identified moderators on intervention efficacy. Older age, female gender, and type of surgical diversion (i.e., non-neobladder) will moderate the relationship between the intervention and QOL (H3). **3b:** To examine the impact of identified

mediators on intervention efficacy. Higher levels of patient activation (i.e., self-care knowledge, self-efficacy) and lower levels of distress will mediate the intervention effect (H4).

Exploratory Aim 4: To examine the costs and potential savings associated with developing and implementing the RSBC intervention. Costs will be recorded in three categories: development, implementation, and maintenance of intervention. Potential savings will be recorded regarding emergency room care and unplanned visiting nurse home visits. Over time, the savings from the reduced ER/Nurse visits will surpass the costs of the intervention (H5) and the intervention will be cost effective (H6).

5. RESOURCES AVAILABLE TO CONDUCT THE HUMAN RESEARCH

- *Explain the feasibility of meeting recruitment goals of this project and demonstrate a potential for recruiting the required number of suitable subjects within the agreed recruitment period*
    - *How many potential subjects do you have access to?*
- *Describe your process to ensure that all persons assisting with the trial are adequately informed about the protocol and their trial related duties and functions*

Advisory Board & Usability Testing (Aim 1): Recruitment goals for this phase of the study are feasible in that this patient recruitment will be completed through the assistance of Drs. Hall and Ellen Barr who work directly with this population and can provide use with referrals of patients who express interest in participating in this phase. Recruitment will involve 6 patient and caregiver pairs who have agreed to serve as a part of our advisory board. Additionally we can base recruitment feasibility off of the data presented below for the RCT.

RCT (Aim 2): Patient availability was reassessed in June 2020 due to the impact of the COVID-19 pandemic. We anticipate 480 participants to be available during the recruitment period (2020-2023) between both study sites. Based on our pilot data, 90% of patients have a caregiver. Given our extensive experience working with cancer patients, we assume, that 70% of patients will agree to participate in the proposed study and 70% of patients will remain in the study at 12 months (i.e., we are projecting a 15% attrition rate). The 70% acceptance rate has been confirmed by a pilot survey of recent bladder cancer patients across all sites. Therefore, we anticipate enrolling 287 participants over three years. This should yield a final sample of 238 participants. Based on these numbers we expect to enroll a total of 97 participants at NWH. Participating physicians and staff at the Arthur Smith Institute for Urology, and Staten Island University Hospital, will be informed and trained in the procedures of this protocol. PI, Dr. Diefenbach will advise staff of their duties and functions of this study.

6. RECRUITMENT METHODS

- *Describe the source of potential subjects*
- *Describe the methods that will be used to identify potential subjects*
- *Describe any materials that will be used to recruit subjects. A copy of any advertisements (flyers, radio scripts, etc.) should be submitted along with the protocol.*
- *If monetary compensation is to be offered, this should be indicated in the protocol*

Advisory Board and Usability Testing (Aim 1): Advisory board and usability testing recruitment will utilize the assistance of Drs. Hall and Ellen Barr, who will refer eligible patients and caregivers who express interest in participating in this phase to the CRC/RA. These patients and caregivers will be called by the CRC/RA to reassess interest. If the patient or caregiver are still willing to participate, the CRC/RA will either mail or email the web-based intervention wireframes to participants. The CRC/RA will schedule a mutually agreeable time to speak over the phone to discuss the RSBC intervention. At this time, the CRC/RA will ask participants if they are interested in participating in the usability testing. If the patient and their caregiver are willing to participate, the CRC/RA will schedule a mutually agreeable time to meet for enrollment and usability testing. On the day of the testing, the CRC/RA will approach the patient and their caregiver. If patient and caregiver agree to participate, they will be asked to sign an IRB approved consent forms once the study has been fully explained to them and after they have had an opportunity to ask clarifying questions. They will then be asked to go through the testing process alongside the PI and research staff.

Patients and caregivers will be compensated $150 in the form of a ClinCard for their participation.

RCT (Aim 2): Patients will be recruited from the Smith Institute for Urology at Northwell Health. CRC/RAs will have access to the EMR of collaborating Northwell Health physicians that perform radical cystectomy and urinary diversion. They will screen these physician's schedules regularly to identify potentially eligible patients. CRC/RAs should confirm with the treating physician that the patient is eligible to be enrolled. Eligible patients will be called by the CRC/RA prior to enrollment to assess interest. If the patient and their caregiver are willing to participate, the CRC/RA will schedule a time to review the study, aiming for 1 week prior to surgery (or at an alternate time that that is convenient for the participant) for enrollment, baseline, and pre-treatment intervention. On the day of their visit, the CRC/RA will approach the patient and their caregiver. If patient and caregiver agree to participate, they will be asked to sign an IRB approved consent forms once the study has been fully explained to them and after they have had an opportunity to ask clarifying questions. If patients and caregivers are not interested in the study, reasons for declining will be recorded, and they will be thanked for talking to the research team. They will then be asked to complete the baseline assessment and the CRC/RA will introduce the study modules of the intervention.

Patients and caregivers will be compensated $30 in the form of a ClinCard for each completed assessment (Baseline, 1-, 3-, 6-, 12-month). In total, they may receive up to $150 in compensation.

