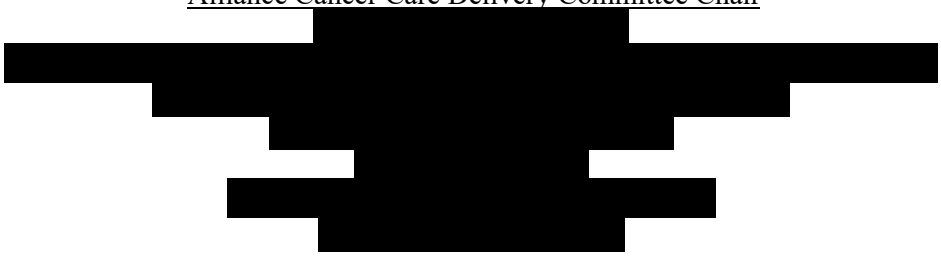
ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

ALLIANCE A231601CD

IMPROVING SURGICAL CARE AND OUTCOMES IN OLDER CANCER PATIENTS THROUGH IMPLEMENTATION OF AN EFFICIENT PRE-SURGICAL TOOLKIT (OPTI-SURG)

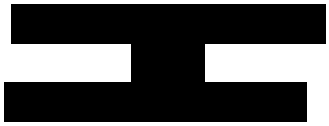
ClinicalTrials.gov Identifier: NCT03857620

Study Chair and
Alliance Cancer Care Delivery Committee Chair



Community Oncology Co-chair

Study Co-chair



Cancer in the Elderly Co-Chair

Modality Co-chair

Modality Co-chair

Primary Statistician

Secondary Statistician

Data Manager

Protocol Coordinator

Institutions participating in this study will be randomized to one of three arms. This protocol provides general information for all participating practices. In order to maintain institutional blinding, information specific to the intervention (OPTI Surg) arms is provided separately in Appendices III-VII. Practices will receive the appendices specific to the arm to which they are randomized following randomization.

Participants: NCORP components of the Alliance (lead), ECOG-ACRIN, NRG, and SWOG NCORP Research Bases

Study Resources:

Expedited Adverse Event Reporting [redacted]	**Medidata Rave® iMedidata portal** [redacted]
OPEN (Oncology Patient Enrollment Network) [redacted]	**Biospecimen Management System** [redacted]

Protocol Contacts:

A231601CD Nursing Contact

[redacted]

Protocol-related questions may be directed as follows:	
Questions	**Contact (via email)**
Questions regarding patient eligibility, treatment, and dose modification:	Study Chair, Nursing Contact, Protocol Coordinator, and (where applicable) Data Manager
Questions related to data submission, RAVE or patient follow-up:	Data Manager
Questions regarding the protocol document and model informed consent:	Protocol Coordinator
Questions related to IRB review	Alliance Regulatory Inbox [redacted]
Questions regarding CTEP-AERS reporting:	Alliance Pharmacovigilance Inbox [redacted]

CANCER TRIALS SUPPORT UNIT (CTSU) ADDRESS AND CONTACT INFORMATION

For regulatory requirements:	For patient enrollments:	For data submission:
Regulatory documentation must be submitted to the CTSU via the Regulatory Submission Portal. (Sign in at [redacted] and select the Regulatory > Regulatory Submission.) Institutions with patients waiting that are unable to use the Portal should alert the CTSU Regulatory Office immediately at [redacted] to receive further instruction and support. Contact the CTSU Regulatory Help Desk at [redacted] for regulatory assistance.	Refer to the patient enrollment section of the protocol for instructions on using the Oncology Patient Enrollment Network (OPEN). OPEN is accessed at [redacted] Contact the CTSU Help Desk with any OPEN related questions by phone or email : [redacted]	Data collection for this study will be done exclusively through Medidata Rave. Refer to the data submission section of the protocol for further instructions.

The most current version of the **study protocol and all supporting documents** must be downloaded from the protocol-specific page located on the CTSU members' website [redacted] Access to the CTSU members' website is managed through the Cancer Therapy and Evaluation Program - Identity and Access Management (CTEP-IAM) registration system and requires log in with a CTEP-IAM username and password.

Permission to view and download this protocol and its supporting documents is restricted and is based on person and site roster assignment housed in the CTSU Regulatory Support System (RSS).

For clinical questions (i.e. patient eligibility or treatment-related) see the Protocol Contacts, Page 2.

For non-clinical questions (i.e. unrelated to patient eligibility, treatment, or clinical data submission)
Contact the CTSU Help Desk by phone or e-mail:
CTSU General Information Line – [redacted] All calls and correspondence will be triaged to the appropriate CTSU representative.

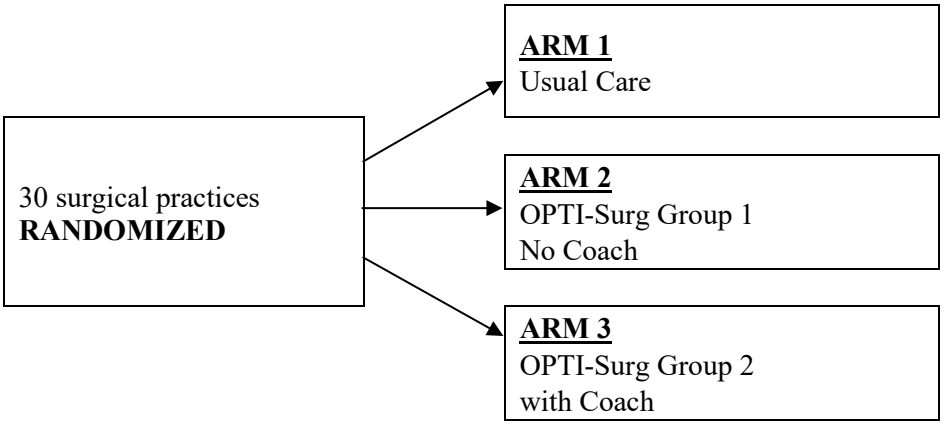
IMPROVING SURGICAL CARE AND OUTCOMES IN OLDER CANCER PATIENTS THROUGH IMPLEMENTATION OF AN EFFICIENT PRE-SURGICAL TOOLKIT (OPTI-SURG)

Patient Eligibility Criteria: (See Section 3.1)

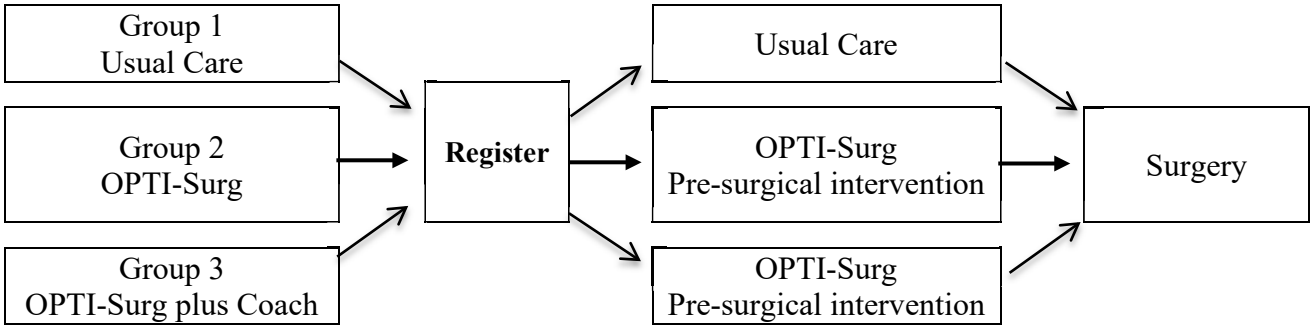
Required Initial Lab Values
None

- Patients must have known or suspected cancer diagnosis and have one of the following cancer-directed operations planned: Gastrectomy; Colectomy; Proctectomy; Esophagectomy; Pancreatectomy; Hepatectomy; Total cystectomy; Partial or Total Nephrectomy; Lung resection (wedge resection, segmentectomy, lobectomy, or pneumonectomy)
- Age ≥ 70 years
- Patients with known metastatic disease with a plan for curative intent resection are eligible.
- Patients with double primaries undergoing planned curative operation for both are eligible.
- Patients undergoing emergent surgery are not eligible.
- Patients under active treatment for second primary are not eligible.
- Patients with known metastatic disease who are undergoing palliative resection are not eligible.
- Patients with psychiatric illness or other mental impairment that would preclude their ability to give informed consent or to participate in the prehabilitation program are not eligible.
- Patients must be able to speak and complete questionnaires in English.

Institutional Randomization:



Patient Schema:



Sample size is about 15 (target 15, maximum 25) consented patients per each of 30 surgical practices (450 consented patients).

Consented patients will complete the CHAMPS and EQ-5D questionnaires at baseline and 8 weeks post-surgery.

NOTE: Practice-level data will be collected for all eligible patients (including those not registered to the trial) until the site has completed accrual, study procedures and data collection of consenting patients.

Surgical complications will be assessed for all eligible patients at 8 and 12 weeks after surgery.

See Sections 7.1 and 4.3.1 for institutional participation requirements.

TABLE OF CONTENTS

1.0 BACKGROUND

1.1 Introduction

The number of older adults who undergo major surgery is expected to double from 7 million to 14 million by 2030.[1] Frailty, an age-related decline in physiologic reserve, is present in least half of older adults who undergo elective surgery.[2-4] There is strong evidence that components of frailty–functional and cognitive impairment, malnutrition, depression, and social vulnerability–put patients at risk for complications, mortality, prolonged length of stay, discharge to an institution and not home, functional decline, and poor quality of life.[3-10] Mounting evidence indicates that multimodal interventions aimed at optimizing vulnerabilities associated with frailty before surgery result in decreased complications, enhanced functional recovery, increased discharge to home, reduced length of stay, and decreased hospital cost.[11-14] Recently published best practices guidelines for the optimal care of the geriatric surgical patient released by the American Geriatrics Society and the American College of Surgeons state that these vulnerabilities should be identified and optimized preoperatively.[15] In current surgical practice, however, routine screening for or attempt to address these vulnerabilities before surgery is not performed. Screening tools are perceived to be cumbersome and primary surgical providers are not equipped to directly address the uncovered vulnerabilities. The goal of the proposed study is to evaluate the implementation of an efficient tool in surgical practices that can *detect and optimize* the components of frailty before surgery.

1.2 Current state of knowledge and clinical/care delivery practice

Well-coordinated perioperative and practice-based interventions can improve older patients' functional status after surgery but few surgical practices have implemented these strategies. A recent survey of surgical oncologists reported that although the majority of surgeons expressed interest in preoperative optimization for older patients, only 6% of them currently perform geriatric assessments in their older patients.[16] Factors contributing to the low level of adoption include perceptions regarding the amount of time required to assess for vulnerabilities and lack of specific programs designed to address them within typical surgical oncology practices. This project focuses on implementing an efficient tailored tool to determine the potential for a package toolkit that identifies and addresses geriatric vulnerabilities preoperatively to affect the delivery of surgical cancer care to elderly frail patients. Moreover, we will determine which practice-change strategies effectively integrate these interventions into routine delivery. Practice facilitation and quality improvement methods have been shown to be effective in improving implementation of guidelines and evidence based practices (EBP).[17] Practice facilitation has been defined as "a process of interactive problem solving and support that occurs in a context of a recognized need for improvement and a supportive interpersonal relationship."[31] Within practice facilitation, quality improvement methods are used to facilitate the implementation of the new EBP, such as the plan-do-study-act (PDSA) cycles from the Institute for Healthcare Improvement model. For practice facilitation, we will use a centralized implementation coach to assist practices to implement the pre-surgical optimization intervention. Prior research also shows that tailoring interventions to account for variance in practice culture can improve intervention uptake and effectiveness. Our study design thus focuses not only on assessing the effectiveness of an efficient tool on improving outcomes for patients, but also on assessing the cultural climate in which practice facilitation and care delivery improvement efforts are deployed.

Frailty and surgical outcomes in cancer patients: Frailty is common in older adults presenting for surgery. Emerging data indicates that frailty, compared to advanced age alone, is more strongly associated with morbidity and mortality after surgery.[6-8] Although published studies

often use different instruments to measure frailty, the overwhelming majority of studies have found that frailty is associated with complications, early and late mortality, prolonged length of stay, poor functional recovery, discharge to an institution, and lower quality of life.[3-10] Cancer surgery among frail older adults is associated with a 3 to 4-fold increase in both 30-day post-operative complications and mortality.[7,10] An analysis of SEER-Medicare showed an 11 item frailty measure was associated with a 10-fold increase in 90-day mortality following colorectal surgery.[8]

Evidence supports multimodal optimization to improve functional outcomes before major surgery: Studies evaluating preoperative optimization of a single domain of vulnerability (e.g., nutrition or fitness) have had mixed results.[14] However, multimodal interventions that address multiple vulnerabilities have demonstrated impressive results.[12,13] In a study of elderly patients undergoing colorectal surgery, 81% of older patients who were enrolled in a trimodal prehabilitation program, including protein supplementation, anxiety reduction, and an exercise program, had returned to baseline function at 8 weeks compared with only 40% in the pre-intervention control group.[13] In another before-and-after study of the effect of pre-operative comprehensive geriatric assessment and multimodal prehabilitation education (home exercise, nutrition, relaxation techniques, and pain management), outcomes were significantly improved among patients who underwent the intervention (pneumonia, 4% post-intervention period vs 20% pre-intervention period; delirium, 6% post-intervention period vs 19% pre-intervention period; and length of stay, 12 days post-intervention period vs 16 days pre-intervention period).[12] A recent single center study of older patients undergoing thoracic and abdominal surgery demonstrated that preoperative program consisting of exercise, nutritional supplementation, and stress management education significantly reduces hospital costs and length of stay.[30] Multimodal interventions aimed at modifying frailty traits are likely to yield the most benefit in older patients.

1.3 Preliminary Data

Our group at the UCSF Center for Surgery in Older Adults developed a program to identify and optimize frail patients prior to major surgery. Pilot implementation of the Edmonton Frail Scale (EFS) in our clinic showed that it required the following administration time: by first-year medical students mean 10.1/median 9.5 minutes, range 6-16 minutes. During the pilot phase, our team which includes a surgeon, geriatrician, occupational therapist, physical therapist, and dietician, developed and refined written materials and resource guides to support optimization of frailty before surgery. Materials were developed in an iterative approach incorporating feedback from a patient and family advisory panel and older surgical patients preparing for surgery.

For practices randomized to Arm 2, see also, Appendix III; for practices randomized to Arm 3, see also Appendix X.

1.4 Contribution to cancer care delivery

Major surgery in frail older adults often results in complications, death, functional decline, loss of independence, affecting quality of life and causing significant resource burdens to patients, families, and health care systems. Older adults with limited life-expectancy often value function and independence over potential gains in life-expectancy.[19] Surgical care pathways that assess and attempt to optimize frailty traits before surgery will enhance functional recovery for frail cancer patients and ensure that frail adults who undergo major cancer surgery achieve their treatment goals and maintain independence. To implement frailty screening and optimization into diverse surgical practices, a robust study is needed that tests an efficient screening and optimization tool and addresses clinical culture and barriers to implementation in a broad variety

of clinical settings. If feasible and effective on the practice level, the OPTI-Surg toolkit will improve the delivery of cancer surgery and quality of life for frail older adults in the U.S.

