MSK PROTOCOL COVER SHEET

Feasibility and Effectiveness of Automated Geriatric Co Management Program on Improving the Perioperative Care of Older Patients with Solid Mass or Nodule Suspicious for Cancer

Principal Investigator/Department: Armin Shahrokni, MD, MPH /Medicine

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1.0 PROTOCOL SUMMARY AND/OR SCHEMA

Title: Feasibility and Effectiveness of Automated Geriatric Co-Management Program on Improving the Perioperative Care of Older Patients with Solid Mass or Nodule Suspicious for Cancer

Study Center: MSKCC

Expected Time to Study Completion: 24 months

Objectives:

Primary objective:
To determine the feasibility of *automated geriatric co-management program* in the care of geriatric oncology patients.

Secondary objectives:
- To compare the effect of *automated geriatric co-management program* with in-person geriatric co-management on adverse surgical events.
- To compare the effect of *automated geriatric co-management program* with in-person geriatric co-management on postoperative functional recovery.

Study Design:
- Prospective Randomized Trial
- Patients will be randomized 1:1 to receive either *automated geriatric co-management* during surgery visit when they are considered for surgery, or to be referred to geriatrics service for in-person geriatric co-management which can be done either in the clinic or via telemedicine.

Study Population

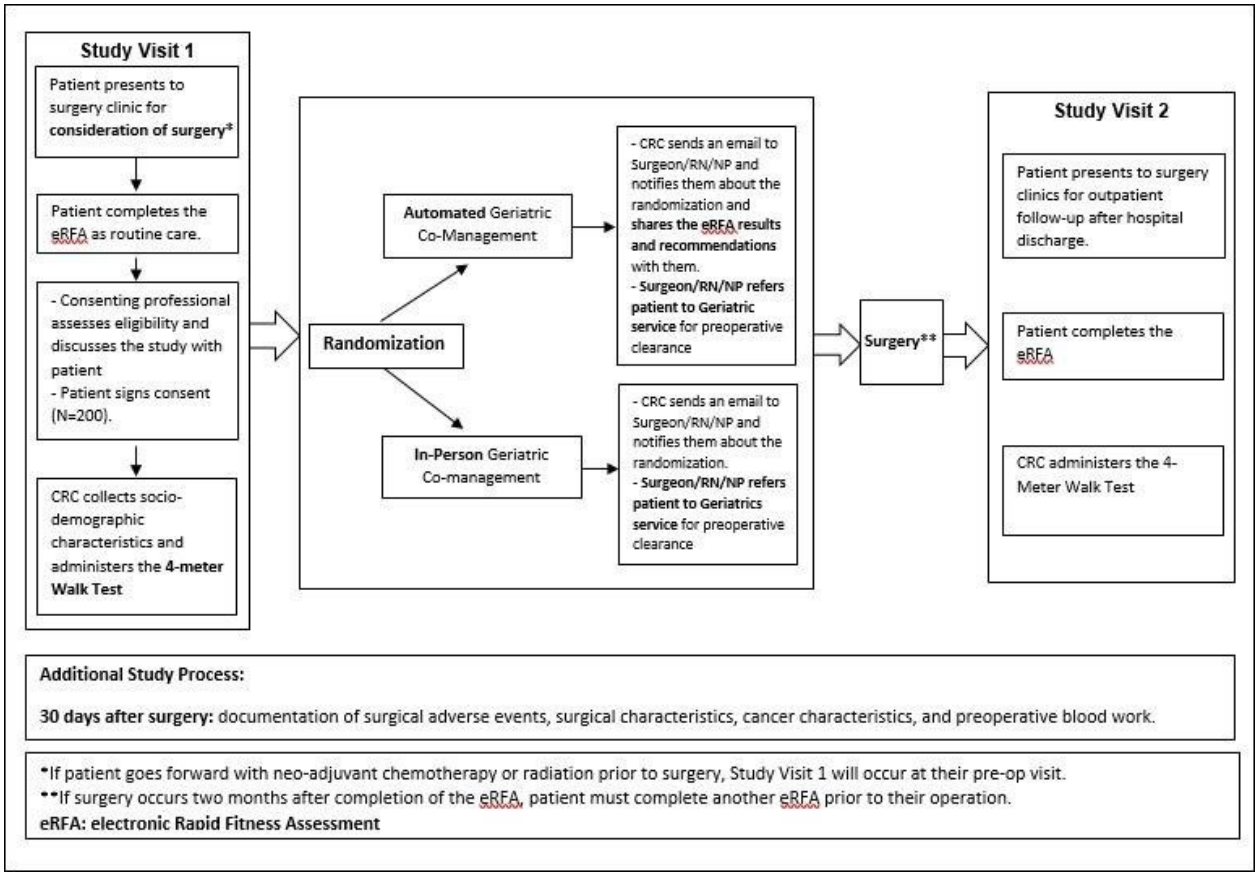
Patients with a solid mass or nodule aged 65 or older who are presenting to MSKCC's surgery clinics for consideration of surgery.

Number of patients: 77 patients evaluable in the automated arm, estimated to be 200 patients in the study

Inclusion and Exclusion Criteria:
Inclusion:
1) Solid mass or nodule suspicious for cancer,
2) Aged 65 or older,
3) Being considered for surgical resection of the solid mass or nodule, with anticipated hospital length of stay of at least two days,
4) Completed Electronic Rapid Fitness Assessment

Exclusion:
1) Unable to read or comprehend English
2) Not having a completed electronic Rapid Fitness Assessment within 2 months of surgery
3) Being discharged in one day or earlier from the hospital

Figure 1- Study schema



2.0 OBJECTIVES AND SCIENTIFIC AIMS

Aim 1: To determine the feasibility of *automated geriatric co-management program* in the care of geriatric oncology patients.

The feasibility of the program will be assessed by the percentage of patients in whom at least half of the recommendations made by the program are followed by the surgical team.
Our program will be deemed **feasible** if at least 50% of recommendations are followed in at least 70% of patients with impairments.

We based our cutoff based on multiple studies. A study done on surgeons' attitude toward assessment and management of older cancer patients, Ghignone et al[1], showed that only 6.4% of surgeons use geriatric assessment in their daily practice and only 36% collaborate with geriatricians in some form. Studies on geriatric comanagement of older adults who are receiving chemotherapy also showed that the pickup rate of interventions by the medical oncologists is around 35% [2]. Given these findings, we hypothesized that a more than 50% adoption of recommendations would be a reasonable rate for then refining the intervention and conducting an R01 study in the future.

Aim 2: To compare the effect of *automated geriatric co-management* program with in-person geriatric co-manage ment on adverse surgical events.

Aim 3: To compare the effect of automated geriatric co-management program with in-person geriatric co-manage ment on postoperative functional recovery.