Hybrid Remote and In-Person Recruitment for RCT: Due to the COVID-19 pandemic, we will utilize a hybrid remote and in-person recruitment process. The study team will ask to meet with subjects in-person at their pre-surgical testing visit at 450 Lakeville road for the Baseline visit (in-person enrollment detailed above). Alternatively, if patients prefer to complete everything remotely online, via phone, or mail, the study team will accommodate this. All recruitment at SIUH will be remote as there are no research assistants onsite. Screening procedures will remain the same as detailed above. However, for remote enrollment, the consent process, administration of intervention materials, baseline and follow-up visits will be conducted via phone, REDCap (email) or mail. Please see section 11, page 13 for more details regarding remote enrollment.

7. ELIGIBILITY CRITERIA

- *Describe the characteristics of the subject population, including their anticipated number, age, ranges, sex, ethnic background, and health status. Identify the criteria for inclusion or exclusion of any subpopulation.*
- *Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners or other institutionalized individuals, or others who are likely to be vulnerable. You cannot include these populations in your research, unless you indicate such in the protocol*
- *Similarly, detail exclusionary criteria: age limits, special populations (minors, pregnant women, decisionally impaired), use of concomitant medications, subjects with other diseases, severity of illness, etc.*

Advisory Board and Usability Testing (Aim 1): Since this group of patients has already been determined based on a previous IRB approved study below is an overview of the current advisory board that has agreed to participate in this current research study:

- Members of the NWH/MMC AB are diverse with respect to age, race, and BC treatment. Specifically, two-thirds of the board is male, which is consistent with the prevalence of the disease among men. Two members had a neobladder, one a catheterizable pouch and three an ileal conduit. Board members are on average 63 years old and completed treatment an average of two years ago.

RCT (Aim 2):
1) **Patients**: Eligible patients will include men and women who been diagnosed with BC (as confirmed by a biopsy), and scheduled a radical cystectomy. We will include patients diagnosed with any bladder malignancy which includes both muscle invasive bladder cancer (MIBC) and non-muscle invasive bladder cancer (NMIBC) patients, so long as the patient is having a cystectomy with one of the three urinary diversions (i.e., ileal conduit, neobladder or Indiana pouch). 2)

Caregivers: Enrollment will occur for any person who has agreed to a caregiving relationship (e.g., spouse, partner, son, daughter, sister, brother) as stated by both patient and caregiver. **Exclusion Criteria**: Patients and Caregivers will be excluded if they meet one or more of the following criteria: 1) Less than 18 years old or 2) Unable to read and understand English.

Note: Due to the limited number of cystectomies performed at Northwell per year, we will allow patients to enroll in the study if they meet one of the following criteria: 1) Do not have a caregiver, 2) Have a caregiver that does not want to participate, or 3) Caregiver is ineligible for the study for another reason. We will also allow the enrollment of caregivers without the patient if the patient is not eligible or does not want to enroll for similar reasons listed above.

8. NUMBER OF SUBJECTS

- *Indicate the total number of subjects to be accrued locally. If applicable, distinguish between the number of subjects who are expected to be pre-screened, enrolled (consent obtained), randomized and complete the research procedures.*
- *If your study includes different cohorts, include the total number of subjects in each cohort.*
- *If this is multisite study, include total number of subjects across all sites.*

Advisory Board and Usability Testing (Aim 1):
Patient and Caregiver Pairs *n=6 NWH / n=6 FCCC/Temple*
12 Pairs Total

RCT (Aim 2):

Total	N=238 (N=287 + 15% attrition) • Patients=153, Caregivers=85
NWH	N=78 (N=97 + 15% attrition)
FCCC	N=141 (N=190 + 15% attrition)

9. STUDY TIMELINES

- *Describe the duration of an individuals participation in the study*
- *Describe the duration anticipated to enroll all study subjects*
- *The estimated date of study completion*

Advisory Board and Usability Testing (Aim 1): The advisory board members will speak over the phone with the study team once in Year 1 for approximately 20 minutes to discuss RSBC intervention. At the end of phone call, CRC/RA will ask participants if they would be interested in the usability testing. Individuals participating in the usability testing will be enrolled into the study for 1 day for approximately 60 minutes per pair.

RCT (Aim 2): An individual's participation in this phase is expected to last for 12 months. To better understand participant satisfaction and use of the RSBC intervention program (CRIS), they may be invited for a brief follow-up interview.

Duration to Enroll: Duration of enrollment is expected to last 2.5 years, from the 1st enrollment of individuals for the advisory board to the final enrollment of individuals for the RCT phase.

Date of Study Completion: We anticipate study completion by December 2024.

10. ENDPOINTS

- *Describe the primary and secondary study endpoints*
- *Describe any primary or secondary safety endpoints*

Primary outcomes for both patients and caregivers will be improved QOL, which is hypothesized to be significantly higher among participants randomized into *Recovery Support for Bladder Cancer* intervention. Secondary outcomes will be fewer infections and nurse-ER visits for patients randomized into the *Recovery Support for Bladder Cancer* intervention.

11. RESEARCH PROCEDURES

- *Include a detailed description of all procedures to be performed on the research subject and the schedule for each procedure.*
- *Include any screening procedures for eligibility and/or baseline diagnostic tests*
- *Include procedures being performed to monitor subjects for safety or minimize risks*
- *Include information about drug washout periods*
- *If drugs or biologics are being administered provide information on dosing and route of administration*
- *Clearly indicate which procedures are only being conducted for research purposes.*
- *If any specimens will be used for this research, explain whether they are being collected specifically for research purposes.*
- *Describe any source records that will be used to collect data about subjects*
- *Indicate the data to be collected, including long term follow-up*

The entire study will first be reviewed by the Institutional Review Boards (IRB) for each site. With the help of the participating physicians, we will inform key staff within NWH, FCCC/TUH and MMC about our study and design. Any concerns will be addressed in advance of initiating recruitment for any phase of the study.