This study will inform care and improve outcomes for frail older adults who undergo major cancer surgery. If successful, this study will demonstrate that implementation of frailty screening is feasible in a busy clinic setting, acceptable to clinic staff, and that practice-based implementation of OPTI-Surg improves functional recovery in frail older adults and reduces post-operative morbidity. Furthermore, this trial has the potential for broad impact for cancer care delivery by serving as a model for testing and implementing practice-based interventions aimed at improving surgical outcomes not only among frail older adults but for patients with a variety of conditions.

1.5 Study design

We plan a cluster randomized trial to evaluate the effectiveness of practice-level implementation of OPTI-Surg. Practices will be randomized to the OPTI-Surg package intervention alone, OPTI-Surg with an implementation coach, or usual care. Interventions at the practice level are most likely to result in standardized approaches to patient evaluation and management with the highest likelihood of successful broad-based implementation. Randomization by practice will also prevent contamination. The comparison of coach versus no-coach arms will provide data on which practice change strategies are effective while ensuring that strategies are feasible and acceptable. Through this study design, we will both evaluate the effectiveness of the OPTI-Surg intervention to improve surgical outcomes at the patient level, but we will also gain further insight on the effectiveness of implementing this intervention at the practice level. We will gain knowledge about the implementation process as practices implement the OPTI-Surg Toolkit in order to better understand how practice level interventions should be conducted. Our design also includes direct measurement of practice culture and intervention roll-out through mixed methods (surveys, observation, and qualitative interviews). These mixed-methods data will identify barriers to implementation and acceptability, inform continuous improvement of the intervention, and provide insights into how to tailor the intervention to individual practice sites to ensure effective dissemination.

Study population: The target of intervention will be surgical practices. The study will include evaluation of patients, providers, and practice organizational and structural factors. Practices will be randomized to utilize the OPTI-Surg package intervention alone, OPTI-Surg with an implementation coach, or usual care. Eligible practices will be engaged in elective cancer operations that are high risk in older adults. Based on administrative data on operative mortality, the following have been identified as high risk in older adults: Gastrectomy 3-10%; colectomy 1-2%; proctectomy 2%; esophagectomy 6-16%; pancreatectomy 2-10%; hepatectomy 3-7%; nephrecetomy 2%; total cystectomy 3%; and lung lobectomy/pneumonectomy 3-9%.[19] Eligible practices will have a high prevalence of patients among whom there is a high risk of frailty and be categorized as either a thoracic, major abdominal, or urologic practice. Prior research has shown that > 50% of patients aged 70+ presenting for major surgery are frail.[6] Based on this data, patients included in the study will be (a) age ≥ 70 years who are presenting for surgical evaluation for (b) one of the noted high risk procedures (listed above). To address the variation in expected functional recovery by procedure type, we plan to stratify randomization by three practice types: (1) thoracic, (2) major abdominal, and (3) urologic. Esophagogastric procedures may be included in either the thoracic or major abdominal surgery categories, depending upon the specialty of the operating surgeon.

Endpoints: This study will incorporate both patient-level and site-level data collection. For patient-level data collection, individual eligible patients will be approached for participation and

will sign a consent form for completion of questionnaires preoperatively—at baseline prior to surgery or optimization intervention—and at 8 weeks after surgery.

For site-level data collection, data collection will consist of chart review and will include all eligible patients within the practice during the duration of the study. The primary study endpoint (patient-level data) is the function level 8 weeks after surgery. Physical function will be measured preoperatively at baseline and 8 weeks after surgery using the Community Healthy Activities Model Program for Seniors (CHAMPS) questionnaire. CHAMPS includes 41 questions that ask the senior to estimate the time spent on a range of activities. Among older adults with limited life-expectancy, function and independence are highly valued. A major goal of preoperative optimization of frailty traits is to improve baseline function and mitigate social vulnerability so that functional recovery is accelerated after surgery. The secondary endpoints (site-level data) are post-operative morbidity (grade I or higher surgical complications) and penetration of OPTI-Surg administration (i.e., screening rate among eligible patients) in the OPTI-Surg alone and OPTI-Surg plus coaching arms. Proctor and colleagues defined penetration as the "integration of a practice within a service setting and its subsystems."[21] Penetration will be calculated as the number of older adults administered the OPTI-Surg, divided by the total number of older adults eligible for OPTI-Surg.

1.6 Goals

The goal of this study is to improve the delivery of surgical cancer care in OPTI-Surg to identify vulnerabilities and promote targeted interventions to improve outcomes. This cluster-randomized trial will assess the effectiveness of the OPTI-Surg package within the NCORP community oncology research programs. The **primary goal** is to improve 8-week postoperative function among elderly patients through incorporation of a practice level targeted pre-surgical geriatric intervention. 8-week post-operative function will be compared between the combined OPTI-Surg arms versus the usual care arm. We hypothesize that among surgical practices that employ the frailty assessment and intervention, patient-reported function 8 weeks after surgery will be higher than the usual care sites.

Secondary goals are to assess the potential of the OPTI-Surg toolkit to decrease postoperative morbidity. We hypothesize that among surgical practices that employ the OPTI-Surg intervention, a lower proportion of patients will experience postoperative complications. We also seek to assess and compare the penetration of the OPTI-Surg within surgical practices between arms with and without an implementation coach. We will assess practice level rates of completion of the brief assessment for all older surgical patients and compare them between sites randomize to either no coach or coach.

We also hope to learn about how practice level changes can be implemented to impact global outcomes in the real-world setting. We will:

1) Assess the impact of the OPTI-Surg toolkit on postoperative mortality, length of hospital stay, discharge to a facility, and hospital readmission. Mortality, length of hospital stay, discharge to a facility, and hospital readmissions will be compared between the *combined* OPTI-Surg arms versus the usual care arm.
2) Assess subsequent referral for the indicated optimization intervention and assess practice-level structural factors associated with penetration of the OPTI-Surg package. We hypothesize that OPTI-Surg implementation rates will vary depending on the available resources and capacity and the presence or absence of stakeholder buy-in, but that it can be influenced by the presence of an implementation coach.

3) Explore the acceptability, feasibility, and appropriateness of the intervention (Section 10) [More information for institutions randomized to OPTI-Surg arms is provided in Appendices III and X.].
4) Document and assess barriers and facilitators to implementation through mixed-methods research. To facilitate interpretation of the trial results and to facilitate future dissemination and implementation, we propose to use mixed-methods (qualitative and quantitative) to collect and analyze data. To collect quantitative data, we will use a validated survey, the Organizational Readiness to Change Assessment (ORCA), to assess practice readiness and identify potential barriers or challenges.[22]

Qualitative data will be collected during site visits with selected study sites. These in-depth ethnographic case studies will occur at a total of 12 Alliance sites – 2 usual care sites, 5 sites with the OPTI-Surg intervention only, and 5 sites that have the OPTI-Surg intervention plus the coach. The site visit will include observation of everyday clinic processes and interviews with clinic leaders, staff, and front-line workers. Site visits will be conducted before, during, and after the implementation of the OPTI-Surg intervention in order to examine barriers and facilitators to implementing the intervention. Specifically, we will plan site visits at the 12 case-study sites at the following three points in time: 1) a **baseline** site visit will occur before the OPTI-Surg intervention has been introduced at the site; 2) an **in-progress** site visit will occur after OPTI-Surg intervention has been implemented and while it is still active; we will schedule this visit after the 5th patient has been recruited and ensure that the site visit occurs before enrollment at the site is complete; 3) a **post-intervention** visit will occur 6-9 months after the final (15th) patient has been recruited at the study site; this visit will assess what, if any, lasting impact OPTI-Surg appears to have had on practice culture and routines at the site.

2.0 OBJECTIVES

2.1 Primary objective

To compare 8-week postoperative function among elderly patients between sites randomized to implement the OPTI-Surg toolkit with or without a coach versus sites randomized to usual care.

2.2 Secondary objectives

2.2.1 To compare postoperative morbidity between sites randomized to implement the OPTI-Surg toolkit with or without a coach versus sites randomized to usual care.

2.2.2 To compare the penetration of the OPTI-Surg toolkit between sites randomized to implement the OPTI-Surg toolkit with a coach versus sites randomized to implement the OPTI-Surg toolkit without a coach.

2.3 Exploratory objectives

2.3.1 To compare postoperative mortality, hospital length of stay, discharge to a facility, and hospital readmission between sites randomized to implement the OPTI-Surg toolkit with or without a coach versus sites randomized to usual care.

2.3.2 To assess subsequent initiation and follow through of appropriate referral for the indicated optimization intervention and assess practice-level structural factors associated with uptake of the OPTI-Surg package.

2.3.3 To document and assess barriers and facilitators to implementation and dissemination through mixed-methods research.

3.0 PATIENT SELECTION

For questions regarding eligibility criteria, see the Study Resources page. Please note that the Study Chair cannot grant waivers to eligibility requirements.

3.1 Eligibility Criteria

___ **3.1.1 Eligible patients must have known or suspected cancer diagnosis and have one of the following cancer-directed operations planned:**

- Gastrectomy
- Colectomy
- Proctectomy
- Esophagectomy
- Pancreatectomy
- Hepatectomy
- Total cystectomy
- Partial or Total Nephrectomy
- Lung resection (wedge resection, segmentectomy, lobectomy, or pneumonectomy)

___ **3.1.2 Age ≥ 70 years**

___ **3.1.3 Patients with known metastatic disease with a plan for curative intent resection are eligible** (e.g., curative liver resection for metastatic colorectal cancer).

___ **3.1.4 Patients with double primaries undergoing planned curative operation for both are eligible** (e.g., synchronous colon cancers undergoing colectomy to treat both)**.**

___ **3.1.5 Patients undergoing emergent surgery are not eligible.**

___ **3.1.6 Patients under active treatment such as chemotherapy, targeted therapy, immunotherapy, radiation treatment, etc. for second primary, are not eligible.** However, patients not currently receiving treatment are eligible, including patients who have been previously treated for another cancer. Patients are not considered to have a "currently active" malignancy if they have completed therapy and are free of disease for ≥ 2 years.

___ **3.1.7 Patients with known metastatic disease who are undergoing palliative resection are not eligible.**

___ **3.1.8 Patients with psychiatric illness or other mental impairment that would preclude their ability to give informed consent or to participate in the prehabilitation program are not eligible.**

___ **3.1.9 Patients must be able to speak and complete questionnaires in English.**

4.0 PATIENT REGISTRATION

4.1 Investigator and Research Associate Registration with CTEP

Food and Drug Administration (FDA) regulations and National Cancer Institute (NCI) policy require all individuals contributing to NCI-sponsored trials to register and renew their registration annually. To register, all individuals must obtain a Cancer Therapy Evaluation Program (CTEP) Identity and Access Management (IAM) account at [redacted] In addition, persons with a registration type of Investigator (IVR), Non-Physician Investigator (NPIVR), or Associate Plus (AP) must complete their annual registration using CTEP's web-based Registration and Credential Repository (RCR) at [redacted]

RCR utilizes five person registration types.

- IVR — MD, DO, or international equivalent;
- NPIVR — advanced practice providers (e.g., NP or PA) or graduate level researchers (e.g., PhD);
- AP — clinical site staff (e.g., RN or CRA) with data entry access to CTSU applications such as the Roster Update Management System [RUMS], OPEN, Rave, acting as a primary site contact, or with consenting privileges;
- Associate (A) — other clinical site staff involved in the conduct of NCI-sponsored trials; and
- Associate Basic (AB) — individuals (e.g., pharmaceutical company employees) with limited access to NCI-supported systems.

RCR requires the following registration documents:

Documentation Required	IVR	NPIVR	AP	A	AB
FDA Form 1572	✓	✓			
Financial Disclosure Form	✓	✓	✓		
NCI Biosketch (education, training, employment, license, and certification)	✓	✓	✓		
GCP training	✓	✓	✓		
Agent Shipment Form (if applicable)	✓				
CV (optional)	✓	✓	✓		

An active CTEP-IAM user account and appropriate RCR registration is required to access all CTEP and Cancer Trials Support Unit (CTSU) websites and applications. In addition, IVRs and NPIVRs must list all clinical practice sites and Institutional Review Boards (IRBs) covering their practice sites on the FDA Form 1572 in RCR to allow the following:

- Addition to a site roster;
- Assign the treating, credit, consenting, or drug shipment (IVR only) tasks in OPEN;
- Act as the site-protocol Principal Investigator (PI) on the IRB approval; and
- Assign the Clinical Investigator (CI) role on the Delegation of Tasks Log (DTL).

In addition, all investigators acting as the Site-Protocol PI (investigator listed on the IRB approval), consenting/treating/drug shipment investigator in OPEN, or as the CI on the DTL must be rostered at the enrolling site with a participating organization.

Additional information is located on the CTEP website at [redacted]For questions, please contact the **RCR Help Desk** by email at [redacted]

4.2 Cancer Trials Support Unit Registration Procedures

Permission to view and download this protocol and its supporting documents is restricted and is based on person and site roster assignment housed in the CTSU Regulatory Support System (RSS).

This study is supported by the NCI Cancer Trials Support Unit (CTSU).

IRB Approval:

For CTEP and Division of Cancer Prevention (DCP) studies open to the National Clinical Trials Network (NCTN) and NCI Community Oncology Research Program (NCORP) Research Bases after March 1, 2019, all U.S.-based sites must be members of the NCI Central Institutional Review Board (NCI CIRB). In addition, U.S.-based sites must accept the NCI CIRB review to activate new studies at the site after March 1, 2019. Local IRB review will continue to be accepted for studies that are not reviewed by the CIRB, or if the study was previously open at the site under the local IRB. International sites should continue to submit Research Ethics Board (REB) approval to the CTSU Regulatory Office following country-specific regulations.

Sites participating with the NCI CIRB must submit the Study Specific Worksheet for Local Context (SSW) to the CIRB using IRBManager to indicate their intent to open the study locally. The NCI CIRB's approval of the SSW is automatically communicated to the CTSU Regulatory Office, but sites are required to contact the CTSU Regulatory Office at [redacted] to establish site preferences for applying NCI CIRB approvals across their Signatory Network. Site preferences can be set at the network or protocol level. Questions about establishing site preferences can be addressed to the CTSU Regulatory Office by email or calling [redacted]

In addition, the Site-Protocol Principal Investigator (PI) (i.e. the investigator on the IRB/REB approval) must meet the following criteria in order for the processing of the IRB/REB approval record to be completed:

- Holds an active CTEP status;
- Rostered at the site on the IRB/REB approval *(applies to US and Canadian sites only)* and on at least one participating roster;
- If using NCI CIRB, rostered on the NCI CIRB Signatory record;
- Includes the IRB number of the IRB providing approval in the Form FDA 1572 in the RCR profile; and
- Holds the appropriate CTEP registration type for the protocol.

Additional Requirements

Additional requirements to obtain an approved site registration status include:

- An active Federal Wide Assurance (FWA) number;

- An active roster affiliation with the Lead Protocol Organization (LPO) or a Participating Organization (PO); and
- Compliance with all protocol-specific requirements (PSRs).