3.1 BACKGROUND AND RATIONALE

Surgery remains the mainstay of cure for many older cancer patients.[3] As cancer incidence increases with age and with an aging population, it is expected that more older adults will be diagnosed with cancer.[4] Further, with the approval of lung cancer screening by Medicare, in addition to other cancer screening recommendations such as colonoscopy, it is expected that more older patients be diagnosed with cancer at an earlier stage.[5]

Older Cancer Patients and Surgical Outcomes: Prediction

Older and especially older frail cancer patients are at a highest risk for adverse surgical events and slower functional recovery following cancer surgery.[6] In an attempt to assess and lower the risk of a procedure for a patient, the American College of Surgeons and the American Geriatrics Society recommend incorporating geriatric assessment (GA) into the preoperative evaluation.[7] The goal of the GA is to identify geriatric syndromes and manage them perioperatively.[8] Studies have shown that components of GA are associated with the surgical outcomes. For example, a study of 120 patients aged 60 years or older who underwent thoracic surgery (85 of whom had lung cancer) showed that patients with dependency for performing basic activities of daily living (bADL) and those with dementia were more likely to develop postoperative complications.[9]

The Modified Frailty Index (m-FI) is a frailty index based on the American College of Surgeons National Surgical Quality Improvement Project.[10] It is a mix of 10 comorbid and medical conditions and one item on the level of independenc y for bADL and instrumental activities of daily living (iADL). The score runs from 0 to 11 and the score of 3 or higher is considered as frail. A study of 1940 patients who underwent thoracotomies and lung lobectomy showed that 5.6% of frail patients died after surgery compared to just 1% of fit patients. Moreover, major complications occurred in 4.2% of fit patients compared to 14.4% of frail patients.[11]

In addition to studies specific for oncologic thoracic surgery procedures, other studies have shown the same correlation with postoperative outcomes of other oncologic surgical procedures. A recent systematic review found that six separate prospective studies assessed the correlation between components of the GA and adverse surgical outcomes of older cancer patients. These studies confirmed that impairments in bADL, iADL and cognitive function are associated with an increased risk of postoperative complications.[12]

Interventions Aimed at Improving Surgical Outcomes of Older Patients; Collaboration between Surgeons and Geriatricians

It is important to note that identification of geriatric syndromes without appropriate perioperative interventions to manage the detected deficits will not improve surgical outcomes. In non-oncologic surgery setting, collaboration between surgeons and geriatricians has led to significant improvement in surgical outcomes by identifying and managing geriatric syndromes. In a study on 297 patients aged 70 years or older who underwent hip surgery, patients were randomly assigned to postoperative care in a geriatric ward vs. routine care in a surgical ward. At one and four months after surgery, patients in the geriatric ward showed more improvement in their mobility as measured by Short Physical Performance Battery, than patients in the surgical ward.[13] In another trial, 162 patients with hip fractures were randomized to geriatric consultation and care before and after surgery during the hospital course vs. care by the surgical team alone.[14] Patients in the intervention group experienced better performance on iADL, recovery of walking ability, fewer falls, fewer depressive symptoms and better quality of life during the first 24 months after hospital discharge. Another study on 319 patients aged 65 years or older who underwent hip fracture surgery showed that geriatric co-management after surgery can reduce in-hospital mortality from 5.8% to 0.6%, and reduce complication rates from 61% to 45%. Notably, this study showed that 57% of patients in the intervention group achieved partial or complete recovery compared to 44% in the control group.[15]

Limitations of Current Evidence in the Cancer Setting:

There is only very limited data on the effectiveness of such collaborations between surgical oncologist and geriatricians. In one study on oncologic surgeons' attitude toward perioperative care for older adults with cancer, among 11% who responded to the survey, only one out of three surgeons stated that they routinely collaborate with geriatricians.

The reasons for such a low rate of collaboration is likely multi-faceted. **First,** there is a shortage of geriatricians with only 7000 practicing in the United States.[16] **Second,** with geriatricians involved in various other critical initiatives such as long-term care or caring for older patients with Alzheimer, only limited time may be available to provide postoperative geriatric co-management for older cancer patients routinely.

The shortage of geriatricians could be addressed in two ways:

1- by training more providers, either geriatricians or geriatric nurse practitioners: This will be costly, requires significant amount of time and effort, and will not be available to provide an immediate answer to such need.
2- by providing surgeons with easy to administer GA and developing an ***Automated Geriatric Co-management Program,*** which will automatically provide geriatric recommendations based on impairments found via the GA to the surgical team. If this

program is shown to be feasible, acceptable to treating clinicians, and as effective in improving surgical outcomes as in-person geriatric co-management, then it can be adopted by all institutions that have limited or no geriatric service resources.

In summary, the rationale for this project is as follows.

1- The US population is aging.
2- The Incidence of cancer increases with age.
3- The introduction of cancer screening such as lung cancer screening will further increase the number of older adults with early stage cancer increases in the near future.
4- Surgery is the mainstay of cure for early stage cancer patients.
5- The likelihood of adverse surgical events and slow functional recovery increases in older adults, and especially older frail adults with cancer.
6- Geriatric Assessment can assess patient frailty and identify potentially manageable geriatric syndromes.
7- Management of geriatric syndromes can lead to improved surgical outcomes.
8- Collaboration between non-oncologic surgeons and geriatricians to manage geriatrics syndromes have substantially improved surgical outcomes.
9- Even if such collaboration is effective, it may not be scalable due to a limited number of geriatric healthcare providers.

As a result, an automated geriatric co-management program, if shown to be feasible and as effective as in-person geriatric co-management, could be used to provide peri-operative geriatric care routinely in institutions that have limited or no geriatrics services.

The Electronic Rapid Fitness Assessment (the eRFA) at Memorial Sloan Kettering Cancer Center (MSKCC)

The eRFA was developed at MSKCC through collaboration between the Geriatrics Service and the Web Survey Core Facility (Webcore) in 2015. During the eRFA development process, the Geriatrics Service held multiple discussions to determine which GA domains to assess and which validated assessment methods to use. The name “Electronic Rapid Fitness Assessment” was selected to reflect the purpose of the GA, which is to distinguish patients who are fit from those who are frail.

Administration and Reporting of the eRFA:

The eRFA was first implemented in the Geriatrics clinic. In 2016, the Thoracic surgery clinic implemented the eRFA at the point of care. All patients who present to MSKCC geriatric clinics or thoracic surgery clinics complete the eRFA while they are waiting to be seen by their healthcare providers for their initial consultation. Patients may complete the eRFA on their own or with assistance from others (e.g., a caregiver), or they may allow someone else

(e.g., a caregiver) to complete the assessment for them. Patients may also complete the eRFA at home, before their appointment, if they have Internet access and an e-mail account. After the assessment has been completed, a registered nurse (RN) performs a cognitive assessment using the Mini-Cog[17, 18] and establishes the patient's mobility using the Timed Up and Go (TUG)[19] test, the results of which are then entered into the eRFA by the RN. The Mini-Cog and TUG assessments will be omitted if the patient is being seen via telemedicine.