Advisory Board and Usability Testing (Aim 1):
Board members will be contacted to reassess interest in participating and determine phone call meeting time. RSBC intervention wireframes will be sent to participants through his/her preferred method of delivery (mail or email) prior to the scheduled

phone call meeting. During phone call meeting, participants will be asked to provide feedback on the wireframes provided. The phone call will last for approximately 20 minutes and only document participant feedback on the wireframes themselves. Following completion of this phone call the PI and RA/CRC will ask if they would be interested in participating in usability testing.

If the patient and their caregiver are willing to participate, the CRC/RA will schedule a mutually agreeable time to meet for the 1 day of testing. Upon arrival the CRC/RA will explain the study in detail, and participants will have the opportunity to ask clarify questions. If they agree to participate, they will be asked to sign an IRB approved consent and video authorization form. Each usability session will be audio recorded and transcribed and will begin by asking the participant to explore the software on their own, followed by accomplishing specific tasks that are given to them. Participants will be asked to talk aloud while performing these tasks. Lastly, participants will complete the System Usability Survey. Procedures for analyzing the results will be identical to those used for the pre-treatment component. Any issues with content, functionality, and features will be addressed in the second round of development.

RCT (Aim 2):
Recruitment: Patients will be recruited from the Smith Institute for Urology at Northwell Health. CRC/RAs will have access to the EMR of collaborating Northwell Health physicians that perform radical cystectomy and urinary diversion. They will screen these physician's schedules regularly to identify potentially eligible patients. CRC/RAs should confirm with the treating physician that the patient is eligible to be enrolled. Eligible patients will be called by the CRC/RA prior to enrollment to assess interest. If the patient and their caregiver are willing to participate, the CRC/RA will schedule time to meet, aiming for 1 week prior to surgery (or at an alternate time that is convenient for the participant) to conduct the enrollment/ baseline visit.

Hybrid Remote/In-Person Recruitment due to COVID-19 pandemic: In March 2020, in-person recruitment for research was stopped in order to protect patients and research personnel. However, as of March 2021, limited in-person study procedures are allowed. To maintain recruitment efforts, research coordinators will reach out to patients and enroll them in-person at 450 Lakeville Road, or remotely. The research assistants will ask which method of recruitment the participant is comfortable with. In-person enrollment was detailed previously. For remote enrollment, the consent process can be conducted over the phone. CRCs/RAs will first send the written consent form electronically or by mail, as per the participant's request. The participant will read the consent form and call or email the investigator if he/she wishes to discuss the research and resolve issues/questions. If the participant agrees to participate, they will be directed to sign the consent form and return back to the study team. This can be accomplished electronically (i.e., via the REDCap informed consent form link or scanned copy of consent form sent to the study team) or via mail (i.e., study team provides stamped return envelope for

participants to mail back consent form). Once the ICF is complete, enrollment, randomization, baseline and follow-up procedures will proceed as described below. Regarding the intervention materials, participants in both groups will receive all of their information electronically or by mail (e.g., link to website, username/password, PDFs of the brochures, etc.). Coordinators will also offer to send the Samsung Tablets and Facing Forward brochures via mail.

Enrollment (Baseline Visit): On the day of their enrollment visit, the CRC/RA will approach the patient and their caregiver. Interest in the study will be confirmed for both patients and caregivers and they will be provided with an electronic or physical copy of the consent form according to their preference. The study will be explained in detail, and participants will have the opportunity to ask clarifying questions. If they agree to participate, they will be asked to sign the IRB approved consent form. Following the completion of the consent form the CRC/RA will administer the baseline questionnaire, separately for patients and caregivers. Participants will have the option of completing the baseline questionnaire electronically (i.e., via REDCap link), via hard copy (i.e., mailed form), and over the phone or in-person with the CRC/RA. In the event that participants opt to complete the questionnaire via mailed copy, over the phone or in-person, the CRC/RA will input participant responses into REDCap. All surveys will be created and data housed in REDCap and the CRC/RA will be in charge of maintain the database alongside the assistance of Northwell's REDCap team.

Randomization: All participants who have agreed to participate will be block randomized by study site to either RSBC or the comparison condition. This procedure will ensure that an even number of participants will be allocated to the two conditions and even numbers per condition across sites are maintained overall.

Module 1: The first part of the intervention, Module 1, will consist of the standard of care (SOC) pre-surgery education that all patients undergoing a radical cystectomy receive. Both of the study sites have a robust pre-surgery education that includes information on pre and post treatment care that is conducted by a trained health care provider. Since Module 1 is not conditional upon enrollment in the study and is part of standard of care, it can be performed before informed consent is obtained and/or after Module 2 is administered. The content of Module 1 will be the same for both the intervention and control groups. It is estimated that the entire session will last approximately 50-60 minutes.