4.2.1 Protocol-Specific Requirements for A231601CD Site Registration

- Institutional Approval Document (see Section 4.3.1)
- Practice Level Data Collection Form – The enrolling affiliate/sub affiliate will complete the NCORP Practice Level Data Collection Form and submit it to the CTSU Regulatory Office using the Regulatory Submission Portal located in the Regulatory section of the CTSU website. The form will collect various attributes about the enrolling affiliate/sub affiliate. All of the questions on the form must be complete and the distribution for the analytic cases question must equal 100%. (See form for directions.) The form must be received and complete for site registration approval in RSS. The Practice Level Data Collection Form requirement is submitted once for participation on all NCORP Cancer Care Delivery (CCDR) trials, but will expire two years after it is received. NCORP sites will need to resubmit the Practice Level Data Form to the CTSU in order to continue to enroll to CCDR trials.

4.2.2 Downloading site registration documents

Download the site registration forms from the protocol-specific page located on the CTSU members' website. Permission to view and download this protocol and its supporting documents is restricted based on person and site roster assignment. To participate, the institution and its associated investigators and staff must be associated with the LPO or a Protocol Organization (PO) on the protocol. One way to search for a protocol is listed below.

- Log in to the CTSU members' website [redacted] using your CTEP-IAM username and password;
- Click on *Protocols* in the upper left of the screen
    - Enter the protocol number in the search field at the top of the protocol tree; or
    - Click on the By Lead Organization folder to expand, then select *Alliance*, and protocol number *A231601CD.*
- Click on Documents, select Site Registration, and download and complete the forms provided.

  (Note: For sites under the CIRB, IRB data will load automatically to the CTSU.)

4.2.3 Submitting Regulatory Requirements

Submit required forms and documents to the CTSU Regulatory Office using the Regulatory Submission Portal on the CTSU website.

To access the Regulatory Submission Portal log in to the CTSU members' website, go to the Regulatory section and select Regulatory Submission.

Institutions with patients waiting that are unable to use the Regulatory Submission Portal should alert the CTSU Regulatory Office immediately at [redacted] in order to receive further instruction and support.

4.2.4 Checking Site's Registration Status

Site registration status may be verified on the CTSU members' website.

- Click on *Regulatory* at the top of the screen;
- Click on *Site Registration*; and
- Enter the site's 5-character CTEP Institution Code and click on Go.
    - Additional filters are available to sort by Protocol, Registration Status, Protocol Status, and/or IRB Type.

Note: The status shown only reflects institutional compliance with site registration requirements as outlined within the protocol. It does not reflect compliance with protocol requirements for individuals participating on the protocol or the enrolling investigator's status with NCI or their affiliated networks.

4.3 Institutional randomization and arm-specific protocols

4.3.1 Institutional Registration

Institutions that are interested in participating in this study must contact the study Project Manager, [redacted] for site approval procedures:

[redacted]

Sites should complete the information required in the Institutional Approval Document posted along with Supplementary materials on the Alliance and CTSU websites, and send it to [redacted] at the email address listed above. The document will ask for the following information: Name of the site, CTEP Site Code, CTEP Site Code of Main NCORP and contact information (Full name and email) of site staff who will complete the site/practice survey in Medidata Rave.

To approve the site for participation, the project manager will return this document to the institution with a signature of approval. As soon as the site receives IRB approval, it must submit this Institutional Approval Document to the Alliance Registration Office via fax [redacted] or email at [redacted] The registration office will register the site to the study and send confirmation to the site via email within 1 business day, in order to be invited to enter site level data in Medidata Rave. The study will not use OPEN for site/practice enrollment. The contact person listed on the Institutional Approval Document will be sent an invitation to enter site level data in Medidata Rave.

Additionally, the site will also submit this document to the CTSU Regulatory portal (see Section 4.2.3) in order to begin patient enrollment.

4.3.2 Randomization will be stratified by practice type (thoracic, major abdominal, and urologic).

The Alliance Statistics and Data Management Center will randomize surgical practices once an institution is interested and eligible to participate. All participants enrolled at a site will receive the intervention to which the treating institution is randomized.

Institutions will be randomized to one of three intervention arms:

1) Usual Care
2) OPTI-Surg without coach
3) OPTI-Surg with coach

4.3.3 Intervention-specific appendices

In order to maintain institutional blinding with respect to OPTI-Surg interventions, information specific to the OPTI Surg arms is provided separately in Appendices III and X. Following randomization, practices should contact [redacted] to obtain the appendices specific to the intervention arm to which the practice has been randomized. The OPTI-Surg Toolkit/Manual will also be provided to sites at this time.

4.4 Patient Registration Requirements

Informed consent: The patient must be aware of the neoplastic nature of his/her disease and willingly consent after being informed of the procedure to be followed, the experimental nature of the intervention, alternatives, potential benefits, side-effects, risks, and discomforts. Current human protection committee approval of this protocol and a consent form is required prior to patient consent and registration.

Patient completed booklets: Patient questionnaire booklets are to be ordered prior to the registration of any patients. Patient completed booklets can be ordered by downloading and completing the CTSU supply request form, located on the CTSU Forms webpage under the Resources tab. The form must be submitted via the Regulatory Submission Portal on the CTSU website, located under the Regulatory tab. Samples of the booklets are found in Appendix I, which are to be used for reference and IRB submission only. They are not to be used for patient completion.

4.5 Patient Registration/Randomization Procedures

The Oncology Patient Enrollment Network (OPEN) is a web-based registration system available on a 24/7 basis. OPEN is integrated with CTSU regulatory and roster data and with the LPOs registration/randomization systems or the Theradex Interactive Web Response System (IWRS) for retrieval of patient registration/randomization assignment. OPEN will populate the patient enrollment data in NCI's clinical data management system, Medidata Rave.

Requirements for OPEN access:

- A valid CTEP-IAM account;
- To perform enrollments or request slot reservations: Must be on an LPO roster, ETCTN corresponding roster, or participating organization roster with the role of Registrar. Registrars must hold a minimum of an Associate Plus (AP) registration type;
- If a Delegation of Tasks Log (DTL) is required for the study, the registrars must hold the OPEN Registrar task on the DTL for the site; and
- Have an approved site registration for the protocol prior to patient enrollment.

To assign an Investigator (IVR) or Non-Physician Investigator (NPIVR) as the treating, crediting, consenting, drug shipment (IVR only), or receiving investigator for a patient transfer in OPEN, the IVR or NPIVR must list the IRB number used on the site's IRB approval on their Form FDA 1572 in RCR. If a DTL is required for the study, the IVR or NPIVR must be assigned the appropriate OPEN-related tasks on the DTL.

Prior to accessing OPEN, site staff should verify the following:

- Patient has met all eligibility criteria within the protocol stated timeframes; and
- All patients have signed an appropriate consent form and HIPAA authorization form (if applicable).

Note: The OPEN system will provide the site with a printable confirmation of registration and treatment information. You may print this confirmation for your records.

Access OPEN at [redacted] or from the OPEN link on the CTSU members' website. Further instructional information is in the OPEN section of the CTSU website at [redacted] For any additional questions, contact the CTSU [redacted]

4.6 Stratification (or Grouping) Factors and Treatment Assignments

Site randomization will be stratified by practice type:

- Thoracic vs.
- Major abdominal vs.
- Urologic

Patients will be grouped by site randomized arm:

- Arm 1: Usual Care
- Arm 2: OPTI-Surg without coach
- Arm 3: OPTI-Surg with coach

5.0 STUDY CALENDAR

The pre-study testing intervals are guidelines only. Laboratory and clinical parameters during treatment are to be followed using individual institutional guidelines and the best clinical judgment of the responsible physician. It is expected that patients on this study will be cared for by physicians experienced in the treatment and supportive care of patients on this trial.

Pre-Study Testing Intervals

To be completed ≤ 28 DAYS before registration: History and physical.

5.1 Patient-level Study Calendar

[Patient-level study calendars for practices randomized to Arms 2 and 3 are provided are Appendices III and X.]

	Screening	**Baseline***	**Day of Surgery**	**8 weeks following surgery**	**12 weeks following surgery**
	Collected for all eligible (screened) patients				
Postoperative complications and outcomes				X (1)	X (1)
Adverse Event Assessment			X (1)		
	Administered to all consenting patients				
Laboratory Studies					
HgB, WBC, Platelets		X		X***	
Serum creatinine		X		X***	
Serum albumin		X		X***	
Tests & Observations**					
ECOG PS		X		X***	
CHAMPS and EQ-5D Qx		X		X***	

* At initial surgical consultation. Questionnaires may be completed at any time following consent, before or after registration. Additionally, sites may leverage satellite NCORP locations to obtain baseline and 8-week follow-up labs and forms.

** Site staff may contact participants via email, U.S. mail, telephone and/or telehealth to administer and obtain questionnaires and assessments, including the CHAMPS Survey and the ECOG Performance Score.

*** Post surgery visits can be +/- 7 days

1. For the purposes of collecting and reporting adverse events into the Alliance database using Rave "adverse events" are those potentially resulting from intervention occurring between baseline and surgery. "Surgical complications" will be assessed 8 and 12 weeks after surgery using the Clavien-Dindo Classification. All CTEP-AERS events should be reported as outlined in Section 9.0.

5.2 Site-level Study Calendar

[Site level study calendars for practices randomized to Arms 2 and 3 are provided in Appendices III and X.]

	Baseline*	Monthly	After 5th patient is enrolled and 6 to 9 mos. after last patient is enrolled	6, 12 and 24 months
Demographic and structural data	X			
Organizational Readiness to Change Assessment (ORCA)	X			X
Ethnographic interviews and observations	X (1)		X (1)	
Listing of eligible patients		X		
Postoperative Complications	Administered per patient schedule and submitted monthly (3)			

* Following local IRB approval/activation of the study.

1. To be administered to staff at 5 sites randomized to each intervention arm.
3. Clavien Dindo Classification for grading severity of complications and American College of Surgeons' National Quality Improvement Program geriatric outcome variables (Section 10.3.1). To be collected for all eligible patients (including those who do not consent to completing the CHAMPS and EQ-5D questionnaires).

6.0 DATA SUBMISSION

6.1 Data Collection and Submission

Medidata Rave is a clinical data management system being used for data collection for this trial/study. Access to the trial in Rave is controlled through the CTEP-IAM system and role assignments.
Requirements to access Rave via iMedidata:

- A valid CTEP-IAM account; and
- Assigned a Rave role on the LPO or PO roster at the enrolling site of: Rave CRA, Rave Read Only, Rave CRA (LabAdmin), Rave SLA, or Rave Investigator.

Rave role requirements:

- Rave CRA or Rave CRA (Lab Admin) role must have a minimum of an Associate Plus (AP) registration type;
- Rave Investigator role must be registered as an Non-Physician Investigator (NPIVR) or Investigator (IVR); and
- Rave Read Only role must have at a minimum an Associates (A) registration type.

Refer to [redacted] for registration types and documentation required.

Upon initial site registration approval for the study in Regulatory Support System (RSS), all persons with Rave roles assigned on the appropriate roster will be sent a study invitation e-mail from iMedidata. To accept the invitation, site staff must log in to the Select Login [redacted] using their CTEP-IAM username and password and click on the accept link in the upper right-corner of the iMedidata page. Site staff will not be

able to access the study in Rave until all required Medidata and study specific trainings are completed. Trainings will be in the form of electronic learnings (eLearnings) and can be accessed by clicking on the link in the upper right pane of the iMedidata screen. If an eLearning is required and has not yet been taken, the link to the eLearning will appear under the study name in iMedidata instead of the Rave EDC link; once the successful completion of the eLearning has been recorded, access to the study in Rave will be granted, and a Rave EDC link will display under the study name.

Site staff that have not previously activated their iMedidata/Rave account at the time of initial site registration approval for the study in RSS will receive a separate invitation from iMedidata to activate their account. Account activation instructions are located on the CTSU website in the Data Management section under the Rave resource materials (Medidata Account Activation and Study Invitation Acceptance). Additional information on iMedidata/Rave is available on the CTSU members' website in the Data Management > Rave section at [redacted] or by contacting the CTSU Help Desk at [redacted]

A Schedule of Forms is available on the Alliance study webpage, within the Case Report Forms section. The Schedule of Forms is also available on the CTSU site within the study-specific Education and Promotion folder, and is named Time & Events.

Patient-completed questionnaire booklets for this study are to be ordered prior to the registration of any patients (see Section 4.4). Samples of questionnaire booklets are available in Appendix I for reference and IRB submission only. They are not to be used for patient completion. Booklets must be given to patients to complete and patients should be instructed to return the booklets to site staff either in person or by mail and site staff will enter patient and caregiver responses into Rave.

6.1.1 Data Quality Portal

The Data Quality Portal (DQP) provides a central location for site staff to manage unanswered queries and form delinquencies, monitor data quality and timeliness, generate reports, and review metrics.

The DQP is located on the CTSU members' website under Data Management. The Rave Home section displays a table providing summary counts of Total Delinquencies and Total Queries. DQP Queries, DQP Delinquent Forms and the DQP Reports modules are available to access details and reports of unanswered queries, delinquent forms, and timeliness reports. Review the DQP modules on a regular basis to manage specified queries and delinquent forms.

The DQP is accessible by site staff that are rostered to a site and have access to the CTSU website. Staff that have Rave study access can access the Rave study data using a direct link on the DQP.

To learn more about DQP use and access, click on the Help icon displayed on the Rave Home, DQP Queries, and DQP Delinquent Forms modules.

Note: Some Rave protocols may not have delinquent form details or reports specified on the DQP. A protocol must have the Calendar functionality implemented in Rave by the Lead Protocol Organization for delinquent form details and reports to be available on the DQP. Site staff should contact the LPO Data Manager for their protocol regarding questions about Rave Calendaring functionality.

6.1.2 Supporting Documentation to be Submitted to the Alliance

This study requires supporting documentation for diagnosis and treatment of the cancer that is the target of the planned surgery. Supporting documentation will include:

- Preoperative imaging reports (CT, MRI, PET/CT).
- Operative reports.
- Surgical pathology reports.

Supporting documentation is to be submitted via Rave. Note: The pre-operative imaging is to be submitted within 12 weeks after registration.

6.1.3 Practice level data

Demographic and Structural Data: At baseline, the study team will collect basic practice-related demographic information and details regarding the organizational structure and resource availability (e.g., practice volume; payer mix; solo, single specialty, or multi-specialty group practice; availability of geriatric specialists, palliative care providers, advanced practice providers, patient navigators, on site occupational and physical therapy, social workers, pharmacists, dietetics, integrative medicine).

Qualitative Data: The team will collect qualitative data to document practice-level barriers and facilitators to OPTI-Surg implementation from 12 practices: 5 each from the two OPTI-Surg arms and 2 practices from the usual care arm. In-person site visits to collect qualitative data will take place at the following time points: Baseline (prior to the introduction of the OPTI-Surg intervention); after the fifth patient has been enrolled at the practice; and 6 to 9 months after the last patient has been enrolled at the practice. Qualitative data will be collected via direct observation of clinic processes and key-informant interviews with practice leadership and with front-line staff.

7.0 STUDY IMPLEMENTATION

7.1 Eligible Practices

Eligible practices will be engaged in elective cancer operations that are high risk in older adults. Based on administrative data on operative mortality, the following have been identified as high risk in older adults: gastrectomy 3-10%; colectomy 1-2%; proctectomy 2%; esophagectomy 6-16%; pancreatectomy 2-10%; hepatectomy 3-7%; nephrectomy 2%; total cystectomy 3%; and lung lobectomy/pneumonectomy 3-9%.