The eRFA contains 28 questions about functional status, cognition, social support, social activity interference, emotional status, nutrition, vision, hearing and polypharmacy. On average, it takes between 10 to 20 minutes to complete. The eRFA is accessible using computers, tablets, and smartphones. It is partially integrated with the electronic medical record (EMR), with patients' names and medical record numbers pulled from the EMR as patient-specific questionnaires are generated.

The components of the eRFA, the 12 major instruments utilized, and the cutoff for significantly abnormal values are shown in figure 2.

Figure 2. Twelve major instruments of Electronic Rapid Fitness Assessment (the eRFA)

Domain	Instrument	Completed by	Description	Score range	Frail values
Functional Domain	**Activities of Daily Living (ADL) [20]**	Patient	Basic Activities of Daily Living (bADL or ADL) assesses patients' level of independence in 7 activities: bathing, dressing, grooming, feeding, bladder and bowel control, and walking inside and outside of the house. Answer choices to each are: limited a lot (0), limited a little (1), not limited (2).	0-14	≤13
	Instrumental Activities of Daily Living (iADL) [21]	Patient	Instrumental Activities of Daily Living (iADL) assesses patients' level of independence in 8 activities: telephone use, doing laundry, shopping, preparing meals, doing housework, handling own medications, handling money and finances, and transportation. Answer choices to each are: unable to do (0), able with some help (1), able without help (2).	0-16	≤15
	Karnofsky Performance Status (KPS) [22]	Patient	Karnofsky Performance Status rates patient's functional independence in performing ordinary tasks. The score ranges from 100 (Normal with no symptoms) to 0 (Dead) in increments of 10.	30-100	≤80

			The patient-rated KPS in answered in 8 levels:		

			100- Normal, no symptoms 90- Able to carry on normal activity, minor symptoms 80- Normal activity, with effort, some symptoms of disease 70- Can care for self, but unable to do normal activity or work 60- Require occasional assistance, but able to care for most needs 50- Require considerable assistance 40- Disabled, require special care and assistance 30- Severely disabled, require continuous nursing care		
	Fall inthe past year	Patient	The number of falls in the past year	None, One time, More than one time	≥1 time
	Timed Up and Go test [19]	Nurse	Patients are asked to stand from the chair, walk ten feet, turn and return to the chair. The total time is recorded.	<10 seconds, 10-19 seconds, ≥20 seconds	≥10 seconds
Social support/ activity	**Social support survey [23]**	Patient	The Medical Outcome Study- Social Support Survey- 4 item asks 4 questions on how often patients have someone to receive support from: All the time (5), Most of the time (4), Some of the time (3), A little of the time (2), Not at all (1). Higher scores mean better social support.	4-20	≤16
	Social activity limitation [24]	Patient	The Medical Outcome Study- Social Activity Survey asks how much patients' social activity is limited and how much/ often it has become limited/ interfered with recently. 3 questions with 5 answers (1-5) are counted. Higher scores mean more limited social activity.	3-15	≥8
Cognition	**Mini Cog test [17, 18]**	Nurse	Patients are told three words to memorize. Then they are asked to draw a clock with hands showing ten past eleven. Then they are asked to recall the three words. Clock draw is evaluated either normal with 2 points or abnormal with 0 point. Each correctly recalled word has 1 point (0-3).	0-5	≤2

Emotional wellbeing	**Distress [25]**	Patient	The Distress Thermometer ranges from 1 (no distress) to 10 (extreme distress).	1-10	≥4
	Depression [26, 27]	Patient	The Geriatric Depression Scale- 4 item is a yes/no questionnaire. Patients receive 1 point for each answer that indicates depression.	0-4	≥1
Poly-pharmacy	**Poly-pharmacy [28]**	Patient	The number of medications currently taken	1-4 medications, 5-9 medications, ≥10 medications	≥5 medications
Nutritional status	**Weight change**	Patient	Weight change in the past 6 months	no change or weight gain, lost < 5 lbs, lost 5-10 lbs, lost 10-20 lbs, lost ≥20 lbs	lost ≥10 pounds

The eRFA in the Thoracic Surgery Clinics as a Model for other Surgical Clinics:

After development and successful implementation of the eRFA in all MSKCC Geriatric clinics[29], more than 4000 older cancer patients with a median age of 80 have completed the eRFA. Patients have shown very high levels of satisfaction with the instrument, and, as a result, thoracic surgery clinics have implemented the eRFA in their clinics as a routine care for the new patients. We have shown that implementation of eRFA in the thoracic surgery clinics is feasible and can yield useful clinical information that can be managed perioperatively.[30]

For the purpose of this study, thirteen comorbid conditions are queried and combined as one item in addition to the 12 items in the eRFA report.

Throughout the study, we have realized the most limiting factor in efficiently accruing patients was very strict inclusion and exclusion criteria that required a significant amount of time from research coordinators, and healthcare providers to properly assess these patients. Because this is a pilot study, based on R21 study, we have realized that such strict inclusion and exclusion criteria are not needed at this time.

Thus far, we have made significant improvements in the study process itself. For example, in the beginning, the electronic Rapid Fitness Assessment was on the Webcore platform with limited resources. Over the past months, we have moved to MSK Engage platform, and further enhanced our collaboration with the Engage team, which has more supportive staff than the Webcore platform.

During the course of the study, The PI has given lectures to various surgery services about the importance of assessing fitness/frailty of older adults with cancer before surgery and the need to properly optimize the status of these patients. These lectures were met with significant enthusiasm and surgeons expressed the desire to be able to accrue patients for this study.

Finally, proper assessment of fitness/frailty of older adults with cancer is not unique to one disease or one surgery service. In fact, frailty is considered a global syndrome without sociodemographic or clinical boundaries. As a result, in order to allow patients with other diseases who are going to undergo various surgeries to be accrued, we would like to broaden the study.

In the proposed study, we will continue to advance the eRFA. We will assess whether performing eRFA along with *automated recommendation* for each eRFA impairment is feasible, and to collect preliminary data on its impact of patients' surgical outcomes and functional recovery compared to in-person geriatric co-management.

Our intervention, if feasible, will be scalable, and will likely improve care for hundreds of thousands of older cancer patients who are evaluated every year for their fitness for undergoing surgery.

4.1 OVERVIEW OF STUDY DESIGN/INTERVENTION

4.2 Design

The proposed study is a randomized controlled trial study. The primary aim of this study is to assess the feasibility of an automated geriatric co-management program for perioperative management of patients with solid mass or nodule who present to MSKCC Surgery Service clinics, and being considered for surgery.

Secondary aims are to collect preliminary data on its impact on postoperative adverse surgical outcomes, and functional recovery compared to in-person geriatric co-management.

The first visit (surgery clinics when patients are being considered for surgical resection of their solid mass or nodule suspicious for cancer): In surgery clinics, all patients complete the eRFA as a routine care.