Module 2: Following completion of the baseline surveys during the enrollment visit, participants will receive the Module 2 study materials for the group they were randomized to. Subjects randomized to the control group will receive the Facing Forward brochures (either electronically or via mail, according to participants' preferences). Those randomized to the intervention group will be given the link to the intervention website and assigned unique usernames and passwords to access the site. If participants do not have a personal tablet, smartphone, or computer, a tablet with Internet access (Samsung Galaxy Tablet) will be provided. Only 1 tablet

will be provided per dyad. In certain circumstances where the dyad does not live together, and neither party has a personal tablet, smartphone or computer, 2 tablets may be provided. Both participants will be asked to sign a "Study Device: Code of Conduct" agreement which explains that the tablets do not belong to the subject, must be cared for, and must be returned at the end of the study or at the request of the study team. All participants will be thanked and reminded that study personnel will contact them to complete their 1-month follow-up assessment. At the six-month time point, the CRC/RA will contact the participants in the intervention group to schedule a time to return the tablet. At this point, the CRC/RA will also remind patients and caregivers in both study arms to complete their 6-month assessments. Participants will also complete assessments at 12-months. It should be noted that participants will have the option of completing all follow-up assessments electronically (i.e., via REDCap link), via hard copy (i.e., mailed form), and over the phone or in-person with the CRC/RA. In the event that participants opt to complete the questionnaire via mailed copy, over the phone or in-person, the CRC/RA will input participant responses into REDCap.

To better understand participant satisfaction and the use of the RSBC intervention program (CRIS), participants may be invited for a brief follow-up interview, which will be conducted over the phone.

Procedures for obtaining tablets in which participants are not responsive will be to reach out to the physician for the patient and confirm their next appointment during which the physician will remind the patient that the tablet is required to be returned and further this by having the CRC/RA present before or after the appointment to ensure they know who they can reach out to in order to set up a time to have the tablet returned.

12. STATISTICAL ANALYSIS

- *Describe how your data will be used to test the hypotheses.*
- *State clearly what variables will be tested and what statistical tests will be used.*
- *Include sample size calculations.*
- *If this is a pilot study, state which variables will be examined for hypothesis generation in later studies.*

Preliminary analyses. Summary scales of standardized measures will be computed. Univariate and descriptive analysis will be performed on all continuous outcome variables and, if necessary, normalizing and/or variance stabilizing transformations will be sought before the inferential analyses are conducted. We will examine the data for outliers and will use descriptive and inferential statistical techniques for data characterization. First, correlations will be computed, separately for patients and caregivers among background, moderator, mediator, and outcome variables. Any differences between patients and caregivers will be explored with t-tests or ANOVA procedures. Differences among study sites will also be explored and adjusted for in all subsequent analyses. Google analytics (GA) will be applied

to assess program usage, using the following parameters: time/date of login, duration of page views, and document download. These data will be summarized and correlated with study outcomes.

Analyses of the intervention effect. Analyses for patients and caregivers will be conducted separately. A multivariate linear mixed effect model will be used to examine predictors of the primary study outcome QOL after adjusting for other patients/caregivers and clinical characteristics (e.g. comorbidities, study site; Aim 2). This model will be used because we assume outcomes within each patient/caregivers may be correlated over time and also patients/caregivers outcomes may be correlated within each site.

Moderator analyses (Aim 3a) with the hypothesized moderators age, gender, and diversion type will be conducted with Proc Mixed in SAS v9.4 to examine whether the intervention works best for patients of older age, caregivers of female gender, and among patients with an ileal conduit diversion type. Specifically, in the linear mixed effect model, we will add separate interaction terms of intervention group and age, gender, and diversion type. Any interaction term that is statistically significant ($p<.05$) will stay in the final model so that the independent effects of the corresponding moderators will be determined. If an interaction term, for incidence, gender, and intervention group is statistically significant, it means gender is a moderator of the causal effect of intervention on QOL (i.e. the effect of intervention on QOL differs between male and female). **Mediating analyses** (Aim 3b) will explore if higher patient activation and lower levels of distress will mediate the intervention effect. We are following MacKinnon's[106,107] recommendation to assess either the difference between the direct effect of the intervention in a model with vs. without the mediator, or the product of two path coefficients to examine mediational effects. These approaches are superior to that of Baron and Kenny. The significance of the mediated effect is tested via bootstrapping. First, mediators will be tested separately. If significant mediation effects are found, we will then simultaneously incorporate all significant components in the regression for a multiple mediation model.

Cost analysis. To analyze the costs and potential savings of the intervention over time, we will first assess the overall development, implementation and maintenance costs of the intervention and compare them to the potential savings realized by reduced visiting nurse and ER/Hospital visits. We will conduct a cost-benefit analysis (CBA) between RSBC and comparison groups. To evaluate the cost-effectiveness of RSBC , we will conduct an analysis using QALY and ICER. We will calculate average QALYs for each group and compare ICER between group.[106,107,110] We will then perform a stratified analysis for different subgroups (e.g., age groups; diversion type groups) to further understand how cost-effectiveness might differ across subgroups. We will conduct sensitivity analysis and we will examine the cost-effectiveness from the societal cost angle.