Eligible practices will have a high prevalence (at least 10 cases per year) of patients among whom there is a high risk of frailty (age ≥70 years old) and be categorized as either a thoracic, major abdominal, or urologic practice. Practices should identify a clinical research professional, allied health professional, or equivalent to implement OPTI-Surg.

Eligible practices should provide a brief description of any existing programs for frailty assessment and intervention. If their current practice includes the assessment and interventions specified in the protocol, they will be ineligible.

See Section 4.3.1 for information regarding site approval procedures.

7.2 OPTI-Surg Toolkit

For practices randomized to Arm 2, see Appendix III; For practices randomized to Arm 3, see Appendix X.

7.3 Institutional training

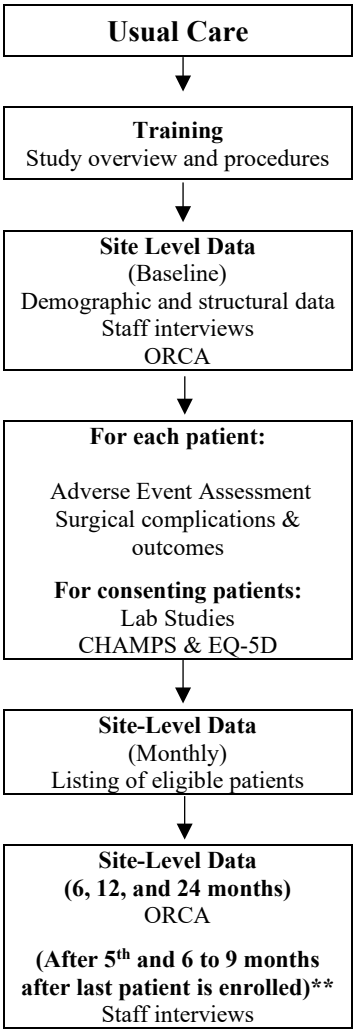
For practices randomized to Arm 2, see Appendix III; For practices randomized to Arm 3, see Appendix X.

7.4 Randomization

Randomization will be stratified by practice type (thoracic, major abdominal, and urologic). Pocock-Simon dynamic allocation with a 5% level of randomness (to ensure that the algorithm is not deterministic) added to the algorithm such that practices will be assigned to the arm in a 1:1:1 fashion that leads to more imbalance 5% of the time. Site randomization will be centrally performed by the Alliance Statistical and Data Center once an institution is interested and eligible to participate (see Section 4.3).

7.5 Site/Practice implementation

For institutions randomized to Arm 2 see Appendix III; for institutions randomized to Arm 3, see Appendix X.



** Only to be done at 2 practices randomized to the Usual Care arm.

7.5.1 Usual Care

These practices will not get the OPTI-Surg intervention. Practices randomized to usual care will complete the practice demographic and structural survey and the ORCA questionnaire at baseline (i.e., as soon as the practice site agree to participate and before training) and at 6, 12, and 24 months following site activation. Two practices randomized to usual care will also undergo staff interviews at baseline, after the fifth patient is enrolled, and 6 to 9 months after the last patient is enrolled to the study at the practice.

For all patients (consented and unconsented) aged ≥ 70 years, practices will keep a log of all patients seen. The practice will submit the log monthly. In addition, the practices will submit data abstracted from patient charts. Practices will report surgical complications for all eligible patients. The log will be a spreadsheet format of the case report form variables.

The CHAMPS and EQ-5D-5L questionnaires will be administered to consenting eligible patients at the time of the initial surgical consultation and 8 weeks after surgery.

7.5.2 OPTI-Surg without Coach

For institutions randomized to Arm 2. See Appendix III.

7.5.3 OPTI-Surg with Coach

For institutions randomized to Arm 3. See Appendix X.

8.0 STUDY INTERVENTION

[Additional information for practices randomized to Arm 2 or Arm 3 can be found in Appendix III and Appendix X, respectively.]

The patient-level intervention will involve identification of eligible patients utilizing medical record review at all participating institutions.

After patient registration to the study, the CHAMPS and EQ-5D-5L questionnaires will be administered. Patients will then proceed to surgery. The follow-up CHAMPS and EQ-5D-5L questionnaires will be administered 8 weeks after surgery.

All eligible patients (including those not consented to the study) will be assessed for surgical complications 8 and 12 weeks after surgery.

8.1 Electronic Medical Review (EMR)

[Additional information for practices randomized to Arm 2 or Arm 3 can be found in Appendix III and Appendix X, respectively.]

All eligible patients at all participating institutions will be identified using EMR monthly and as needed to screen patients for participation. Eligibility of all patients whether consenting to participate in the questionnaire portion of the study or not will be determined. Surgical complications will also be recorded for all patients.

8.2 Frailty assessment

For practices randomized to Arm 2, see Appendix III; For practices randomized to Arm 3. See Appendix X.

8.3 Patient consent and registration

All eligible patients at all participating practices should then be asked to participate in the questionnaire portion of this study, and if willing, consented.

8.4 Baseline questionnaire administration and pre-surgical interventions

8.4.1 Baseline questionnaires (all practices)

Following patient consent to the study (before or after registration), patients will be asked to complete the CHAMPS and questionnaire and the EQ-5D-5L.

8.4.2 Pre-surgical intervention—Practices randomized to usual care arm

Patients treated at practices randomized to usual care will undergo pre-operative management for surgery per usual institutional practices.

8.4.3 Pre-surgical intervention—Practices randomized to OPTI-Surg arms

For practices randomized to Arm 2, see Appendix III; For practices randomized to Arm 3, see Appendix X.

8.5 Surgery and Follow-up (all sites)

Surgery will be performed per the treating physician.

For all patients, **adverse events** occurring from the patient's initial evaluation to surgery will be collected. In addition, **surgical complications** will be assessed 8 and 12 weeks after surgery.

For registered patients only, **the questionnaires (CHAMPS and EQ-5D-5L)** will be administered at 8 weeks.

9.0 ADVERSE EVENTS

The prompt reporting of adverse events is the responsibility of each investigator engaged in clinical research, as required by Federal Regulations. Adverse events must be described and graded using the terminology and grading categories defined in the NCI's Common Terminology Criteria for Adverse Events (CTCAE), Version 5.0. The CTCAE is available at [redacted] Attribution to protocol treatment for each adverse event must be determined by the investigator and reported on the required forms. Please refer the NCI Guidelines: Adverse Event Reporting Requirements for further details on AE reporting procedures.

9.1 Routine Adverse Event Reporting

Adverse event data collection and reporting, which are required as part of every clinical trial are done to ensure the safety of patients enrolled in the studies as well as those who will enroll in future studies using similar agents. Adverse events are reported in a routine manner at scheduled times according to the study calendar in Section 5.0. For this trial, "Adverse Event: Other" form is to be used for routine AE reporting in Rave.

9.2 CTCAE Routine Reporting Requirements

In addition to the solicited adverse events listed in Section 9.1, the following table outlines the combinations of time points, grades and attributions of AEs that require routine reporting to the Alliance Statistics and Data Center. Questions about routine reporting should be directed to the Data Manager.

Combinations of CTCAE Grade & Attribution Required for Routine AE Data Submission on Case Report Forms (CRFs)

Attribution	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Unrelated			a	a	a
Unlikely			a	a	a
Possible		a	a, b	a, b	a, b
Probable		a	a, b	a, b	a, b
Definite		a	a, b	a, b	a, b

a) Adverse Events: Other CRF - Applies to AEs occurring between registration and within 30 days of the patient's last treatment date, or as part of the Clinical Follow-Up Phase.

b) Adverse Events: Late CRF - Applies to AEs occurring greater than 30 days after the patient's last treatment date.

9.3 Expedited Adverse Event Reporting (CTEP-AERS)

Investigators are required by Federal Regulations to report serious adverse events as defined in the table below. Alliance investigators are required to notify the Alliance Central Protocol Operations Program, the Study Chair, and their Institutional Review Board if a patient has a reportable serious adverse event. The descriptions and grading scales found in the NCI Common Terminology Criteria for Adverse Events (CTCAE) version 5.0 will be utilized for AE reporting. The CTCAE is identified and located on the CTEP website at: [redacted] All appropriate treatment areas should have access to a copy of the CTCAE. All reactions determined to be "reportable" in an expedited manner must be reported using the Cancer Therapy Evaluation Program Adverse Event Reporting System (CTEP-AERS).

For further information on the NCI requirements for SAE reporting, please refer to the 'NCI Guidelines for Investigators: Adverse Event Reporting Requirements' document published by the NCI.

Note: All deaths on study require both routine and expedited reporting regardless of causality. Attribution to treatment or other cause should be provided.

9.3.1 Expedited Reporting Requirements for Adverse Events that Occur in a Non-IND/IDE trial ≤ 30 Days of the Last Administration

FDA REPORTING REQUIREMENTS FOR SERIOUS ADVERSE EVENTS (21 CFR Part 312)

NOTE: Investigators **MUST** immediately report to the sponsor (NCI) **ANY** Serious Adverse Events, whether or not they are considered related to the investigational agent(s)/intervention (21 CFR 312.64)

An adverse event is considered serious if it results in **ANY** of the following outcomes:

1) Death
2) A life-threatening adverse event
3) An adverse event that results in inpatient hospitalization or prolongation of existing hospitalization for ≥ 24 hours
4) A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
5) A congenital anomaly/birth defect.
6) Important Medical Events (IME) that may not result in death, be life threatening, or require hospitalization may be considered serious when, based upon medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. (FDA, 21 CFR 312.32; ICH E2A and ICH E6).

ALL SERIOUS adverse events that meet the above criteria **MUST** be immediately reported to the NCI via CTEP-AERS within the timeframes detailed in the table below.

Hospitalization	• Grade 1 Timeframes	• Grade 2 Timeframes	• Grade 3 Timeframes	Grade 4 & 5 Timeframes
Resulting in Hospitalization ≥ 24 hrs.	10 Calendar Days			24-Hour; 5 Calendar Days
Not resulting in Hospitalization ≥ 24 hrs.	Not required		10 Calendar Days	

NOTE: Protocol specific exceptions to expedited reporting of serious adverse events are found in the Specific Protocol Exceptions to Expedited Reporting detailed below.

Expedited AE reporting timelines are defined as:

- "24-Hour; 5 Calendar Days" - The AE must initially be reported via CTEP-AERS ≤ 24 hours of learning of the AE, followed by a complete expedited report ≤ 5 calendar days of the initial 24-hour report.
- "10 Calendar Days" - A complete expedited report on the AE must be submitted ≤ 10 calendar days of learning of the AE.

[1] Serious adverse events that occur more than 30 days after the last administration of investigational agent/intervention and have an attribution of possible, probable, or definite require reporting as follows:

Expedited 24-hour notification followed by complete report ≤ 5 calendar days for:

- All Grade 4, and Grade 5 AEs

Expedited 10 calendar day reports for:

- Grade 2 adverse events resulting in hospitalization or prolongation of hospitalization
- Grade 3 adverse events

- Expedited AE reporting timelines defined:
  - "24 hours; 5 calendar days" – The investigator must initially report the AE via CTEP-AERS ≤ 24 hours of learning of the event followed by a complete CTEP-AERS report ≤ 5 calendar days of the initial 24-hour report.
  - "10 calendar days" - A complete CTEP-AERS report on the AE must be submitted ≤ 10 calendar days of the investigator learning of the event.
- Any medical event equivalent to CTCAE grade 3, 4, or 5 that precipitates hospitalization (or prolongation of existing hospitalization) must be reported regardless of attribution and designation as expected or unexpected with the exception of any events identified as protocol-specific expedited adverse event reporting exclusions (see below).
- Any event that results in persistent or significant disabilities/incapacities, congenital anomalies, or birth defects must be reported via CTEP-AERS if the event occurs following treatment with an agent under a CTEP IND.
- Use the NCI protocol number and the protocol-specific patient ID provided during trial registration on all reports.

9.3.3 Additional Instructions or Exclusion to CTEP-AERS Expedited Reporting Requirements for Alliance A231601CD

All adverse events reported via CTEP-AERS (i.e., serious adverse events) should also be forwarded to your local IRB.

Death due to progressive disease should be reported as Grade 5 "Disease progression" in the system organ class (SOC) "General disorders and administration site conditions." Evidence that the death was a manifestation of underlying disease (e.g., radiological changes suggesting tumor growth or progression: clinical deterioration associated with a disease process) should be submitted.

Any death occurring within 30 days of the last intervention, regardless of attribution to the investigational agent/intervention requires expedited reporting within 24 hours.

Any death occurring greater than 30 days after the last intervention of the investigational agent/intervention requires expedited reporting within 24 hours only if it is possibly, probably, or definitely related to the investigational agent/intervention.

All new malignancies must be reported via CTEP-AERS whether or not they are thought to be related to either previous or current treatment. All new malignancies should be reported, i.e. solid tumors (including non-melanoma skin malignancies), hematologic malignancies, myelodysplastic syndrome/acute myelogenous leukemia, and in situ tumors. In CTCAE version 4.0, the new malignancies (both second and secondary) may be reported as one of the following: (1) Leukemia secondary to oncology chemotherapy, (2) Myelodysplastic syndrome, (3) Treatment-related secondary malignancy, or (4) Neoplasms benign, malignant and unspecified-other. Whenever possible, the CTEP-AERS reports for new malignancies should include tumor pathology, history or prior tumors, prior treatment/current treatment including duration, any associated risk factors or evidence regarding how long the new malignancy may have been present, when and how the new malignancy was detected, molecular characterization or cytogenetics of the original tumor (if available) and of any new tumor, and new malignancy treatment and outcome, if available.

10.0 MEASURES

10.1 Definitions of endpoints

Primary endpoint: Function at 8 weeks post-surgery as measured by the CHAMPS questionnaire.

Secondary and exploratory endpoints: (1) Postoperative complications (Clavien-Dindo grades I-V) mortality, American College of Surgeons' National Quality Improvement Program geriatric outcome variables, hospital length of stay, discharge to a facility, and hospital readmission within 8 and 12 weeks of surgery. (2) Penetration of the EFS screening tool among all eligible patients within each of the OPTI-Surg arms defined as the total number of eligible patients who underwent screening divided by the total number of eligible patients (actual point estimate will take into account site clustered, see statistical analysis plan).

10.2 Schedule of evaluations

10.2.1 Schedule of evaluations for participating practices

Practices will be evaluated by ORCA at baseline and at 6, 12, and 24 months following site activation. Practices will complete the Intervention Appropriateness Measure (IAM), the Acceptability of Intervention Measure (AIM), and the Feasibility of Intervention Measure (FIM) at baseline, and at 6, 12, and 24 months. [32] For practices allocated to the OPTI-Surg + Coach arm, penetration will also be assessed after each PDSA cycle.

Site visits will take place at 5 practices randomized to each arm. These site visits will take place prior to implantation of the OPTI-Surg intervention, after the fifth patient is enrolled at the practice, and 6 to 9 months after the last patient is enrolled at the practice.

10.2.2 Schedule of evaluations for patients

All eligible patients will be evaluated for surgical complications 8 and 12 weeks following surgery.