Inclusion criteria are: 1) solid mass or nodule suspicious for cancer, 2) aged 65 or older, 3) being considered for surgical resection of the solid mass or nodule with anticipated hospital length of stay of at least two days, 4) completed eRFA.

Exclusion criteria: 1) unable to read or comprehend English, 2) not having a completed eRFA within the two months of undergoing surgery, 3) being discharged in one day or earlier from the hospital.

Note) To avoid excluding patients based on item 2, patients have to complete another eRFA within two months of surgery.

Following patients' consent to participate in the study, patients will also complete a 4-Meter walk test (4MWT)[31]. Their sociodemographic characteristics will also be recorded.

Subsequently, they will be randomized either to in-person geriatric co-management or the automated geriatric co-management program, using MSKCC's Clinical Research Database, a secure randomization system ensuring full allocation concealment.

The automated geriatric co-management program group: Through literature review, consideration of American College of Surgeons and American Geriatrics Society recommendation[32], and our years of collective experience for postoperative care for older adults with cancer, we have developed perioperative geriatric recommendations for each of the 12 eRFA impairments and comorbid conditions (appendix 1).

Following completion of the eRFA, the summary of impairments as well as the recommendations generated by the study team (hard-copy or email) will be provided in real-time to the thoracic surgery team for their attention. A sample is provided below. In this case, patient has impairments in various domains that ranges from KPS to number of medications.

☑ **eRFA Summary**

Global recommendation: If 3 or more impairments are listed in the summary below, consider referral to geriatrics.
T = Threshold | **P** = Percentile | **PS** = Patient Score

KPS	**T:**	≤ 80	**P:**	37%	**PS:** 60.
☐ More Information:					
ADL	**T:**	< 14	**P:**	52%	**PS:** 12.
☐ More Information:					
iADL	**T:**	< 16	**P:**	45%	**PS:** 13.
☐ More Information:					
Timed Up and Go Test	**T:**	≥ 10 seconds	**P:**	36%	**PS:** 10-19 seconds.
☐ More Information:					
Social Support	**T:**	≤ 16	**P:**	43%	**PS:** 16.
☐ More Information:					
Limited Social Activity	**T:**	≥ 8	**P:**	50%	**PS:** 12.
☐ More Information:					
Weight Change	**T:**	10 pound loss or more	**P:**	16%	**PS:** 10-20.
☐ More Information:					
Distress Level	**T:**	≥ 4	**P:**	55%	**PS:** 7.
☐ More Information:					
Number of Medications	**T:**	≥ 5	**P:**	45%	**PS:** More than ten.
☐ More Information:					

Subsequently, the research staff member clicks on various impairments and would be able to view and print the recommendations for each impairment. For example, the following are the recommendations for a Timed Up and Go test impairment.

Timed Up and Go Test **T:** ≥ 10 seconds **P:** 36% **PS:** 10-19 seconds.

☑ More Information:

☑ Pre/Postop Recommendation:

A- Consider consultation with physical therapy and occupational therapists.

B- Encourage use of appropriate assistive devices.

C- Encourage resistance exercises such as repeated chair stand in the preoperative period.

D- Consider use of stationary bike or bike pedals in the preoperative period.

☐ Medical Recommendation:

☐ Education:

☐ Supportive Services:

A copy of the recommendations will be available in EMR. After preoperative clearance by patients' primary care providers, general internal medicine service, or other services such as cardiology, patients will undergo surgery. The geriatrics service will see patients before or after surgery if the consult is requested by the surgery service. The automated co-management program is not expected to lengthen the patients' first visits.

The in-person geriatric co-management group. Patients randomized to the in-person geriatric management will be seen by MSKCC's geriatrics service for preoperative evaluation. The evaluation may be done either in clinic or via telemedicine. Based on the eRFA results and other issues found during the preoperative evaluation, geriatricians will make recommendations to be executed in the postoperative period. Patients are then co-managed by the geriatrics service during hospital course after surgery. The geriatrics service sees these patients for at least 2 postoperative days, if deemed clinically necessary by the geriatrician. During the inpatient hospital course, the geriatrics service will ensure the execution of preoperative recommendations and will discuss with the surgical team, who will act as a primary team, any additional recommendation in order to improve postoperative care.[33]

The 2nd study visit (outpatient follow-up visit by the surgery team, usually within 2 weeks after hospital discharge): During this meeting, once again patients complete the eRFA as a routine care, and perform 4MWT. The 2nd visit may also be conducted via telemedicine, depending on patient preference.

Patients' follow up continues until day 30 after surgery with hospital length of stay of at least two days in which the surgical adverse events (surgical complications grade 2+, disposition to any place other than home, length of stay, and readmission), surgery characteristics, cancer characteristics, and preoperative lab results will be collected by the study team.

Patients go off-study either at the 2nd study visit or 30 days after surgery, whichever happens later.

4.3 Intervention

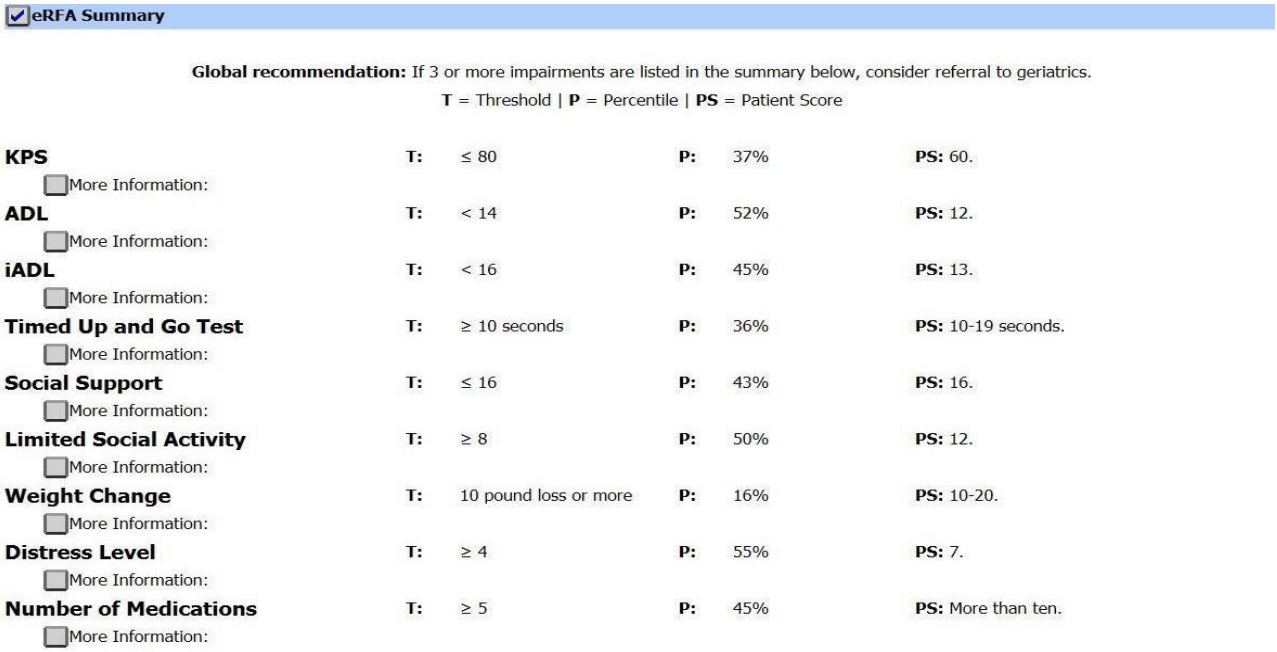
The automated geriatric co-management program group: Through literature review, consideration of American College of Surgeons and American Geriatrics Society recommendation[27], and our years of collective experience for postoperative care for older adults with cancer, we have developed perioperative geriatric recommendations for each of 12 eRFA impairments and comorbid conditions (appendix 1)