13. SPECIMEN BANKING

- *If specimens will be banked for future research, describe where the specimens will be stored, how long they will be stored, how they will be accessed and who will have access to the specimens*
- *List the information that will be stored with each specimen, including how specimens are labeled/coded*
- *Describe the procedures to release the specimens, including: the process to request release, approvals required for release, who can obtain the specimens, and the information to be provided with the specimens.*

14. DATA MANAGEMENT AND CONFIDENTIALITY

- *Describe the data and specimens to be sent out or received. As applicable, describe:*
  - *What information will be included in that data or associated with the specimens?*
  - *Where and how data and specimens will be stored?*
  - *How long the data will be stored?*
  - *Who will have access to the data?*
  - *Who is responsible for receipt or transmission of data and specimens?*
- *Describe the steps that will be taken to secure the data during storage, use and transmission.*

15. DATA AND SAFETY MONITORING PLAN

A specific data and safety monitoring plan is only required for greater than minimal risk research. For guidance on creating this plan, please see the Guidance Document *on the HRPP website.*

- *Part I – this part should be completed for all studies that require a DSMP.*
- *Part II – This part should be completed when your study needs a Data and Safety Monitoring Board or Committee (DSMB/C) as part of your Data and Safety Monitoring Plan.*

Part I: Elements of the Data and Safety Monitoring Plan

- *Indicate who will perform the data and safety monitoring for this study.*
- *Justify your choice of monitor, in terms of assessed risk to the research subject's health and well being. In studies where the monitor is independent of the study staff, indicate the individual's credentials, relationship to the PI, and rationale for selection*
- *List the specific items that will be monitored for safety (e.g. adverse events, protocol compliance, etc)*
- *Indicate the frequency at which accumulated safety and data information (items listed in # above) will be reviewed by the monitor (s) or the DSMB/C.*

- *Where applicable, describe rules which will guide interruption or alteration of the study design.*
- *Where applicable, indicate dose selection procedures that will be used to minimize toxicity.*
- *Should a temporary or permanent suspension of your study occur, in addition to the IRB, indicate to whom will you report the occurrence.*

The research material collected will be data from focus groups, self-reported internet surveys, self-report assessment questionnaires, and medical record abstraction data. The questionnaire and qualitative interview data will be collected specifically for the proposed research project. The medical chart data is collected in the regular course of patient treatment. All data pertaining to individual subjects will be identified only by code number and kept in a locked file cabinet at 600 Community Drive Suite 403. Only the study personnel will have access to links between subjects and subject identities. Upon completion of a subject's participation, these links will be destroyed. De-identified questionnaire data will be entered into an electronic database (REDCap) stored in a password-protected and encrypted secure folder. Digital audio recordings of advisory board meetings and usability testing will be transcribed without identifiers. The researchers take the issue of confidentiality very seriously. Extensive efforts will be undertaken to maintain study participants' confidentiality and privacy. Upon study entry, each study subject will be given a unique numeric identifier. All study materials (focus groups voice files, focus group transcriptions, self-reported internet surveys, self-report assessment questionnaires, and medical record abstraction data, and any subsequent databases generated for the study) will be stored in locked file cabinets to which only study staff will have access. Informed consent forms will be filed in separate locked file cabinets. Identifying information, such as a patient's name, will not be included in the data files, such as the completed questionnaires or any study databases.

In addition, The Principle Investigators will meet with the RC's on a regular basis to ensure data accuracy and protocol adherence. Quarterly meetings (either in person or via phone) with the entire study team will also ensure protocol adherence. To ensure the validity and integrity of study data, the PIs will also oversee all data management responsibilities. The PIs will discuss all data management issues with the study team at NWH and FCCC/Temple.

The Feinstein Institute for Medical Research will be used as a central location for data processing and management. Vanderbilt University, with collaboration from a consortium of institutional partners, has developed a software toolset and workflow methodology for electronic collection and management of research and clinical trial data. REDCap (Research Electronic Data Capture) data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the research team with planning assistance from the Biostatistics Unit of the *Feinstein Institute for Medical Research*. The iterative development and testing process results in a well-planned data collection strategy for individual studies. REDCap servers are housed in a local data center at the

Feinstein and all web-based information transmission is encrypted. REDCap was developed specifically around HIPAA-Security guidelines and is recommended to Northwell Health researchers by both our Clinical Research Service, Research Compliance Office and Institutional Review Board. REDCap has been disseminated for use locally at other institutions and currently supports 965 active institutional partners and other institutions in 78 countries (www.project-redcap.org).

Part II: Data and Safety Monitoring Board or Committee

- *When appropriate, attach a description of the DSMB.*
- *Provide the number of members and area of professional expertise.*
- *Provide confirmation that the members of the board are all independent of the study.*

16. WITHDRAWAL OF SUBJECTS

- *Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent*
- *Describe procedures for orderly termination*
- *Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.*

Circumstances in which participates may be withdrawn from the research without their consent may include the following:

- Failure to follow instructions,
- Failure to adhere to scheduled study visits,
- If it is not in your best interest to continue on this study, or
- If the study is stopped

This decision may be made by the PIs, or the IRB.

Participants will be able to withdraw from the study at any time. The consent form will make explicit to patients that they may discontinue the study at any time without penalty and without prejudice to their medical care.

Any subjects withdrawn from the research, including partial withdrawal from RCT phase where continued data collection will occur will be instructed that per the consent form we may still use information we have already collected for research purposes but will not continue to collect any further data. Finally, the subject will have their information removed from any future correspondence that was planned for the study.