Consenting patients will be evaluated for function as measured by the CHAMPS questionnaire at baseline and at 8 weeks following surgery. Patients will also be evaluated for quality of life by the EQ-5D-5L at baseline and at 8 weeks following surgery.

10.3 Practice-level reported measures

10.3.1 Practice level postoperative morbidity

Postoperative complications (Clavien-Dindo grades I-V)[24] and ACS-NSQIP geriatric outcome variables will be assessed 8 and 12 weeks following surgery.

Clavien-Dindo Classification of Surgical Complications	
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions.
Grade II	Requiring pharmacological treatment with drug other than such allowed for Grade I complications.
Grade III	Requiring surgical, endoscopic or radiological intervention.
Grade IIIa	Intervention not under general anesthesia.
Grade IIIb	Intervention under general anesthesia.
Grade IV	Life-threatening complication.
Grade IVa	Single organ dysfunction.
Grade IVb	Multiorgan dysfunction.
Grade V	Death of a patient.

American College of Surgeons' National Quality Improvement Program Geriatric Outcome Variables	
Postoperative occurrences	Definition
Postoperative pressure ulcer	A pressure ulcer is present at discharge; did it occur during the hospital stay—yes/no
Postoperative delirium	Delirium is present if there are one or more episodes of acute confusion during hospitalization—yes/no
Do not resuscitate (DNR) order during hospitalization	New DNR order during hospitalization—yes/no
Palliative care consult	Palliative care consult obtained during hospitalization or patient made comfort care—yes/no
Discharge functional health status	Ability to perform activities of daily living at discharge—independent/partially dependent/dependent
Fall risk on discharge	Fall risk at time of discharge—high/low
Need of mobility aid on discharge	New use of mobility aid walker/cane at time of discharge—yes/no)
Discharge with/without services	Home alone with self-care, home alone with skilled care, home with support and self-care, home with support and skilled care

Death (yes versus no, with date and cause), hospital length of stay (computed as days between date of surgery and discharge date), discharge to a facility (yes versus no), and hospital readmission (yes versus no, with reason for readmission) within 8 and 12 weeks will be documented in the medical record and reported on electronic case report forms in Rave.

10.3.2 Penetration of the OPTI-Surg intervention (i.e., Practice level uptake)

For practices randomized to Arm 2, see Appendix III; For practices randomized to Arm 3, see Appendix X.

10.3.3 Organizational Readiness to Change Assessment (ORCA)

The Organization Readiness to Change Assessment (ORCA) will be used to characterize the practice sites' readiness to implement the OPTI-Surg intervention at baseline, 6, 12, and 24 months and will be used as a diagnostic tool by the implementation coach (see Intervention with Implementation Coach). ORCA is a validated instrument that assesses key factors thought to be important in implementing change at the organizational level.[25] The scale has 77 items with three primary subscales: evidence, context, and facilitation.

From each practice site, a mix of clinical and non-clinical staff will be asked to complete the survey. For each site, the following roles will be asked to complete the survey: the surgeon champion, nurse practitioner/nurse, and clinical operations manager. As sites agree to participate, the research team will contact the site to determine the above mentioned roles and ask the identified staff to complete the survey. The survey will be administered as an online survey or on paper. The average score will be taken from each practice site.

10.3.4 Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and the Feasibility of Intervention Measure (FIM)

For practices randomized to Arm 2, see Appendix III; For practices randomized to Arm 3, see Appendix X.

10.3.5 Ethnographic Assessment

Overview: Ethnography is a social science research method that uses qualitative data to provide insights into clinic culture, including how the organizational culture of medical practices shapes implementation of practice-improvement interventions.[34-37] We will use ethnographic methods, including direct observation of clinic routines and interviews with stakeholders, to examine how organizational culture shapes clinic's ability to implement OPTI-Surg as well as the longer term impact of the OPTI-Surg intervention on clinic culture and routines.

Site Selection: We will include 5 sites from both of the two intervention arms (Opti-Surg, and OPTI-Surg with coach) and 2 sites from the control arm for a total of 12 study sites in the ethnographic assessment. This purposeful approach to site selection reflects our focus on understanding the relationship between clinic culture and Opti-Surg implementation as well as on how Opti-Surg shapes clinic culture.

After randomization to one of the three study arms (see Section 4.3), 5 sites within each intervention arm will be selected for ethnographic assessment (a total of 10 sites). We will randomly select one site of each practice type (thoracic, major abdominal, urologic) from each intervention arm, for a total of 6 sites. The final 4 sites (2 from each intervention arm) will be purposefully selected to ensure that we include practices that are diverse with respect to geographic region, practice size, and patient populations. In addition to the 10 intervention sites, we will also randomly select 2 sites from the control arm.

Data Collection: Three data collection site visits will be conducted at each of the 12 ethnographic study sites: a Baseline visit prior to enrollment of the first patient, an In-Progress visit after the 5th patient is enrolled but before enrollment is complete, and a Post-

Intervention visit 6-9 months after the last patient has enrolled (see Section 5.2 Site-level Study Calendar). All site visits will include direct observation of clinic routines and interviews with staff; the In-Progress site visit at the 10 intervention arm sites will also include interviews with patients.

All site visits will be carried out by trained study personnel and will be scheduled and arranged in coordination with the study site to minimize clinic disruption and burden. During all site visits, observational data will be recorded via longhand field notes following standard ethnographic practice.[38] Interviews will be audio recorded for later transcription and analysis.

The table below summarizes the subjects and activities planned for each type of visit.

Site Visit	Activities & Subjects
Baseline	*Clinic Observation*: Up to 2 half-days observing clinic flow that may be impacted by OPTI-Surg intervention. *Leadership Interviews (20-30 mins)*: Global assessment of clinic capacity and culture including awareness to needs of frail adults. **Planned Enrollment: 4 /site (1 Practice Manager & 3 Surgeons)** *Implementation Interviews (15-20 mins)*: Document current care practices for older adults and planned deployment of OPTI-Surg at intervention sites. **Planned Enrollment: 6-8/site (MA/RN/Mid-Level & Ancillary Service Providers)**
In-Progress	*Clinic Observation*: Up to 2 half-days observing clinic flow that may be impacted by OPTI-Surg intervention. *Leadership Interviews (20-30 mins)*: Global assessment of clinic capacity and culture including awareness to needs of frail adults. **Planned Enrollment: 4 /site (1 Practice Manager & 3 Surgeons)** *Implementation Interviews (15-20 mins)*: Document current care practices for older adults and planned deployment of OPTI-Surg at intervention sites. **Planned Enrollment: 6-8/site (MA/RN/Mid-Level & Ancillary Service Providers)** *Patient Interviews (30-45 mins)*: Document patient experiences of OPTI-Surg at Intervention sites. **Planned Enrollment: 3/site at Intervention Sites only (30 patients total)**
Post-Intervention	*Clinic Observation*: Up to 2 half-days observing clinic flow that may be impacted by OPTI-Surg intervention. *Leadership Interviews (20-30 mins)*: Global assessment of clinic capacity and culture including awareness to needs of frail adults. **Planned Enrollment: 4 /site (1 Practice Manager & 3 Surgeons)** *Implementation Interviews (15-20 mins)*: Document current care practices for older adults and planned deployment of OPTI-Surg at intervention sites. **Planned Enrollment: 6-8/site (MA/RN/Mid-Level & Ancillary Service Providers)**

Baseline site visits will include the following elements.

- Clinic Observation: Site visitors will spend up to 2 half-days observing routine clinic flow. These observations will provide insights into how the OPTI-Surg intervention might be implemented in the practice and into aspects of clinic culture such as how responsibility for patient-care activities are allocated among clinic staff and providers, how staff communicate with each other, and the routines that patients experience as they receive care in the clinic.
- Leadership Interviews: Site visitors will conduct semi-structured interviews with the clinic practice manager and up to 3 surgeons. These interviews will provide a global perspective on clinic culture and the extent to which clinics are aware and responsive to needs of frail adults. We anticipate interviews will last 20-30 minutes; an interview guide is available at the Alliance and CTSU Web sites.
- Implementation Interviews: Site visitors will conduct semi-structured interviews with 6-8 front-line staff (Medical Assistants and Nurses), mid-level providers (Nurse Practitioners and Physician Assistants), and other service providers (Nutrition, Physical/Occupational Therapy, Mental Health, Social Work, etc.). These interviews will focus on the ways that these staff and providers are already engaged in care of frail adults as well as how they anticipate implementing OPTI-Surg at intervention sites. We anticipate interviews will last 15-20 minutes; an interview guide is available at the Alliance and CTSU Web sites.

In-Progress site visits will include the following elements.

- Clinic Observation: Procedures replicate those of Baseline visits. During the In-Progress site visit, observations will focus on documenting how OPTI-Surg is being implemented at Intervention sites and whether there are notable practice changes in Control sites that may reflect secular change.
- Leadership Interviews: Procedures replicate those of Baseline visits. During the In-Progress site visit, visitors will document leadership experiences with the implementation of Opti-Surg at Intervention sites. They will document changes that have occurred in clinic routines or awareness of the needs of frail adults at Control sites.
- Implementation Interviews: Procedures replicate those of Baseline visits. During the In-Progress site visit, visitors focus on staff and provider experiences implementing OPTI-Surg at Intervention sites and document any changes that have occurred in clinic routines or awareness of needs of frail adults at Control sites.
- Patient Interviews: We will interview 3 patients who enrolled at each practice randomized to the OPTI-Surg arms. Prior to the visit, visitors will work with research staff to identify eligible patients and arrange to conduct an interview during the site visit. Interviews will be conducted in-person in a private setting where confidentiality can be maintained and that is convenient for the patient. Interviews will last approximately 30 minutes and will focus on patients' experiences of care including their experiences with the components of the OPTI-Surg intervention. an interview guide is available at the Alliance and CTSU Web sites.

Post-Intervention site visits will include the following elements.

- Clinic Observation: Procedures replicate those of Baseline visits. During the Post-Intervention site visit, observations will focus on documenting the extent to which OPTI-Surg routines remain in place or have impacted ongoing clinical operations at Intervention sites as well as documenting any secular trends at Control sites.

- Leadership Interviews: Procedures replicate those of Baseline visits. During the Post-Intervention site visit at Intervention sites, Leadership Interviews will document reflections and experiences related to OPTI-Surg and care of frail adults since the end of the study period. At Control sites, Leadership interviews will focus on reflections concerning the needs of frail adults and probe whether the clinic has adopted or considered adopting any interventions related to care for frail adults.
- Implementation Interviews: Procedures replicate those of Baseline visits. During the Post-Intervention site visit at Intervention sites, site visitors at Intervention sites will use these interviews to obtain first-hand accounts of how clinic routines have been changed by OPTI-Surg. At control sites, these interviews will be used to document any changes that have occurred in clinic routines or awareness of needs of frail adults.

Data Management: As soon as feasible after completion of site visits, longhand field notes will be expanded into full field reports and saved as word processing documents. Audio-taped interviews will be transcribed by a professional transcription service and reviewed for accuracy.

Field reports and interview transcripts will be entered into Atlas.ti, a software package that facilitates management and analysis of qualitative data. Using Atlas.ti, we will code all data. Coding is the process by which segments of text are "tagged" according to their thematic content. Each ethnographic research project has its own coding scheme, e.g. a unique list of themes or issues that are relevant to the project's research question. Developing the coding scheme and applying the codes to the field data is a core data management task of any ethnographic analysis. The coding scheme will be developed by the OPTI-Surg research team, and the codes will be applied to the data by trained research assistants. During training, a portion of the data will be double-coded to ensure fidelity in the application of the coding scheme, and double coding will be carried out at intervals throughout the data management to ensure coding reliability.

Data Analysis: Once the Atlas.ti dataset has been assembled and coded, we will carry out analyses to address the central study questions of this exploratory aim including (1) what are the barriers and facilitators at the clinic level to implementation and adoption of the OPTI-Surg intervention and (2) what are the longer term effects of the OPTI-Surg intervention on clinic culture and routines.

- To address Question 1, data tagged with codes related to barriers and facilitators will be extracted from the Atlas database and reviewed by the analytical team. The analysis will focus on comparisons of data collected from sites in intervention study arms (OPTI-Surg v OPTI-Surg+coach) at different clinical practices to identify which barriers/facilitators impact OPTI-Surg implementation at all sites versus which barriers/facilitators are notable within specific study arms, clinical sites, geographic regions, patient populations, etc.
- To address Question 2, we will examine data tagged with codes related to clinic culture and care routines. Our analysis will focus on examining how these data change over time, e.g. comparing data collected at Baseline v. In-Progress v. Post-Intervention time periods across all three study arms (including usual care). These analysis will shed light on whether and how clinic culture or routines was impacted by OPTI-Surg as well as the extent to which any observed changes might be due to secular changes that are unrelated to the OPTI-Surg intervention.

10.4 Patient-reported measures

10.4.1 Frailty Assessment

For practices randomized to Arm 2, see Appendix III; For practices randomized to Arm 3, see Appendix X.

10.4.2 Functional Assessment (CHAMPS)

Physical function will be measured preoperatively and 8 weeks after surgery using the CHAMPS questionnaire in patients who consent for this portion of the study. CHAMPS includes 41 questions that ask the senior to estimate the time spent on a range of activities in the previous week. It has been validated as a measure of recovery of physical function after surgery and significantly correlates with SF-36 Physical Function, pain with movement, and 6 minute walking test distance.[26]

10.4.3 EQ-5D-5L

EQ-5D-5L is a short, 6-question, instrument which assesses a patient's health state. The addition of the EQ-5D-5L will allow for computation and comparison of health utilities between arms.

11.0 END OF INTERVENTION

11.1 Duration of Intervention

Patient-level intervention will continue until surgery.

For practices randomized to the OPTI-Surg plus Coach arm, **site-level intervention** will continue until 24 weeks after site activation.

11.2 Follow-up

11.2.1 Duration of follow up

Patient level follow-up: Patients will be followed for surgical complications until 12 weeks after surgery.

Practice level follow-up: For practices selected to undergo site interviews, follow up will continue until 6-9 months after the last patient is registered at that practice.

11.2.2 Extraordinary Medical Circumstances

If, at any time the constraints of this protocol are detrimental to the patient's health and/or the patient no longer wishes to continue protocol therapy, protocol therapy shall be discontinued. In this event:

- Document the reason(s) for discontinuation of therapy on data forms.
- Follow the patient for protocol endpoints as required by the Study Calendar.

11.3 Managing ineligible patients and registered patients who never receive protocol intervention

Definition of ineligible patient

A study participant who is registered to the trial but does not meet all of the eligibility criteria is deemed to be ineligible.

Follow-up for ineligible patients who continue with protocol treatment

Patients who are deemed ineligible after registering may continue protocol treatment, provided the treating physician, study chair, and executive officer agree there are no safety concerns if the patient continues protocol treatment. All scans, tests, and data submission are to continue as if the patient were eligible. Notification of the local IRB may be necessary per local IRB policies.

Follow-up for patients who are registered, but who do not undergo surgery

For all study participants who are registered to the trial but who never receive study intervention (regardless of eligibility), baseline and off-treatment notice data submission are required. See the Data Submission Schedule accompanying the All Forms Packet.