Following completion of the eRFA, the summary of impairments as well as the recommendations generated by the study team (hard-copy or email) will be provided in real-time to the surgery team for their attention.

It will be up to the surgeons and the surgical team whether they follow the recommendations or not. The rate of follow up of the recommendation is the primary aim of this study.

A sample is provided below. In this case, patient has impairments in various domains

that ranges from KPS to number of medications.



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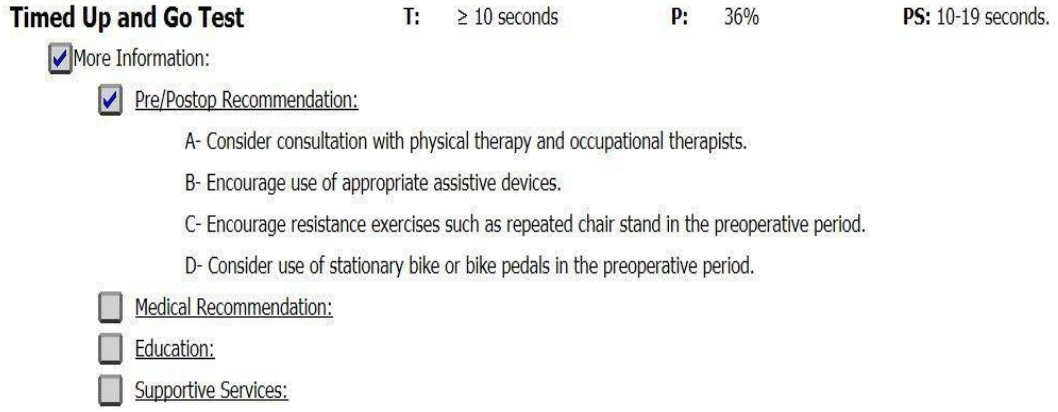

Timed Up and Go Test **T:** ≥ 10 seconds **P:** 36% **PS:** 10-19 seconds.

☑ More Information:

☑ Pre/Postop Recommendation:

A- Consider consultation with physical therapy and occupational therapists.

B- Encourage use of appropriate assistive devices.

C- Encourage resistance exercises such as repeated chair stand in the preoperative period.

D- Consider use of stationary bike or bike pedals in the preoperative period.

☐ Medical Recommendation:

☐ Education:

☐ Supportive Services:

A copy of the recommendations will be available in EMR. After preoperative clearance by patients' primary care providers, general internal medicine service, or other services such as cardiology, patients will undergo surgery. The geriatrics service will see patients before or after surgery if the consult is requested by the surgery service. The automated co-management program is not expected to lengthen the patients' first visits.

5.1 CRITERIAFOR SUBJECT ELIGIBILITY

Patients who present to MSKCC surgery clinics for consideration of surgery for their solid mass or nodule will be selected.

5.2 Subject Inclusion Criteria

1) Solid mass or nodule/lesion suspicious for cancer,

2) Aged 65 or older,

3) Being considered for surgical resection of solid mass / nodule/lesion with anticipated hospital length of stay of at least two days,

4) Completed the eRFA per routine care

5.3 Subject Exclusion Criteria

1) Unable to read or comprehend English

2) Not having a completed eRFA within the two months of undergoing surgery

Note) To avoid excluding patients based on item 2, patients have to complete another eRFA within two months of surgery.

3) Being discharged in one day or earlier from thehospital.

6.0 RECRUITMENT PLAN

The patients' surgeons and nurse practitioners who will have an established medical relationship with potential participants will identify potentially eligible patients for the proposed study in advance of their consultations. Patients of both genders and all ethnicity will be considered for participation in the proposed study. Patient eligibility will be determined by the clinical research staff. A consenting professional will comprehensively go through the details of the study with patients and provide patients with time to ask questions and have them answered fully. Patients will be encouraged to take adequate time before making their decision regarding participation in the study. For those that indicate a desire to participate in the study, they will be consented by a consenting professional and the first study visit assessment will take place at that time. The surgery team will also be informed of the data they will be required to collect and document from their consultation with the patient. For patients that require more time to make their decision regarding participation, subjects may be enrolled at any time prior to their surgery. They will be informed that they will be contacted by a member of the research team in the coming days to learn of their decision.

During the initial conversation between the investigator/research staff and the patient, the patient may be asked to provide certain health information that is necessary to the recruitment and enrollment process. The investigator/research staff may also review portions of their medical records at MSKCC to further assess eligibility. They will use the information provided by the patient and/or medical record to confirm that the patient is eligible and to contact the patient regarding study enrollment. If the patient turns out to be ineligible for the

research study, the research staff will destroy all information collected on the patient during the initial conversation and medical records review, except for any information that must be maintained for screening log purposes or processes.

For patients that are not interested in taking part in the proposed study, an expression of thanks will be offered for the opportunity to discuss potential study enrolment with them. Patients will be asked if they would be willing to provide their primary reason for declining participation. They will be informed that this answer will be anonymously recorded for the purpose of understanding factors that influence patient decisions regarding participation in the study. If a patient declines to offer a reason this will be recorded as "patient declined to offer a reason for non-participation in the study".

Payment to Participants Study participants will not receive any payment for their participation in the proposed study.

7.1 ASSESSMENT/EVALUATION PLAN

Assessment and Measurement Instruments:

In this study, the data will be collected using the following instruments and measurements methods:

- **Electronic Medical Record review:**
    - **1-** For patients in the intervention group (automated geriatric co-management), we will assess the percentage of recommendations that were followed by the surgery team. For example, if automated geriatric co-management recommends consultation with physical therapy perioperatively, we will assess whether the consult has been obtained.
    - **2-** For patients in both groups, we will assess the adverse surgical events by day 30 following surgery. Adverse surgical event is a composite of surgical complications grade 2 or higher, mortality after surgery, or discharge to any place other than home, or prolonged length of stay (defined as length of stay longer than 75% of the cohort who underwent the same surgical procedure), or readmission to the hospital within 30 days from surgery.