17. RISKS TO SUBJECTS

- *Describe any potential risks and discomforts to the subject (physical, psychological, social, legal, or other) and assess their likelihood and seriousness and whether side effects are reversible. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.*
- *Include risks to others , like sexual partners (if appropriate)*
- *Discuss why the risks to subjects are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be expected to result.*
- *Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness.*

. There is a slight risk that participants might be distressed or uncomfortable when being asked questions about their BC. All research personnel with patient contact will be trained by Dr. Diefenbach, to be vigilant and sensitive to expressions of distress. All participants will be encouraged to contact the PI if any concerns arise. In the event of high levels of distress, the patient will be referred to counselors in the Department of Social Work, or appropriate medical health professionals.

The risks to subjects are reasonable in that this is a minimally invasive study, no subject's treatment will be altered in any way and the only potential risk is that of distress with questions being asked which they are free to skip. The risks are outweighed by the anticipated benefits and knowledge to be gained that may help men and women in the future in addition to providing subjects with enhanced knowledge and awareness of bladder cancer.

The procedures to protect subjects against or minimize the described risks in addition to risks to confidentiality include allowing participants to skip or choose not to respond to any questions that may cause them distress. Confidentiality will be protected by ensuring that all patient information gathered will be kept on Northwell's secured server and in password protected files that only the research team has access to. Further, information will only be accessed when needed and the research team will be trained to ensure confidentially and the correct procedures when accessing and saving patient information are used.

18. RESEARCH RELATED HARM/INJURY

- *Describe the availability of medical or psychological resources that subjects might need as a result of anticipated problems that may be known to be associated with the research.*
- *If the research is greater than minimal risk, explain any medical treatments that are available if research-related injury occurs, who will provide it, what will be provided, and who will pay for it.*

We do not anticipate any risks to participants beyond the potential discomfort of thinking about and discussing, bladder cancer patients' informational support and

health care needs. Loss of confidentiality may occur if someone other than those on the study team were to access the audio recording. However, measures will be taken to ensure that only the investigators listed on this IRB application will have access to the study data including the audio recordings.

Patients may be at risk for slight emotional distress, which might result from being asked questions about personal cancer and treatment experiences. Participants will be informed during the focus group sessions and at the beginning of the assessment that potentially sensitive topics will be discussed and that they may skip any part that would make them uncomfortable. Further, all study personnel involved in the study will be trained by the PIs to recognize distress and embarrassment of participants and will be instructed to address any distress caused by the study in a sensitive and supportive manner. Although unlikely, any patient requesting consultation will be referred immediately to the Principle Investigator.

19. POTENTIAL BENEFIT TO SUBJECTS

- *Explain what benefits might be derived from participation in the study, noting in particular the benefit over standard treatment (e.g. a once-a-day administration instead of four times a day, an oral formulation over an IV administration).*
- *Also state if there are no known benefits to subjects, but detail the value of knowledge to be gained*

Empirical data from the advisory board meetings will be used to develop an innovative multimodal intervention to help patients and caregivers cope with BC and to facilitate adjustment being a survivor of bladder cancer after treatment. Data from the longitudinal surveys will ultimately be used to inform the future development of information and emotion-focused interventions that will improve well-being and help patients with BC better cope with life after cystectomy and urinary diversion. The proposed study is also aimed to examine the costs and benefits of the RSBC intervention to facilitate integration into clinical practice.

20. PROVISIONS TO PROTECT PRIVACY INTERESTS OF SUBJECTS

- *Describe the methods used to identify potential research subjects, obtain consent and gather information about subjects to ensure that their privacy is not invaded.*
- *In addition consider privacy protections that may be needed due to communications with subjects (such as phone messages or mail).*

Patients diagnosed with BC will first be identified by the participating physicians at each study site (NWH, FCCC/TUH). A registry of these potential BC patients will be developed and reviewed on a monthly basis by a physician at each practice site. The physician will review the medical record and determine whether these patients

are diagnosed with biopsy confirmed BC. Eligible patients will be called by the CRC/RA prior to enrollment to assess interest. If the patient and their caregiver are willing to participate, the CRC/RA will schedule a time to review the study, aiming for 1 week prior to surgery (or at an alternate time that that is convenient for the participant) for enrollment, baseline, and pre-treatment intervention. On the day of their visit, the CRC/RA will approach the patient and their caregiver. If patient and caregiver agree to participate, they will be asked to sign IRB approved consent forms once the study has been fully explained to them and after they have had an opportunity to ask clarifying questions. The researchers take the issue of confidentiality very seriously. Extensive efforts will be undertaken to maintain study participants' confidentiality and privacy. For HIPPA privacy purposes, participants will be informed that their names are not attached to study documents. In addition, ongoing protection of confidentiality will be adhered to throughout the study period and thereafter and to ensure the utmost validity and integrity of study data, the PIs will also oversee all data management responsibilities and will discuss all data management issues with the study teams at each site. Any phone calls or emails will be sent to participants through the respective study site's secured server and calls made at each study location in a secured area.

21. COSTS TO SUBJECTS

- *Describe any foreseeable costs that subjects may incur through participation in the research*
- *Indicate whether research procedures will be billed to insurance or paid for by the research study.*

No foreseeable costs that subjects may incur through participation in the research are identifiable at this time, all research procedures will be paid for by the research study.