12.0 STATISTICAL CONSIDERATIONS

12.1 Statistical design

This is a cluster randomized trial to evaluate the effectiveness of OPTI-Surg at the practice level. Practices will be randomized in a 1:1:1 fashion to the OPTI-Surg package intervention alone, OPTI-Surg with an implementation coach, or usual care. The comparison of coach versus no-coach arms will provide data on which practice change strategies are effective while ensuring that strategies are feasible and acceptable. Our design also includes direct measurement of practice culture and intervention roll-out through mixed methods (surveys, observation, and qualitative interviews). These mixed-methods data will identify barriers to implementation and acceptability, inform continuous improvement of the intervention, and provide insights into how to tailor the intervention to individual practice sites to ensure effective dissemination. The primary analysis will be conducted after the last enrolled patient has been followed for at least 12 weeks.

Interim analysis: Futility will be declared if the p-value is ≥ 0.323 based on a non-binding Pocock boundary with a Lan-DeMets spending function after half the consented patients have been observed at 8 weeks (i.e., completed the CHAMPS). We will also prospectively monitor enrollment (both number of practices and number of patients per practice) and modify the planned number of practices in order to lower the number of patients per practice if per-practice enrollment rates are slower than expected.

12.2 Endpoints

12.2.1 Primary endpoint: CHAMPS total score 8 weeks after surgery. Hypothesis: Among surgical practices that are randomized to OPTI-Surg (with or without a coach), patient-reported function will be higher as compared to the surgical practices randomized to usual care.

Secondary endpoints:

12.2.2 Postoperative complications (Clavien-Dindo grades I-V) within 12 weeks of surgery. Hypothesis: Among surgical practices that are randomized to OPTI-Surg (with or without

a coach), a lower proportion of patients will experience postoperative complications as compared to the surgical practices randomized to usual care.

12.2.3 Compliance with administration of the EFS. Hypothesis: Compliance with screening will be higher among surgical practices that are randomized to OPTI-Surg with a coach versus those without a coach.

Exploratory endpoints:

12.2.4 Postoperative mortality, hospital length of stay, discharge to a facility, and hospital readmission within 12 weeks of surgery.

12.2.5 Subsequent administration of interventions as a result of the EFS.

12.2.6 Barriers and facilitators to implementation through mixed-methods research.

12.3 Power and sample size

Target sample size of 15 patients (maximum 25) per each of 30 surgical practices (450 patients total) is based on achieving 90% power with a two sided alpha of 0.05 using a generalized linear mixed model (with Gaussian link function) with a random practice effect to account for clustering within practice to compare function at 8 weeks between the combined OPTI-Surg no-coach and coach arms versus usual care, adjusting for baseline function, with the following assumptions:

1. Among patients who are 70 years of age or older, 59% will be identified as frail with potential maximal benefit from OPTI-Surg screening (we assume partial effectiveness [33% of the full effect size] of OPTI-Surg screening in the remaining 41% of patients who are not found to be frail based on effectiveness of the Li (2013)[27] intervention in a non-screened population).
2. OPTI-Surg screening compliance will be 60% and 80% in the no-coach and coach arms.
3. Impact of OPTI-Surg within frail and screened patients (versus frail patients in the usual care arm) is based on a prior study of a similar intervention showing mean CHAMPS score (kcal) of 23 versus 8 at 8 weeks post-surgery.[27] The overall effect size, taking into account frailty rates and screening rates as described above, is a mean score (kcal) of 19.73 versus 12.10 at 8 weeks post-surgery for the combined OPTI-Surg no-coach/coach arms and usual care arm, respectively (standardized effect size of 0.42 [based on a CHAMPS standard deviation of 18.3] for the difference between arms). This explicitly takes into account the following mean CHAMPS scores in patients of this study:
    a. Among frail patients in the OPTI-Surg arms who are screened, 8-week mean score=23.
    b. Among frail patients in the OPTI-Surg arms who are not screened, 8-week mean score=8.
    c. Among non-frail patients in the OPTI-Surg arms who are screened, 8-week mean score=23.
    d. Among non-frail patients in the OPTI-Surg arms who are not screened, 8-week mean score=18.
    e. Among frail patients in the usual care arm, 8-week mean score=8.
    f. Among non-frail patients in the usual care arm, 8-week mean score=18.
4. Cluster effect will be 0.005.[28]

5. Standard deviation of the CHAMPS score (kcal) is 18.3.[29]
6. Final evaluable sample size (11 patients at each of 30 practices) is inflated by 30% to 15 patients at each of 30 practices (450 patients) to allow for missing primary endpoint data. Note, for the secondary endpoint of surgical complications, we anticipate a larger sample size (since all eligible patients without the individual consent will also be included) and much lower rate of missing data as these data are systematically captured in the medical record and can be extracted for most if not all patients. To ensure that the final sample size of 450 patients is met, we will allow high enrolling sites to enroll up to 25 patients (i.e., we will allow unequal enrollment across sites). Enrollment will be closely monitored centrally and intentionally controlled to achieve as much balance across sites as possible. Under the assumption that 3 sites enroll 25 patients (19 evaluable), 3 sites enroll 5 patients (3 evaluable), and all other sites enroll 15 patients (11 evaluable; equally distributed across arms), power is minimally impacted (variance inflation factor changes from 1.05 to 1.056 which has a negligible impact on power). Even under the maximal coefficient of variation of cluster sizes when cluster size is constrained at 25 and total sample size is constrained at 450, power remains at 90%.

This evaluable sample size also provides 85% power to detect the 60% versus 80% OPTI-Surg screening rates between the no-coach and coach arms with a two-sided alpha of 0.05 using a generalized linear mixed model (with logit link function) with a random practice effect to account for clustering within practice. Power estimation is based on simulation in R.

While it is possible that the effect size observed in prior studies that included younger patients undergoing less risky surgery may be larger than in older patients undergoing higher risk procedures, it is also plausible that an individualized program that targets multiple domains of frailty may result in substantial improvements in functional recovery – even among the very frail. Studies examining trajectories of functional recovery without prehabilitation, however, show that both community dwelling older adults and frail older nursing home residents, on average, achieve maximum functional recovery at 90 days after abdominal surgery. Based on this evidence, we expect that the benefits of targeted optimization of frailty traits will result in accelerated recovery across the spectrum of frailty and multi-comorbidity.[18] To address this uncertainty, we will conduct an interim analysis as described in Section 9.1. Further, our target power of 90% for an effect size based on Li et al. (2013)[27] maintains reasonable power (i.e., power ≥70%) for slightly smaller effect sizes in the event that the effect is not as robust in the present patient population. Specifically, our sample size ensures 90% power to detect the standardized effect size of 0.42 based on Li et al. (2013), and has power of 80% and 70% power for effect sizes of 0.36 and 0.33, respectively.

12.4 Analysis plan

12.4.1 To assess the balance in randomization, baseline characteristics captured at the patient-level including age, gender, race, ethnicity, disease type, comorbidities, CHAMPS, EQ-5D-5L index and EQ-5D-5L visual analog scale will be compared across randomization arms using a generalized linear mixed model using the appropriate link function based on the distribution of the variable with a random practice effect to account for clustering within practice. Given the small number of sites, comparison of practice characteristics (e.g., practice volume; payer mix; solo, single specialty, or multi-specialty group practice; availability of geriatric specialists, palliative care providers, advanced practice providers,

patient navigators, on site occupational and physical therapy, social workers, pharmacists, dietetics, integrative medicine) across randomization arms will be descriptive.

12.4.2 Primary analysis

The primary analysis will employ a generalized linear mixed model (with Gaussian link function) with a random practice effect to account for clustering within practice and baseline CHAMPS as a covariate to compare 8-week CHAMPS between the combined OPTI-Surg no-coach and coach arms versus usual care. This analysis will include all eligible elderly patients who undergo major cancer surgery, consent to complete CHAMPS questionnaires, and have baseline and 8-week function measured. In supplemental analysis, we will compare pairwise between arms (coach vs usual care, no-coach vs usual care, and coach vs no-coach) using the same method. Supplemental analyses will include model-based analysis with covariates from patient and practice characteristics which appear to differ among randomization arms.

12.4.3 Secondary and exploratory analysis

A generalized linear mixed model (with logit link function) with a random practice effect to account for clustering within practice will be used to compare postoperative complications within 12 weeks of surgery between the combined OPTI-Surg no-coach and coach arms versus usual care followed by pairwise comparisons. This analysis will also include all eligible elderly patients who undergo major cancer surgery (no documentation of postoperative complications will be considered as not having any postoperative complications). A generalized linear mixed model (with logit link function) with a random practice effect to account for clustering within practice will also be used to compare compliance rate for screening between the no-coach and coach arms. This analysis will include all eligible elderly patients with planned major cancer surgery. Generalized linear mixed models (with appropriate link function based on the distribution of the outcome variable being compared) with a random practice effect to account for clustering within practice will be used to compare other surgical outcomes within 12 weeks of surgery and to compare EQ-5D-5L index and visual analog scale scores between the combined OPTI-Surg no-coach and coach arms versus usual care. Models for EQ-5D-5L scores will include the respective baseline EQ-5D-5L score as a covariate. In supplemental analysis, we will compare outcomes and EQ-5D-5L index and visual analog scale scores pairwise between arms (coach vs usual care, no-coach vs usual care, and coach vs no-coach) using the same method. Supplemental analysis will also incorporate patient and practice characteristics which appear to differ among randomization arms.

A variety of supplemental and exploratory analyses will be conducted primarily using descriptive analysis as well as model-based analysis (where applicable and supported by adequate sample size) including to describe the frequency of interventions implemented and to explore the relationship between site characteristics and likelihood of compliance.

With the addition of the virtual EFS effective with Update #03 to the study, we will additionally explore whether outcomes differed according to EFS used (in-person vs. virtual).

12.4.4 Missing data

We first plan to minimize missing data prospectively through use of central data collection in Rave within the Alliance Statistics and Data Center with prospective monitoring of data consistency and completeness. Prospectively, we also plan a staged roll-out with monthly contact with practices to identity missing data problems early. Analytically, for the primary

analysis we will first compare baseline characteristics (age, gender, race, ethnicity, cancer surgery type) among the eligible elderly patients who undergo major cancer surgery with and without 8-week CHAMPS data. We next plan to use all observations available for the initial analysis followed by incorporation of propensity scores in weighted regression in supplemental analysis (assuming there are systematic differences observed in patients with and without missing data). We will also employ a variety of single and multiple imputation methods and results will be descriptively compared across all methods to assess for impact of assumptions on results. In the event of more than 30% missing data for the primary endpoint, we will focus the analysis primarily on the key secondary endpoint of postoperative complications as we expect relatively complete data for this endpoint.

12.5 Study Monitoring

This study will be monitored by the Alliance Data Safety Monitoring Board (DSMB), an NCI-approved functioning body. Reports containing efficacy, adverse event, and administrative information will be provided to the DSMB every six months as per NCI guidelines.

12.6 Inclusion of Women and Minorities

This study will not exclude potential subjects from participating in this study solely on the basis of ethnic origin, gender or socioeconomic status. Efforts will be made to enroll individuals of all genders, races, and ethnic backgrounds. We do not expect a differential effect of the intervention by gender, race, or ethnicity. Predictions of accrual the anticipated accrual in subgroups defined by gender and race is:

DOMESTIC PLANNED ENROLLMENT REPORT					
Racial Categories	**Ethnic Categories**				**Total**
	Not Hispanic or Latino		**Hispanic or Latino**		
	Female	**Male**	**Female**	**Male**	
American Indian/ Alaska Native	1	4	5	2	12
Asian	8	10	0	1	19
Native Hawaiian or Other Pacific Islander	0	1	0	0	1
Black or African American	23	31	0	0	54
White	152	209	0	0	361
More Than One Race	1	1	1	0	3
Total	185	256	6	3	450

Ethnic Categories:

Hispanic or Latino – a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term "Spanish origin" can also be used in addition to "Hispanic or Latino."

Not Hispanic or Latino

Racial Categories:

American Indian or Alaskan Native – a person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment.

Asian – a person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)

Black or African American – a person having origins in any of the black racial groups of Africa.

Native Hawaiian or other Pacific Islander – a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

White – a person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

13.0 General Regulatory Considerations: Waivers of Consent & Remote Informed Consent

13.1 Waivers of documentation of patient consent

13.1.1 Medical record review

Medical records for patients who do not consent to participate in this study will be reviewed for numbers of patients screened to participate, demographic information, types of surgery performed, and adverse events and surgical complications. These data will be collected in aggregate form. We request a waiver of documentation of informed consent for the collection of these data because this activity presents no more than minimal risk of harm to subjects for the following reasons:

- Review of medical records by clinical research staff does not adversely affect the rights or welfare of subjects because medical record information is de-identified and will be collected as practice-level aggregate data,
- Site-level review of medical records involves no more than minimal risk because the person accessing the information has undergone training in confidentiality of medical records, and the records are viewed solely to collect site-level aggregate data and only minimal information will be recorded for research purposes. Names of patients (and other unique identifiers) will not be recorded.

HIPAA waiver or alteration: Although not required by the Alliance, since a waiver of documentation of consent has been granted by the CIRB for the collection of aggregate data for non-consenting subjects, if a site's institutional policies dictate that they obtain a "HIPAA waiver of authorization" from their local IRB to review patient medical records and collect aggregate data, the site may do so. This waiver does not need to be submitted to the CIRB but must be maintained with the regulatory documents for the study at the site, and be available for review by auditors if requested. **Note:** The data is completely de-identified and there is no collection of Protected Health Information (PHI).

13.1.2 Patient screening

For practices randomized to Arm 2, see Appendix III; For practices randomized to Arm 3, see Appendix X.

13.2 Waivers of documentation of healthcare provider consent

13.2.1 Human subjects involvement and characteristics

The ethnographic component of this study will involve human subjects in two ways: 1) individual qualitative interviews with health care professionals and patients; 2) observation of cancer clinic routines.

Research activities will take place at 12 sites with a total of approximately 150 subjects involved in these activities including 120 health care professions and 30 patients. All subjects will be 18 years or older with health statuses ranging from very healthy (no known illnesses) to extremely unhealthy (terminal disease). Inclusion criteria for all subjects will include ability to effectively communicate in English.

The sites for this study will include 12 sites: 10 OPTI-Surg intervention sites and 2 usual care sites.

13.2.2 Sources of materials

All data will be collected specifically for this research study. We will collect data using in-depth interviews and direct observation. These are non-invasive social scientific research methods. In-depth interviews involve questions, answers, and conversation between researcher and subjects. Data is obtained through the long hand recording of field notes which are later expanded into full transcripts for later analysis. Direct observation involves spending time with subjects and observing their routine activities in a non-disruptive manner. Data is obtained by the researcher taking field notes, which are then expanded in to more detailed field reports after the researcher has left the field site.

The data will be identified through pseudonyms and a coding scheme, and the key linking individual subject identifiers to the pseudonyms and codes we use while collecting data will only be accessible to the study team.

13.2.3 Potential risks

Potential risks to subjects from this research include those usually associated with non-invasive social science research and are primarily related to possible social discomfort or embarrassment and potential loss of confidentiality. During direct observation, subjects may experience social discomfort or embarrassment due to the presence of the researcher. Because field notes and interviews will be recorded, there is also the possibility of loss of confidentiality.