      MSKCC's secondary surgical events database in the EMR has been shown to accurately record major postoperative complications within the 30 days after surgery[34].
    - **3-** to assess sociodemographic characteristics (age, gender, ethnicity),
    - **4-** to assess routine preoperative blood work (complete blood cell counts, chemistry panel).
    - **5-** To assess cancer characteristics (stage, receipt and type of neoadjuvant treatment)

6- To assess surgical characteristics (type of surgery: minimally invasive vs open, duration of surgery, intraoperative blood loss, and American Society of Anesthesiologist Physical Status classification)

- **Four Meter Walk Test:** In order to assess functional recovery, the 4-meter walk test will be performed. In the 4-meter walk test, the time that it takes patients to walk 4 meters in their usual pace will be recorded in seconds by the clinical research staff. (This portion will be skipped for patients being seen via telemedicine.)

Assessment and Evaluation Plan

Patients will be screened for study eligibility at the time of attending their surgery appointment at MSKCC for consideration of surgery. The inclusion and exclusion criteria will be reviewed by the clinical research staff firstly to confirm the patients' eligibility status. Once eligibility has been determined and informed consent has been obtained, patients will undergo baseline assessments and subsequently randomization will occur.

There will be two study visits for patients in both groups; baseline or pre-op visit (1st) and the 2nd visit. Baseline visit occurs at the time of new visit by the surgery team, or in the case that two months has passed since baseline, at the pre-op visit. 2nd visit occurs at the time of follow up after hospital discharge by the surgeons. Both baseline and 2nd visit may be conducted via telemedicine if preferred.

Baseline Study Visit/Pre-op Visit: In this visit, following assessments will be performed.

- The 4-Meter Walk test.
- Sociodemographic characteristics.
- eRFA completion per routine care

2nd Study visit: In this visit, following assessment will be performed.

- The 4-Meter Walk test.
- eRFA completion per routine care

Study participant follow up:

Thirty days after surgery:

- Collection of adverse surgical events (grade 2 or more complications, length of stay, readmission, disposition plan), surgery and cancer characteristics, and preoperative blood work results.

	Screening & Baseline study visit	Pre-operative visit	2nd study visit (within 2 weeks of surgery)	30 Day post-surgery follow up

Informed consent	✓			

Eligibility determination	✓			
Randomization	✓ (if proceeding with surgery in 2 months)	✓ (if two months have passed by from baseline visit)		
eRFA completion, per SOC	✓	✓ (if two months have passed since baseline visit)	✓	
Automated geriatric co-management program	✓		✓	
In-person geriatric co-management program		✓	✓	
4 MWT	✓	✓ (if two months have passed by from baseline visit)	✓	
Sociodemographic data	✓			
Preoperative lab results				✓
Cancer characteristics				✓
Surgical characteristics				✓
Adverse events				✓

8.0 TOXICITIES/SIDE EFFECTS

There are minimal adverse events or risks associated with participation in this study. Staff will be adequately trained to identify any signs of distress that may be experienced by a patient during the course of their participation in the study.

Burden of Assessment

It is possible that patients may not be able to or willing to do 4-Meter walk test. This test will only be performed if patients are comfortable with them. Study participants will be given contact details of the clinical research staff dedicated to this study in case they have any questions or concerns regarding study.

Patient Identification of Unmet Clinical Needs

If thoracic surgeons and/or other healthcare providers are concerned about the unmet needs of patients before or after surgery, they are encouraged to obtain proper medical and non-medical consultations.

9.0 PRIMARY OUTCOMES

	Baseline study visit	Preoperative visit (if two months have passed by from baseline study visit)	2nd study visit	30-day post-surgery follow up
eRFA (including Karnosky Performance Status, basic Activities of Daily Living, instrumental Activities of Daily Living, Timed-up-and-Go test)	✓	✓	✓	
4 MWT	✓	✓	✓	
Sociodemographic characteristics	✓			
Preoperative lab results				✓
Cancer characteristics				✓
Surgical characteristics				✓
Adverse events				✓
Hospital Length of Stay				✓
Discharge/Disposition location				✓
30-day readmission to hospital				✓
Number of geriatric recommendations followed				✓

10.1 CRITERIA FOR REMOVAL FROM STUDY

Patients will have completed their participation in this study after the 30-day post-surgery follow-up or the 2nd study visit, whichever occurs later, and will be considered off-study. Participants will be removed from the study if:

- ✓ He/she chooses to withdraw consent for continued participation at any time
- ✓ The participant reports intolerable distress due to study participation
- ✓ He/she becomes ineligible for study participation as designated by the inclusion/exclusion criteria

11.0 BIOSTATISTICS

This is a prospective, randomized trial of automated geriatric co-management in patients presenting to the surgery clinic for surgery compared with standard in-person geriatric co-management. Patients will be randomized 1:1 to either arm according to section 12.2.

Primary Aims

Feasibility of the automated geriatric co-management program in the care of geriatric oncology patients.

Among patients randomized to the automated geriatric arm of the study we will calculate the proportion of patients for whom at least half of the recommendations made were followed by the surgical team. **Our program will be deemed feasible if at least 50% of recommendations are followed in at least 70% of patients with impairments.** We based our cutoff based on multiple studies. A study done on surgeons' attitude toward assessment and management of older cancer patients, Ghignone et al[1], showed that only 6.4% of surgeons use geriatric assessment in their daily practice and only 36% collaborate with geriatricians in some form. Studies on geriatric comanagement of older adults who are receiving chemotherapy also showed that the pickup rate of interventions by the medical oncologists is around 35%[2]. Given these findings, we hypothesized that a more than 50% adoption of recommendations would be a reasonable rate for then refining the intervention and conducting an R01 study in the future.

We will first report the number of patients that were randomized to the automated geriatric comanagement arm but were subsequently referred to the geriatric in-person comanagement arm and report the distribution of recommendations made for these crossover patients. We will analyze 77 patients with at least one eRFA impairment who adhere to the automated geriatric comanagement arm and are not seen by geriatrics service for preoperative evaluation (crossover). In all analyses for the primary aim, we will exclude those who do not have any baseline impairment or have crossed over to the in-person geriatric comanagement arm. An interim analysis will be conducted after 38 patients are accrued. If 50% of recommendations were followed for 21 or fewer patients, the trial will be stopped for futility. Otherwise, accrual of 77 eligible patients will be completed, after which accrual will be closed to additional patients. The

intervention will be deemed feasible if recommendations are followed for 50 patients. Finally, we will present the distribution of number of recommendations made and followed in the automated geriatric comanagement arm.

Secondary Aims

Effect of the automated geriatric co-management program compared to the in-person geriatric co-management on adverse surgical events.