22. PAYMENT TO SUBJECTS

- *Describe the amount of payment to subjects, in what form payment will be received and the timing of the payments.*

Advisory Board & Usability Testing (Aim 1): $150 for participation

RCT (Aim 2): $30 for each completed follow-up (baseline, 1-, 3-, 6-, 12-month)

23. CONSENT PROCESS

If obtaining consent for this study, describe:

- *Who will be obtaining consent*

- *Where consent will be obtained*
- *Any waiting period available between informing the prospective participant and obtaining consent*
- *Steps that will be taken to assure the participants' understanding*
- *Any tools that will be utilized during the consent process*
- *Information about how the consent will be documented in writing. If using a standard consent form, indicate such.*
- *Procedures for maintaining informed consent.*

The site research coordinators, who have experience obtaining informed consent at NWH and FCCC/Temple will describe the study in detail, answer questions, and obtain written informed consent. The study investigator or research coordinator will not enroll a potential subject until the person administering the consent is satisfied that the subject understands all parts of the study. They will be told that their discussions will be recorded for analyses and reports, however, their names and medical information will not appear in any reports and that all records and information will be kept in a secured area where only the research team will have access to them. A copy of the informed consent is provided to the patient at the end of the consultation process.

Advisory Board & Usability Testing (Aim 1):
The consent process will be prior to either the advisory board meeting or the usability testing. In addition to the standard approved consent form, patients will be asked to complete and sign the audio visual authorization form. A copy of the regular consent form and the audio visual authorization document will be provided to the patient at the end of the consent process.

RCT (Aim 2):
The consent process will be at the beginning of the scheduled baseline visit. Patients will not be audio recorded during the RCT. Patients who are enrolled remotely will have a copy of the consent form sent to them (i.e., electronically or mailed).

In the state of NY, any participants under the age of 18 are considered children. If your study involves children, additional information should be provided to describe:

- *How parental permission will be obtained*
- *From how many parents will parental permission be obtained*
- *Whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. The process used to determine these individual's authority to consent for the child should be provided*
- *Whether or not assent will be obtained from the child*
- *How will assent be documented*
- *Whether child subjects may be expected to attain legal age to consent to the procedures for research prior to the completion of their participation in the research. If so, describe the process that will be used to obtain their legal*

consent to continue participation in the study. Indicate what will occur if consent is not obtained from the now-adult subjects.

If the study involves cognitively impaired adults, additional information should be provided to describe:

- *The process to determine whether an individual is capable of consent*
- *Indicate who will make this assessment*
- *The plan should indicate that documentation of the determination and assessment will be placed in the medical record, when applicable, in addition to the research record.*
- *If permission of a legally authorized representative will be obtained,*
  - *list the individuals from who permission will be obtained in order of priority*
  - *Describe the process for assent of subjects; indicate whether assent will be required of all, some or none of the subjects. If some, which subjects will be required to assent and which will not.*
  - *If assent will not be obtained from some or all subjects, provide an explanation as to why not*
  - *Describe whether assent will be documented and the process to document assent*
  - *Indicate if the subject could regain capacity and at what point you would obtain their consent for continued participation in the study*

If the study will enroll non-English speaking subjects:

- *Indicate what language(s) other than English are understood by prospective subjects or representatives*
- *Indicate whether or not consent forms will be translated into a language other than English*
- *Describe the process to ensure that the oral and written information provided to those subjects will be in that language*
- *If non-English speaking subjects will be excluded, provide a justification for doing so*

24. WAIVER OR ALTERATION OF THE CONSENT PROCESS

Complete this section if you are seeking an alteration or complete waiver of the consent process.

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk to the subject:*
- *Explain why the waiver/ alteration will not adversely affect the rights and welfare of subjects*
- *Explain why it is impracticable to conduct this research if informed consent is required*
- *If appropriate, explain how the subjects will be provided with additional pertinent information after participation. If not appropriate to do so, explain why.*

- This is a minimally invasive study and no subject's treatment will be altered in any way and the only potential risk is that of distress with questions being asked which they are free to skip.
- The waiver/alteration will not adversely affect the rights and welfare of the subjects because subjects will be notified multiple times that they may remove themselves from the study or choose not to participate at any time.
- Consent will be obtained following the phone call which is only being done to assess study interest and ensure the subject knows they need to meet with the study team before any physician appointment. Not having the ability to communicate this to subjects through a phone call will hinder the feasibility of this study protocol.
- Subjects will be followed following the initial visit and will be provided with information pertinent to the study at those time points either through telephone call, mail or email.

Complete this section if you are obtaining informed consent but you are requesting a waiver of the documentation of consent (i.e., verbal consent will be obtained). *To proceed with a waiver based on these criteria, each subject must be asked whether they wish to have documentation linking them to this study.* ***Only complete subsection 1 OR subsection 2.***

SUBSECTION 1

- *Explain how the only record linking the subject to the research would be the consent document.*
- *Explain how the principal risk of this study would be the potential harm resulting from a breach in the confidentiality*
- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

- The only record linking the subjects to the research would be the consent document, all other study information that is collected will be de-identified at the time it is input into REDCap by using a unique identifier.
- The principle risk of this study would be the potential harm resulting from a breach in the confidentiality given that this study has minimal risks aside from potentially distressing questions being asked in the surveys. This said, all study information will be kept in the study binder

and locked in a secured filed cabinet that only study team members will be given access to.
- Subjects will be given a copy of the consent form at the time of their initial in-person visit which will contain information regarding the research they are choosing to participate in.