13.2.4 Recruitment

To recruit health professionals (for interviews and observation) we will recruit subjects in conjunction with site enrollment in the primary OPTI-Surg study. As part of the site recruitment process, we will ask clinic leaders to identify appropriate clinic managers and front line staff for initial interviews and observation. Once on site, we will use snowball sampling techniques to identify and gather data from other relevant health professionals who have relevant patient care or clinic management duties. We will recruit patients by asking clinic managers to refer the researchers to 2-5 patients who have been seen at the clinic during the relevant study period.

13.2.5 Informed consent

Surgeons and Clinic Staff: Per the basic HHS Policy for Protection of Human Research Subjects at 45 CFR 46.117(c) we will request a waiver of written consent for participation in the ethnographic component of the study given the minimal risk nature of these activities. Participants in these activities will be provided with written information (Appendix VII) describing the research, their participation, the risks, possible benefits, and all other required elements of informed consent. Additionally, because a signed consent form would be the only documentation of the participants' identities, we feel a waiver of written consent is appropriate. Participants may drop out at any time before, during, or after the interview.

13.2.6 Protections against risk

To protect against risks of social discomfort, embarrassment, or concern that their responses may reflect unfavorably on their practice, researchers will inform subjects that they are free to end their participation in this research at any time by refusing to answer interview questions or by asking the researcher to cease observing activities in clinic. The component lead has substantial experience and expertise in these issues from his work in

prior research studies, and all train team members will be trained in issues that may arise when conducting this type of ethnographic research.

To protect against loss of confidentiality, researchers will maintain control over all hard-copy research materials including field notes and field reports by keeping them within their personal control during the conduct of research or by keeping them in a locked filing cabinet in the principal investigator's research office. Computer files containing field notes, field reports, and the Atlas.ti data base will be password protected. In field notes, researchers will identify subjects using pseudonyms. The key linking field note pseudonyms and interview numeric codes to actual subject names will be kept in the principal investigator's locked file cabinet at all times except for when it is in active use. In papers, reports, publications, and other documents neither the names of individual research subjects nor the specific identities of research sites will be identified. Researchers will suppress or alter distinguishing features of subjects or field sites so that subjects remain anonymous.

13.3 Potential benefits of the proposed research to human subjects and others

This project seeks to better understand how programs to improve surgical care for frail adults can be best implemented and thus may the potential to improve the processes for providing surgical care for this type of cancer patients.

13.4 Importance of the knowledge to be gained

Identifying more effective ways to implement programs that seek to improve decision-making and preparation surrounding surgical oncology has the potential to improve patient and health system outcomes.

13.5 Remote Informed Consent

The NCI CIRB allows "remote" informed consent (i.e., telephone/teleconferencing discussion in conjunction with an informed consent document that can be sent to the patient, signed, and transmitted back to the participating site research team and signed by the consenting physician/healthcare provider before any research procedures begin). Information on the NCI CIRB's support for "remote" informed consent for sites using the NCI CIRB as the IRB of record is available on the NCI CIRB website at [redacted] Sites must also follow their institutional policies regarding remote informed consent. Please contact the NCI CIRB at [redacted] with questions regarding remote informed consent.

14.0 REFERENCES

1. Klopfenstein CE, Herrmann FR, Michel JP, et al: The influence of an aging surgical population on the anesthesia workload: a ten-year survey. Anesth Analg 86:1165-70, 1998.
2. Afilalo J, Eisenberg MJ, Morin JF, et al: Gait speed as an incremental predictor of mortality and major morbidity in elderly patients undergoing cardiac surgery. J Am Coll Cardiol 56:1668-76, 2010.
3. Makary MA, Segev DL, Pronovost PJ, et al: Frailty as a predictor of surgical outcomes in older patients. J Am Coll Surg 210:901-8, 2010.
4. Sundermann S, Dademasch A, Rastan A, et al: One-year follow-up of patients undergoing elective cardiac surgery assessed with the Comprehensive Assessment of Frailty test and its simplified form. Interact Cardiovasc Thorac Surg 13:119-23; discussion 123, 2011.
5. Badgwell B, Stanley J, Chang GJ, et al: Comprehensive geriatric assessment of risk factors associated with adverse outcomes and resource utilization in cancer patients undergoing abdominal surgery. J Surg Oncol 108:182-6, 2013.
6. Dasgupta M, Rolfson DB, Stolee P, et al: Frailty is associated with postoperative complications in older adults with medical problems. Arch Gerontol Geriatr 48:78-83, 2009.
7. Kristjansson SR, Nesbakken A, Jordhoy MS, et al: Comprehensive geriatric assessment can predict complications in elderly patients after elective surgery for colorectal cancer: a prospective observational cohort study. Crit Rev Oncol Hematol 76:208-17, 2010.
8. Neuman HB, Weiss JM, Leverson G, et al: Predictors of short-term postoperative survival after elective colectomy in colon cancer patients >/= 80 years of age. Ann Surg Oncol 20:1427-35, 2013.
9. Pace_Participants, Audisio RA, Pope D, et al: Shall we operate? Preoperative assessment in elderly cancer patients (PACE) can help. A SIOG surgical task force prospective study. Crit Rev Oncol Hematol 65:156-63, 2008.
10. Tan KY, Kawamura YJ, Tokomitsu A, et al: Assessment for frailty is useful for predicting morbidity in elderly patients undergoing colorectal cancer resection whose comorbidities are already optimized. Am J Surg 204:139-43, 2012.
11. Ellis G, Spiers M, Coutts S, et al: Preoperative assessment in the elderly: evaluation of a new clinical service. Scott Med J 57:212-6, 2012.
12. Harari D, Hopper A, Dhesi J, et al: Proactive care of older people undergoing surgery ('POPS'): designing, embedding, evaluating and funding a comprehensive geriatric assessment service for older elective surgical patients. Age Ageing 36:190-6, 2007.
13. Li C, Carli F, Lee L, et al: Impact of a trimodal prehabilitation program on functional recovery after colorectal cancer surgery: a pilot study. Surg Endosc 27:1072-82, 2013.
14. Valkenet K, van de Port IG, Dronkers JJ, et al: The effects of preoperative exercise therapy on postoperative outcome: a systematic review. Clin Rehabil 25:99-111, 2011.
15. Chow WB, Rosenthal RA, Merkow RP, et al: Optimal preoperative assessment of the geriatric surgical patient: a best practices guideline from the American College of Surgeons National Surgical Quality Improvement Program and the American Geriatrics Society. J Am Coll Surg 215:453-66, 2012.

16. Ghignone F, van Leeuwen BL, Montroni I, et al: The assessment and management of older cancer patients: A SIOG surgical task force survey on surgeons' attitudes. Eur J Surg Oncol 42:297-302, 2016.

17. Baskerville NB, Liddy C, Hogg W: Systematic review and meta-analysis of practice facilitation within primary care settings. Ann Fam Med 10:63-74, 2012.

18. Rolfson DB, Majumdar SR, Tsuyuki RT, et al: Validity and reliability of the Edmonton Frail Scale. Age Ageing 35:526-9, 2006.

19. Fried TR, Bradley EH, Towle VR, et al: Understanding the treatment preferences of seriously ill patients. N Engl J Med 346:1061-6, 2002.

20. Schwarze ML, Barnato AE, Rathouz PJ, et al: Development of a list of high-risk operations for patients 65 years and older. JAMA Surg 150:325-31, 2015.

21. Proctor E. et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health 2011. 38:65-76.

22. Helfrich CD, Li YF, Sharp ND, et al: Organizational readiness to change assessment (ORCA): development of an instrument based on the Promoting Action on Research in Health Services (PARIHS) framework. Implement Sci 4:38, 2009.

23. Practice facilitation handbook. Rockville, MD, 2013.

24. Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg 2004; 240: 205-13.

25. Helfrich CD, Li YF, Sharp ND, et al: Organizational readiness to change assessment (ORCA): development of an instrument based on the Promoting Action on Research in Health Services (PARIHS) framework. Implement Sci 4:38, 2009.

26. Feldman LS, Kaneva P, Demyttenaere S, et al: Validation of a physical activity questionnaire (CHAMPS) as an indicator of postoperative recovery after laparoscopic cholecystectomy. Surgery 146:31-9, 2009.

27. Li C, Carli F, Lee L, et al: Impact of a trimodal prehabilitation program on functional recovery after colorectal cancer surgery: a pilot study. Surg Endosc 27:1072-82, 2013.

28. Adams G, Gulliford MC, Ukoumunne OC, et al: Patterns of intra-cluster correlation from primary care research to inform study design and analysis. J Clin Epidemiol 57:785-94, 2004.

29. Stewart AL, Mills KM, King AC, et al: CHAMPS physical activity questionnaire for older adults: outcomes for interventions. Med Sci Sports Exerc 33:1126-41, 2001.

30. Englesbe MJ, Grenda DR, Sullivan JA, Derstine BA, Kenney BN, Sheetz KH, Palazzolo WC, Wang NC, Goulson RL, Lee JS, Wang SC. The Michigan Surgical Home and Optimization Program is a scalable model to improve care and reduce costs. 2017. Surgery 161(6):1659-1666.

31. Powell et al. A refined compilation of implementation strategies: Results from the Expert Recommendations for Implementing Change (ERIC) project. Implementation Science 10:21, 2015.

32. Weiner et al. Psychometric assessment of three newly developed implementation outcome measures. Implementation Science 12:108, 2017.

33. Ritchie MJ, Dollar KM, Miller CJ, Oliver KA, Smith JL, Lindsay JA, Kirchner JE. Using Implementation Facilitation to Improve Care in the Veterans Health Administration (Version 2). Veterans Health Administration, Quality Enhancement Research Initiative (QUERI) for Team-

Based Behavioral Health, 2017. Available at: https://www.queri.research.va.gov/tools/implementation/Facilitation-Manual.pdf

34. Kellogg, K. C. (2009). Operating Room: Relational Spaces and Microinstitutional Change in Surgery. American Journal of Sociology, 115(3), 657–711. https://doi.org/10.1086/603535

35. Kellogg, K. C. (2014). Brokerage Professions and Implementing Reform in an Age of Experts. American Sociological Review, 79(5), 912–941. https://doi.org/10.1177/0003122414544734

36. DIXON-WOODS, M., BOSK, C. L., AVELING, E. L., GOESCHEL, C. A., & PRONOVOST, P. J. (2011). Explaining Michigan: Developing an Ex Post Theory of a Quality Improvement Program. Milbank Quarterly, 89(2), 167–205. https://doi.org/10.1111/j.1468-0009.2011.00625.x

37. Bosk, C. L., Dixon-Woods, M., Goeschel, C. A., & Pronovost, P. J. (2009). Reality check for checklists. The Lancet, 374(9688), 444–445. https://doi.org/10.1016/S0140-6736(09)61440-9.

38. Emerson, R. M., Fretz, R. I., & Shaw, L. L. (1995). Writing ethnographic fieldnotes. Chicago, IL: University of Chicago Press.

15.0 MODEL CONSENT FORM

Study Title for Participants: A study to improve outcomes in older cancer patients undergoing surgery

Official Study Title for Internet Search on [redacted] Improving surgical care and outcomes in older cancer patients through implementation of an efficient pre-surgical toolkit (OPTI-Surg)

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. The study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

You are being asked to take part in this study because you are 70 years of age or older and are preparing to have major cancer surgery.

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

Why is this study being done?

This study is being done to answer the following question:

Can changing how doctors evaluate and prepare elderly patients for major cancer surgery improve the rate of recovery from surgery?

What is the usual approach to my diagnosis?

The usual approach for patients who are not in a study is to get advice about cancer surgery from their doctor.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above without completing questionnaires about your physical, emotional, and social well-being and how well you are functioning.
- You may choose to take part in a different research study, if one is available.

What will happen if I decide to take part in this study?

If you decide to take part in the study, you will be asked to complete questionnaires about your physical, emotional, and social well-being and how well you are functioning. You will be asked to complete these questionnaires at the following time points:

- After you enroll to the study
- 8 weeks after you complete your surgery

These questionnaires should take about 20 to 30 minutes to complete.

In addition, you may be selected to meet with researchers in a private, confidential setting that is convenient for you for an interview that will last about 30 minutes and will focus on your experiences with the surgical team while preparing for surgery.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now. We give you more information in the "What risks can I expect from taking part in this study?" section.

- You may be asked sensitive or private questions which you normally do not discuss. You may choose not to answer any questions that make you feel uncomfortable.

Benefits

You are not expected to have any direct medical benefit from participating in this study.

However, it may help the study doctors learn more about how doctors and clinics are helping patients prepare for cancer surgery.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible. You also may choose to stop participation or skip any questions in the surveys that you do not feel comfortable answering.

Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), or study sponsor (the Alliance). The study sponsor is the organization who oversees the study.

This study is conducted by the Alliance for Clinical Trials in Oncology, a national clinical research group supported by the National Cancer Institute. The Alliance is made up of cancer doctors, health professionals, and laboratory researchers, whose goal is to develop better treatments for cancer, to prevent cancer, to reduce side effects from cancer, and to improve the quality of life of cancer patients.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study staff or nurse.

What is the purpose of this study?

Surgery is the main treatment for many cancer conditions. In many elderly patients, surgery can greatly affect physical condition, and the ability to return to pre-surgery levels of physical functioning. By providing some simple pre-surgical recommendations, it may be possible to improve the rate of recovery from surgery and the possibility that patients will return to their pre-surgery levels of function.

Your doctors are participating in a study to determine if a change in how they evaluate and manage elderly patients will improve recovery rates from major cancer surgery. Doctors and members of the surgical team will use a group of assessment tools called "OPTI-Surg" that helps them make pre-surgery referrals and recommendations. The research study team wants to find out if using OPTI-Surg to guide pre-surgical referrals and recommendations can help improve recovery for elderly patients after cancer surgery.

There will be about 450 people taking part in this study (about 15 to 25 people in this clinic).

What are the study groups?

Clinics that choose to take part in this study will be assigned to one of three groups. A computer will assign each clinic to a group by chance. This is called randomization. Assignment is done by chance because no one knows if one study group is better or worse than the others. Clinics that choose to take part in this study will be randomized to one of the following three groups.

Clinic Group 1: At clinics assigned to Group 1, the OPTI-Surg program will not be used. The study will not ask these clinics to change what they usually do. For patients at these clinics, care will not be different from care that they would receive outside the study. There are ten clinics participating in the study in Group 1.

Clinic Group 2: At clinics assigned to Group 2, the OPTI-Surg program will be used. Clinics will be trained to administer the program. You may receive recommendations about how to prepare for surgery as part of this program. There are ten clinics participating in the study in Group 2.

Clinic Group 3: At clinics assigned to Group 3, the OPTI-Surg program will also be used. Clinics will be trained to administer the program. In addition, clinics in Group 3 will have a "coach" to help with the implementation of the OPTI-Surg program. You may receive recommendations about how to prepare for surgery as part of this program. There are ten clinics participating in the study in Group 3.

Your clinic has been assigned to Group ___.

What exams, tests, and procedures are involved in this study?

You will be asked to complete questionnaires about your physical, emotional, and social well-being and how well you are functioning. You will be asked to complete these questionnaires at the following time points:

- After you enroll to the study
- 8 weeks after you complete your surgery

These questionnaires should take about 20 to 30 minutes to complete.