All between-group comparisons will be by modified intent-to-treat (complete case analysis), with patients analyzed according to randomization, irrespective of whether they were proceeded to automated geriatric co-management or in-person geriatric co-management. To compare, by intervention arm, the proportion of patients with a composite outcome ("adverse surgical event") of either surgical complications grade 2 or higher, or prolonged hospital length of stay, or discharge to another care facility rather than home, or 30-day readmission to the hospital. Prolonged hospital length of stay will be defined as hospital length of stay greater than 75% of the cohort who underwent the similar procedure. We will test the association between intervention arm and adverse surgical event using logistic regression with the randomization stratum as the covariate.

It is plausible that the relative value of in-person vs. automated geriatric *co-management* depends on baseline risk, for instance, it could be that average risk patients are adequately managed by the automated approach, but those at high risk require individualized care. To this end, we will use a logistic regression with adverse surgical event as the outcome, study arm as the predictor, randomization strata as the covariate, and adjust for continuous baseline risk using the MSK-FI, with restricted cubic splines with knots at the tertiles to allow for non-linearity. We will then visualize the risk in both intervention arms across baseline risk to provide an individualized estimate of benefit for a given level of baseline deficit. The MSK-FI is a frailty index defined by ten sets of comorbidities, and one component related to dependency on five activities of daily living. The former will be queried from the institutional database, and the latter is assessed using the bADL and iADL measures on the eRFA.[35]

Effect of the automated geriatric co-management program with in-person geriatric co-management on postoperative functional recovery.

To compare, by intervention arm, postoperative functional recovery. We will consider postoperative functional recovery as reported by the patient, as well as assessed by the study team during the 2nd study visit. Patient-reported recovery will be measured by three domains reported on both pre and post-operatively: Karnofsky Performance Status, basic activities of daily living, and instrumental activities of daily living.
Clinician-evaluated functional recovery will be assessed through the Timed Up and Go

test and the 4MWT. This analysis will only be done for patients who have completed the assessment during in-person visit with the surgery team. Recovery of Karnofsky Performance status, defined as the same or better Karnofsky Performance status during the 2nd study visit compared to baseline, will be compared between groups using a logistic regression with randomization strata as covariates. Basic activities of daily living, instrumental activities of daily living, Timed up and Go test and 4MWT will be compared between groups by ANCOVA, with baseline score and randomization strata as a covariate.

In the case that patient's surgery occurs after two months of completing the eRFA, either the patient has to complete another eRFA within two months of surgery, which then will be the patient's new preoperative baseline eRFA, or in case of not completing the eRFA, the patient will be excluded from the study.

We are additionally interested in using the three components, of the patient-reported functional recovery in three categories: complete recovery (defined as all three post-operative measurement score being greater than or equal to the pre-operative measurement score), partial recovery (defined as at least one, but not all three, post-operative measurement scores being greater than or equal to the pre-operative measurement score), or no recovery (defined as none of the post-operative measurement scores being greater than or equal to the pre-operative measurement score). Similarly we will use two components of the clinician-evaluate functional recovery to define three categories: complete recovery (defined as all both post-operative measurement score being greater than or equal to within 10% of the pre-operative measurement score), partial recovery (defined as at least one, but not both, post-operative measurement scores being greater than or equal to within 10% of the pre-operative measurement score), or no recovery (defined as neither of the post-operative measurement scores being greater than or equal to within 10% of the pre-operative measurement score). We will test the association between intervention arm and degree of recovery by using ordinal regression with randomization strata as covariates.

As it is likewise plausible that the relative value of in-person vs. automated geriatric co-management depends on baseline risk, we will repeat the analysis described above, related to baseline risk, for the outcomes of patient-reported functional recovery and clinician-assessed functional recovery.

Sample size

With a null hypothesis of 55% and the alternative hypothesis of 70% of patients with recommendations followed, and a one-sided α of 5% and a power of 85%, we require 77 eligible patients to be accrued in the in the automated geriatric co-management arm for a two-stage Simon minimax design. We expect about 25% of patients to be excluded for the primary aim due to no impairment (5%) or crossover to the in-person

geriatric comanagement arm (20%) suggesting a total accrual close to 100 per group.

Assuming a correlation of 0.5 between baseline and follow-up, and a standard deviation of 1.8 (as seen in our preliminary dataset for the basic activities of daily living, the score of which ranges from 0 to 14), with ~95 patients per arm (after an estimated 5% loss of patients due to drop out), the power for various effect sizes for our continuous secondary endpoints when analyzed using ANCOVA are shown in the table, where it can be seen that we have high power to detect small differences between groups. Sensitivity analyses will be conducted where missing outcome data will be imputed by Multiple Imputation using Chained Equations.

Difference between groups	Power
0.5	60%
0.67	84%
0.8	94%

In 2017, the surgical services had completed surgical procedures on more than 5000 patients aged 65 or older with a hospital length of stay of 2 days or longer. Therefore, we expect to enroll the 200 patients for our study in less than two-years. We expect most patients to be older (75+) but to ensure that younger patients are not overly represented, we will cease accrual of patients 65 – 74 after 60 are accrued (i.e. 30%).

12.1 RESEARCH PARTICIPANT REGISTRATION AND RANDOMIZATION PROCEDURES

12.2 Research Participant Registration

Confirm eligibility as defined in the section entitled Inclusion/Exclusion Criteria. Obtain informed consent, by following procedures defined in section entitled Informed Consent Procedures. During the registration process registering individuals will be required to complete a protocol specific Eligibility Checklist. The individual signing the Eligibility Checklist is confirming whether or not the participant is eligible to enroll in the study. Study staff are responsible for ensuring that all institutional requirements necessary to enroll a participant to the study have been completed. See related Clinical Research Policy and Procedure #401 (Protocol Participant Registration).

12.3 Randomization

Randomization to either in-person geriatric co-management or automated geriatric co-managements will be accomplished by the method of randomly permuted blocks of random length. Patients will be stratified by planned procedure type (minimally-invasive surgery vs open surgery), age (65-74 vs. 75+) and baseline number of eRFA impairments (<4 vs. ≥4: anticipated median number of eRFA impairments) Randomization will be conducted by use of the Clinical Research Database (CRDB) at MSKCC.

13.1 DATA MANAGEMENT ISSUES

MSKCC clinical research staff will be assigned to this protocol. The responsibilities of the clinical research staff include project adherence, data collection, abstraction and entry, data reporting, regulatory monitoring, problem resolution and prioritization, and coordinating the activities of the protocol study team. Data gathered for this study will be obtained from enrolled patients by thoracic surgery providers, clinical research staff, clinical research nurse specialists. The data collected for this study will be entered into REDCap database to be accessed only by study staff. All data collected will be de-identified to maintain participants' confidentiality. Participants will be assigned unique identification numbers, which will be used to identify all the data. All participant related data will be identified only with a study code number. A list of the names and assigned identification number will be kept in a password protected log on the MSKCC share drive accessible only to relevant research staff.