SUBSECTION 2

- *Describe the possible risks of harm to the subjects involved in this study and explain why the study involves no more than minimal risk.*
- *Confirm that the research only involves procedure for which consent is not normally required outside the research context.*
- *Indicate whether or not subjects will be provided with a written statement regarding the research.*

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25. WAIVER OF HIPAA AUTHORIZATION

Complete this section if you seek to obtain a full waiver of HIPAA authorization to use and/or disclose protected health information.

- *Describe the risks to privacy involved in this study and explain why the study involves no more than minimal risk to privacy:*
- *Describe your plan to protect identifiers from improper use or disclosure and to destroy them at the earliest time.*
- *Indicate why it is not possible to seek subjects' authorization for use or disclosure of PHI.*
- *Indicate why it is not possible to conduct this research without use or disclosure of the PHI.*
- *Indicate if PHI will be disclosed outside NSLIJ Health System, and if so, to whom. Note: PHI disclosed outside NSLIJ Health System, without HIPAA authorization needs to be tracked. Please see guidance at www.nslij.com/irb for information about tracking disclosures.*

Complete this section if you seek to obtain a partial waiver of the patient's authorization for screening/recruitment purposes *(i.e., the researcher does not have access to patient records as s/he is not part of the covered entity)*

Note: Information collected through a partial waiver for recruitment cannot be shared or disclosed to any other person or entity.

- *Describe how data will be collected and used:*
- *Indicate why you need the PHI (e.g.PHI is required to determine eligibility, identifiers are necessary to contact the individual to discuss participation, other)*

- *Indicate why the research cannot practicably be conducted without the partial waiver (e.g. no access to medical records or contact information of the targeted population, no treating clinician to assist in recruitment of the study population, other)*

• Data will be collected following direct physician referral of eligible subject, from which the RA will identify the patient in All Scripts, collect their telephone number and use it to reach out to them to introduce the study and assess potential interest. • PHI is needed to reaffirm eligibility of potential subjects, identifiers are necessary to contact the individual to discuss participation in the study. • This research cannot practicably be conducted without the partial waiver because there is no participating physician who has the time to devote to directly reach out to these patients as the first point of contact on our behalf. Without this waiver it would be near impossible to get patients to arrive before their consultation as they would not know to do so any other way.

26. VULNERABLE POPULATIONS:

Indicate whether you will include any of these vulnerable populations. If indicated, submit the appropriate appendix to the IRB for review:

- ☐ *Children or viable neonate*
- ☐ *Cognitively impaired*
- ☐ *Pregnant Women, Fetuses or neonates of uncertain viability or nonviable*
- ☐ *Prisoners*
- ☐ *NSLIJ Employees, residents, fellows, etc*
- ☐ *poor/uninsured*
- ☐ *Students*
- ☐ *Minorities*
- ☐ *Elderly*
- ☐ *Healthy Controls*

If any of these populations are included in the study, describe additional safeguards that will be used to protect their rights and welfare.

27. MULTI-SITE HUMAN RESEARCH (COORDINATING CENTER)

If this is a multi-site study where you are the lead investigator, describe the management of information (e.g. results, new information, unanticipated problems involving risks to subjects or others, or protocol modifications) among sites to protect subjects.

The central site investigator, Michael A. Diefenbach, Ph.D., is responsible for the overall oversight of the data collected at NWH and FCCC/Temple in addition to the monitoring of the data, assuring protocol compliance, and conducting the safety reviews during regular meetings or more frequently if needed. This will be done through weekly phone calls and yearly in-person site visits. The central site investigator will also be responsible for compiling the data sheets, day to day oversight of research and ensuring the integrity and privacy of the data. During the review process the principal investigators, along with the other investigators, will evaluate whether the study should continue unchanged, require modification/amendment, or be closed to enrollment. To aid in this study progress, data and safety concerns will be reviewed after every month and will include the research team. Outside of these scheduled meetings, safety concerns can be raised at any time and by anyone. The principal investigators or the Institutional Review Board (IRB) have the authority to stop or suspend the study or require modifications.

All research data including any subject contact information and protected health information obtained both from the baseline and follow-up measures will be held in strict confidence in a de-identified format, identified only by a study ID number. After data entry, subject information will not have the patient's name, but will be identified only by a study ID number. The database, that will be password-protected, stored, and backed up daily on a protected server, will be designed using REDCap, a secure web-based application designed to support data capture for research studies. There will not be any patient identifiers in the database. All paper data collection forms will be kept in a locked file cabinet, and ongoing protection of confidentiality will be adhered to throughout the study period. The key to linking the study ID number to any personal identifying information (i.e., Contact information used for follow-up) will be kept in a separate locked file cabinet and in a separate password protected file accessible only by the research associates, project manager and principal investigator. All data obtained in the study will be used exclusively for the purposes of the proposed research, which are clearly outlined in the informed consent signed by the patient. Ongoing protection of confidentiality will be adhered to throughout the study period and thereafter. In addition, the PI, Dr. Diefenbach will meet with the study staff at NWH on a regular basis to ensure data accuracy and protocol adherence. Further and as mentioned prior, quarterly meetings (in person) and weekly meetings (via phone) with the FCCC/Temple study team will also ensure protocol adherence. To ensure the validity and integrity of study data, Dr. Diefenbach will also oversee all data management responsibilities and will discuss all data management issues with the study team at both sites.

28. REFERENCES/BIBIOGRAPHY

Provide a reasonable list of references directly related to the study. Any diagrams for new medical devices or brief reprints from journals might also prove useful.

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