In addition, you will have blood sample taken at your first appointment with your surgeon and 8 weeks after surgery.

Lastly, you may be selected to meet with researchers in a private, confidential setting that is convenient for you for an interview that will last about 30 minutes and will focus on your experiences with the study procedures.

Information from your medical records will be obtained at the following times:

- After you enroll to the study
- 8 and 12 weeks after you complete your surgery

The researchers will obtain the following information from your medical record:

- Basic information about you (e.g., gender, height, weight)
- Type of cancer and surgery performed
- Your medical history, current medical issues, health status

What risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual
- You may be asked sensitive or private questions which you normally do not discuss. You may choose not to answer any questions that make you feel uncomfortable.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.

As part of the study, your health care team may recommend different ways that you can prepare for your surgery. It is possible that you may experience side effects after following these recommendations. Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect. The study doctor may be able to treat some side effects.

What are my responsibilities in this study?

If you choose to take part in this study you will need to:

- Keep your study appointments.
- Complete the questionnaires after you enroll to the study and 8 weeks after you complete your surgery
- Tell your doctor about:
    - all medications and supplements you are taking
    - any side effects
    - any doctors' visits or hospital stays outside of this study
    - if you have been or are currently in another research study.

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care just as you would if you were getting the usual care for your cancer.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this clinical trial. Also, find out if you need approval from your plan before you can take part in the study.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer. You may:

- Have more travel costs.
- Need to take more time off work.
- Have other additional personal costs.

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What happens if I am injured because I took part in this study?

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at or receive copies of some of the information in your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

- The study sponsor (Alliance)
- The NCI Central IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The NCI and the groups it works with to review research.
- The NCI's National Clinical Trials Network and the groups it works with to conduct research

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records may be stored for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients. However, right now we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your surgeon will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

Where can I get more information?

You may visit the NCI web site at [redacted] for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: [redacted]

A description of this clinical trial will be available on [redacted] as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You can talk to the study staff about any questions or concerns you have about this study. Contact the study staff (*insert name of study staff*) at (*insert telephone number, and email address if appropriate*).

For questions about your rights while in this study, call the (*insert name of organization or center*) Institutional Review Board at (*insert telephone number*).

My signature agreeing to take part in the study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study.

Participant's signature

Date of signature

Signature of person(s) conducting the informed consent discussion

Date of signature

APPENDIX I CHAMPS AND EQ-5D-5L QUESTIONNAIRES

Patient Booklet

You have been given a booklet to complete for this study. The booklet contains some questions about your 'quality of life' and your level of activity as a patient undergoing surgery for cancer. Your answers will help us to better understand how surgery is affecting the way you feel.

1. This booklet contains two sets of questions:

    a. CHAMPS Activities Questionnaire for Older Adults (41 questions)
    b. EQ-5D-5L Questionnaire (6 questions)

2. Please follow the directions at the top of each questionnaire.

3. You may choose not to answer any questions that make you feel uncomfortable.

4. Please complete the booklet during your scheduled clinical visit and return it to your nurse, physician, or research coordinator.

Thank you for taking the time to help us.

CHAMPS Activities Questionnaire for Older Adults

CHAMPS: [redacted]

[redacted]

[redacted]

Contact: [redacted]

Date:_____

Name or ID:_____

This questionnaire is about activities that you may have done in the past 4 weeks. The questions on the following pages are similar to the example shown below.

INSTRUCTIONS

If you DID the activity in the past 4 weeks:

Step #1 Check the YES box.

Step #2 Think about how many TIMES a week you usually did it, and write your response in the space provided.

Step #3 Circle how many TOTAL HOURS in a typical week you did the activity.

Here is an example of how Mrs. Jones would answer question #1: Mrs. Jones usually visits her friends Maria and Olga twice a week. She usually spends one hour on Monday with Maria and two hours on Wednesday with Olga. Therefore, the total hours a week that she visits with friends is 3 hours a week.

In a typical week during the past 4 weeks, did you…							
1. Visit with friends or family (other than those you live with)? ☒ **YES** How many times a week? 2 ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	(3-4½ hours)	5-6½ hours	7-8½ hours	9 or more hours

If you DID NOT do the activity:

- **Check the NO box and move to the next question**

In a typical week during the past 4 weeks, did you …							
1. Visit with friends or family (other than those you live with)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
2. Go to the senior center? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
3. Do volunteer work? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
4. Attend church or take part in church activities? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
5. Attend other club or group meetings? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours

In a typical week during the past 4 weeks, did you …							
6. Use a computer? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
7. Dance (such as square, folk, line, ballroom) (do not count aerobic dance here)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
8. Do woodworking, needlework, drawing, or other arts or crafts? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
9. Play golf, carrying or pulling your equipment (count walking time only)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
10. Play golf, riding a cart (count walking time only)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours

In a typical week during the past 4 weeks, did you …							
11. Attend a concert, movie, lecture, or sport event? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL <u>hours a week</u> did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
12. Play cards, bingo, or board games with other people? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL <u>hours a week</u> did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
13. Shoot pool or billiards? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL <u>hours a week</u> did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
14. Play singles tennis (do <u>not</u> count doubles)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL <u>hours a week</u> did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
15. Play doubles tennis (do <u>not</u> count singles)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL <u>hours a week</u> did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours

In a typical week during the past 4 weeks, did you …							
16. Skate (ice, roller, in-line)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
17. Play a musical instrument? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
18. Read? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
19. Do heavy work around the house (such as washing windows, cleaning gutters)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
20. Do light work around the house (such as sweeping or vacuuming)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours

In a typical week during the past 4 weeks, did you …							
21. Do heavy gardening (such as spading, raking)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
22. Do light gardening (such as watering plants)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
23. Work on your car, truck, lawn mower, or other machinery? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours

****Please note: For the following questions about running and walking, include use of a treadmill.**

24. Jog or run? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours

In a typical week during the past 4 weeks, did you …							
25. Walk uphill or hike uphill (count only uphill part)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
26. Walk fast or briskly for exercise (do not count walking leisurely or uphill)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
27. Walk to do errands (such as to/from a store or to take children to school (count walk time only)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
28. Walk leisurely for exercise or pleasure? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
29. Ride a bicycle or stationary cycle? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours

In a typical week during the past 4 weeks, did you …							
30. Do other aerobic machines such as rowing, or step machines (do not count treadmill or stationary cycle)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
31. Do water exercises (do not count other swimming)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
32. Swim moderately or fast? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
33. Swim gently? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
34. Do stretching or flexibility exercises (do not count yoga or Tai-chi)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours

In a typical week during the past 4 weeks, did you …							
35. Do yoga or Tai-chi? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
36. Do aerobics or aerobic dancing? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
37. Do moderate to heavy strength training (such as hand-held weights of more than 5 lbs., weight machines, or push-ups)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
38. Do light strength training (such as hand-held weights of 5 lbs. or less or elastic bands)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours

In a typical week during the past 4 weeks, did you …							
39. Do general conditioning exercises, such as light calisthenics or chair exercises (do not count strength training)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
40. Play basketball, soccer, or racquetball (do not count time on sidelines)? ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours
41. Do other types of physical activity not previously mentioned (please specify)? _____ ☐ **YES** How many times a week?_____ ➔ ☐ **NO**	How many TOTAL hours a week did you usually do it? ➔	Less than 1 hour	1-2½ hours	3-4½ hours	5-6½ hours	7-8½ hours	9 or more hours

Thank You

EQ-5D-5L Questionnaire

Under each heading, please check the ONE box that best describes your health TODAY

MOBILITY

I have no problems walking ❑
I have slight problems walking ❑
I have moderate problems walking ❑
I have severe problems walking ❑
I am unable to walk ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

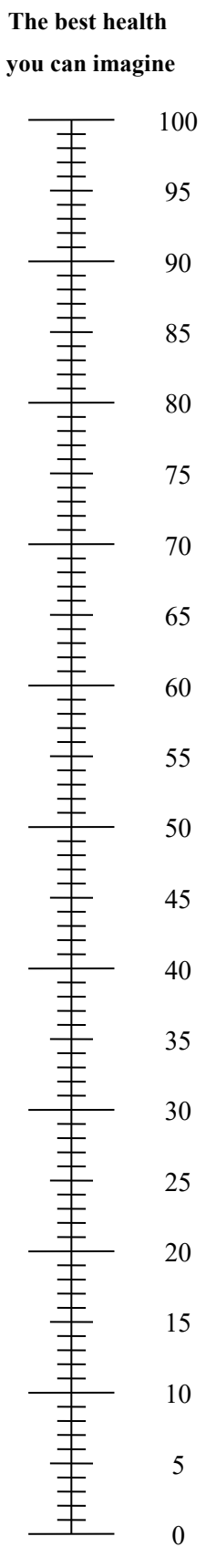
I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



APPENDIX II ORCA SURVEY

Adapted from the Organizational Readiness for Change Assessment (ORCA) Survey

PART I. Evidence Assessment

Finding: Implementing the OPTI-Surge intervention (Edmonton Frail Scale and Targeted Recommendations) into surgical oncology practice will improve the health outcomes of older patients with cancer.

1. Based on your assessment of the evidence basis for this statement, please rate the strength of the evidence in your opinion, on a scale of 1 to 5 where 1 is very weak evidence and 5 is very strong evidence:

Very Weak	Weak	Neither weak nor strong	Strong	Very Strong	Don't Know/Not Applicable
☐	☐	☐	☐	☐	☐

2. Now, please rate the strength of the evidence basis for this statement based on how you think respected clinical experts in your institution feel about the strength of the evidence, on a 1 to 5 scale similar to the one above:

Very Weak	Weak	Neither Weak nor Strong	Strong	Very Strong	Don't Know/Not Applicable
☐	☐	☐	☐	☐	☐

PART II. Context Assessment

For each of the following statements, please rate the strength of your agreement with the statement, from 1 (strongly disagree) to 5 (strongly agree

3. In general, senior leadership/clinical management in your organization:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
a) reward clinical innovation and creativity to improve patient care	☐	☐	☐	☐	☐	☐
b) Solicit opinions of clinical staff regarding decisions about patient care	☐	☐	☐	☐	☐	☐
c) Seek ways to improve patient education and increase patient participation in treatment	☐	☐	☐	☐	☐	☐

4. In general, staff members in your organization

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
a) Have a sense of personal responsibility for improving patient care and outcomes	☐	☐	☐	☐	☐	☐
b) cooperate to maintain and improve effectiveness of patient care	☐	☐	☐	☐	☐	☐
c) are willing to innovate and/or experiment to improve clinical procedures	☐	☐	☐	☐	☐	☐
d) are receptive to change in clinical processes	☐	☐	☐	☐	☐	☐

5. In general, senior leadership/clinical management in your organization:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
a) provide effective management for continuous improvement of patient care	☐	☐	☐	☐	☐	☐
b) clearly define areas of responsibility and authority for clinical managers and staff	☐	☐	☐	☐	☐	☐
c) promote team building to solve clinical care problems	☐	☐	☐	☐	☐	☐
d) promote communication among clinical services and units	☐	☐	☐	☐	☐	☐

6. If your organization was going to implement OPTI-Surg for older patients with cancer, senior leadership/clinical management in your organization would:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
a) provide staff with information on your organization's performance measures and guidelines	☐	☐	☐	☐	☐	☐
b) establish clear goals for patient care processes and outcomes	☐	☐	☐	☐	☐	☐
c) provide staff members with feedback/data on effects of clinical decisions	☐	☐	☐	☐	☐	☐
d) hold staff members accountable for achieving results	☐	☐	☐	☐	☐	☐

7. Regarding cancer care for older patients with cancer, opinion leaders in your organization:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
a) believe that the current practice patterns can be improved	☐	☐	☐	☐	☐	☐
b) encourage and support changes in practice patterns to improve patient care	☐	☐	☐	☐	☐	☐
c) are willing to try new clinical protocol	☐	☐	☐	☐	☐	☐
d) work cooperatively with senior leadership/clinical management to make appropriate changes	☐	☐	☐	☐	☐	☐

8. If there is agreement that change needs to happen for older patients with cancer:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
a) we have the necessary support in terms of budget or financial resources	☐	☐	☐	☐	☐	☐
b) we have the necessary support in terms of training	☐	☐	☐	☐	☐	☐
c) we have the necessary support in terms of facilities	☐	☐	☐	☐	☐	☐
d) we have the necessary support in terms of staffing	☐	☐	☐	☐	☐	☐

PART III. Facilitation Assessment

For each of the following statements, please rate the strength of your agreement with the statement, from 1 (strongly disagree) to 5 (strongly agree) regarding implementing the OPTI-Surg for older patients with cancer:

9. Senior leadership/clinical management would:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
a) propose a project that is appropriate and feasible	☐	☐	☐	☐	☐	☐
b) provide clear goals for improvement in patient care	☐	☐	☐	☐	☐	☐
c) establish a project schedule and deliverables	☐	☐	☐	☐	☐	☐
d) designate a clinical champion(s) for the project	☐	☐	☐	☐	☐	☐

10. The project clinical champion:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
a) accepts responsibility for success of this project	☐	☐	☐	☐	☐	☐
b) has authority to carry out implementation	☐	☐	☐	☐	☐	☐
c) is considered a clinical opinion leader	☐	☐	☐	☐	☐	☐
d) works well with the intervention team and providers	☐	☐	☐	☐	☐	☐

11. Senior leadership/clinical management/staff opinion leaders would:

a) agree on the goals for this intervention
b) be informed and involved in the intervention
c) agree on adequate resources to accomplish the intervention
d) set a high priority on the success of the intervention

Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐

12. The implementation team members would:

a) share responsibility for the success of this project
b) have clearly defined roles and responsibilities
c) have release time or can accomplish intervention tasks within their regular work load
d) have staff support and other resources required for the project

Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐

13. The implementation plan for this intervention would:

a) identify specific roles and responsibilities
b) clearly describes tasks and timelines
c) include appropriate provider/patient education
d) acknowledge staff input and opinions

Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐

14. Communication would be maintained through:

a) regular project meetings with the project champion and team members
b) involvement of quality management staff in project planning and implementation
c) regular feedback to clinical management on progress of project activities and resource needs
d) regular feedback to clinicians on effects of practice changes on patient care/outcomes

Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐

15. Progress of the project would be measured by:

a) collecting feedback from patients regarding proposed/implemented changes
b) collecting feedback from staff regarding proposed/implemented changes
c) developing and distributing regular performance measures to clinical staff
d) providing a forum for presentation/discussion of results and implications for continued improvements

Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐

16. The following would be available to make the selected plan work:

a) staff incentives
b) equipment and materials
c) patient awareness/need
d) provider buy-in
e) intervention team
f) evaluation protocol

Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐

17. Plans for evaluation and improvement of this intervention would include:

a) periodic outcome measurement
b) staff participation satisfaction survey
c) patient satisfaction survey
d) dissemination of plan for performance measures
e) review of results by clinical leadership

Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't Know/Not Applicable
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐

PART IV. About You

18. What is your role?

☐ Surgeon

☐ Nurse Practitioner

☐ Nurse

☐ Physician Assistant

☐ Other, please specify: _____

19. How many years have you been with your current organization? _____ years

THANK YOU!