Study findings will be presented in aggregate form only, with no reference made to individual participant's data. The Principal Investigator and their research team will be responsible for identifying, reviewing and reporting all necessary adverse events to the institutional IRB as appropriate. The data will be used specifically for the purposes outlined in this proposal and not for any other purpose. All study related documents and will be stored in a secure location until the study has ended and all data analyses are complete. At that time, all study material will be placed in a secured long-term storage facility until it is deemed appropriate to destroy the study material.

13.2 Quality Assurance

Reports will be generated to monitor patient accruals and completeness of registration data. Data quality reports will be generated to assess missing data and inconsistencies. Accrual rates and extent and accuracy of evaluations and follow-up will be monitored periodically throughout the study period and potential problems will be brought to the attention of the study team for discussion and action. Random-sample data quality and protocol adherence audits will be conducted by the study team. Additionally, audits will be conducted by the Department of surgery to review consent documents and procedures. Data audits will begin after the first ten participants are enrolled; study staff will assess protocol adherence and review accuracy of data entry into all central tracking systems/databases.

13.3 Data and Safety Monitoring

The Data and Safety Monitoring (DSM) Plans at Memorial Sloan-Kettering Cancer Center were approved by the National Cancer Institute in September 2001. The plans address the new policies set forth by the NCI in the document entitled "Policy of the National Cancer Institute for Data and Safety Monitoring of Clinical Trials" which can be found at: *http://www.cancer.gov/clinicaltrials/conducting/dsm-guidelines/page1.* The DSM Plans at MSKCC were established and are monitored by the Office of Clinical Research. The MSKCC Data and Safety Monitoring Plans can be found on the MSKCC Intranet at: *https://one.mskcc.org/sites/pub/clinres earch/Doc uments/MSKCC%20Data%20and%20Safety%20Monitoring%20Plans.pdf.* There are several different mechanisms by which clinical trials are monitored for data, safety and quality. There are institutional processes in place for quality assurance (e.g. protocol monitoring, adherence and data verification audits, therapeutic response, and staff education on clinical research QA) and departmental procedures for quality control, plus there are two institutional committees that are responsible for monitoring the activities of our clinical trials programs. The committees: Data and Safety Monitoring Committee DSMC) for Phase I and II clinical trials, and the Data and Safety Monitoring Board (DSMB) for Phase III clinical trials, report to the Center's Research Council and Institutional Review Board.

During the protocol development and review process, each protocol will be assessed for its level of risk and degree of monitoring required. Every type of protocol (e.g., NIH sponsored, in-house sponsored, industrial sponsored, NCI cooperative group, etc.) will be addressed and the monitoring procedures will be established at the time of protocol activation.

14.1 PROTECTION OF HUMAN SUBJECTS

Participants will be informed that participation is voluntary and that they have the right to withdraw from the study at any point. Given the nature of this study, the ratio of risk to benefit is quite low and reasonable. Confidentiality of each subject's self-reported information and medical information will be protected with the utmost care. Each study participant will be given a unique numeric identifier upon study entry. Electronic patient data and any hard copy data sheets collected from each subject will be identified solely by a code number. A list matching subject names and code numbers will be maintained separately and kept in a secure area. IRB and HIPAA regulations concerning confidentiality will be strictly enforced. Through the use of password security measures, restrictions will be applied to each user commensurate with their needs to access the data. Confidential information will not be routinely available to all members of the research team but rather on a "need to know" basis. All current and new personnel will be instructed in the ethics of electronic data access, as well as receive training in both HIPAA issues and human subjects training.

14.2 Privacy

MSK's Privacy Office may allow the use and disclosure of protected health information pursuant to a completed and signed Research Authorization form. The use and disclosure of protected health information will be limited to the individuals described in the Research Authorization form. A Research Authorization form must be completed by the Principal Investigator and approved by the IRB and Privacy Board (IRB/PB).

The consent indicates that individualized de identified information collected for the purposes of this study may be shared with other qualified researchers. Only researchers who have received approval from MSK will be allowed to access this information which will not include protected health information, such as the participant's name, except for dates. It is also stated in the Research Authorization that their research data may be shared with others at the time of study publication.

14.3 Serious Adverse Event (SAE) Reporting

Due to the nature of this study, we do not anticipate any SAEs.

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

- Death
- A life-threatening adverse event
- An adverse event that results in inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- 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

Note: Hospital admission for a planned procedure/disease treatment is not considered an SAE.

SAE reporting is required as soon as the participant signs consent. SAE reporting is required for 30-days after the participant's last investigational treatment or intervention. Any events that occur after the 30-day period and that are at least possibly related to protocol treatment must be reported.

If an SAE requires submission to the IRB office per IRB SOP RR-408 'Reporting of Serious Adverse Events', the SAE report must be sent to the IRB within 5 calendar days of the event. The IRB requires an electronic SAE report be submitted electronically to the SAE Office through PIMS.

The report should contain the following information:

Fields populated from PIMS:

- Protocol number and title
- Protocol status
- Sponsoring department
- Principal investigator
- Protocol type and category
- MSK IND

Fields populated from CTMS:

- Medical record number
- Disease/histology (if applicable)
- Date of birth and gender

Data needing to be entered:

- External reporting required
- Treating physician
- The date the adverse event occurred
- The adverse event
- The grade of the event
- Relationship of the adverse event to the treatment (drug, device, or intervention)
- If the AE was expected
- The severity of the AE
- The intervention
- Detailed text that includes the following
    - An explanation of how the AE was handled
    - A description of the subject's condition
    - Indication if the subject remains on the study
- If an amendment will need to be made to the protocol and/or consent form
- If the SAE is an Unanticipated Problem

The PI's signature and the date it was signed are required on the completed report.

15.0 INFORMED CONSENT PROCEDURES

Before protocol-specified procedures are carried out, consenting professionals will explain full details of the protocol and study procedures as well as the risks involved to participants prior to their inclusion in the study. Participants will also be informed that they are free to withdraw from the study at any time. All participants must sign an IRB/PB-approved consent form indicating their consent to participate. This consent form meets the requirements of the Code of Federal Regulations and the Institutional Review Board/Privacy Board of this Center. The consent form will include the following:

1. The nature and objectives, potential risks and benefits of the intended study.
2. The length of study and the likely follow-up required.
3. Alternatives to the proposed study. (This will include available standard and investigational therapies. In addition, patients will be offered an option of supportive care for therapeutic studies.)
4. The name of the investigator(s) responsible for the protocol.
5. The right of the participant to accept or refuse study interventions/interactions and to withdraw from participation at any time.

Before any protocol-specific procedures can be carried out, the consenting professional will fully explain the aspects of patient privacy concerning research specific information. In addition to signing the IRB Informed Consent, all patients must agree to the Research Authorization component of the informed consent form. Each participant and consenting professional will sign the consent form. The participant must receive a copy of the signed informed consent form.

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17.0 APPENDICES

Appendix 1: Recommendations for the impairments in the eRFA