1) Objectives
The ultimate goal of this proposal is to decrease the pain and suffering of patients with advanced cancer who are seen by the Emergency Department (ED) by developing a sustainable and effective model for ED-based palliative care delivery. Because the ED presents a key decision point in which providers set the course for the subsequent trajectory and goals of care for advanced cancer patients, many of whom are underinsured, we believe that ED-based research is essential. However, this is an area which there has been almost no needs-based research, and until recently little emphasis has been placed on education, research, or practice guidelines in end of life or palliative care in this important setting. In order to meet our goal, we must first know which ED patients could benefit from emergent palliative care services, what their palliative care needs are, and what patient, family, provider and system level factors hinder their availability in the ED. To that end, our specific aim is to test the efficacy of a targeted intervention for cancer patients in the ED.

We hypothesize that, as compared to care as usual, a generalizable palliative care intervention designed specifically to meet the needs of ED cancer patients and ED providers will produce measurable improvements in select clinical and utilization outcomes, including detection and management of patient symptoms, clarification of goals of care, better timing of palliative care consultation, and reduction in delays to appropriate treatment.

We will randomize up to 200 ED patients with active cancer (having seen a physician regarding their cancer within last six months) to palliative care consultation or usual care. Balanced block randomization in blocks of 50 will decrease potential for selection bias. All research staff will be blinded to patient assignment. Regular meetings between the research staff and palliative care team, a manual of operations, and continuous systematic monitoring of the intervention will ensure treatment fidelity. The predetermined primary outcomes are ED length of stay, time to palliative care consultation, and disposition (admission, hospice, nursing home or home) and the primary analysis will be based on intention to treat.

2) Background
A.1. State of End of Life Care in the United States: By 2030, 157 million individuals will be living with chronic disease, and approximately 40 million will have cancer. As a result of tremendous advances in diagnosis and treatment, the typical cancer death is no longer sudden, but usually follows a lengthy period of chronic illness and functional dependency. Patients who survive cancer often experience distressing symptoms, functional impairment, and long-term disability and complications as a result of their treatment. Unfortunately, despite major advances in disease-modifying oncological treatments, there have not been corresponding advances in the treatment of cancer-related suffering. Indeed, three Institute of Medicine reports and the NIH State of the Science conference on Improving End-of-Life Care reported extensive national data on chronic diseases as the leading causes of death; a high frequency of institutional deaths; evidence from multiple settings and disease categories of a high prevalence of physical, psychosocial, spiritual, and financial suffering associated with serious illness; and a healthcare system that does not deliver appropriate care to patients and their caregivers. In addition, we spend a large portion of Medicare dollars at the end of life. One-quarter of Medicare dollars are spent in the last year of life, with half of that being spent in the last month. High costs result from the use of marginally effective, technologically advanced therapies that are often inconsistent with the patient’s values or goals of care. Little
attention has historically been paid to relief of pain and suffering and coordination of fragmented care across many providers, further increasing costs and reducing patient and family satisfaction.

A.2. Cancer Burden: Cancer is a common and costly problem that affects many Americans, their families, and their caregivers. According to the ACS, there were almost 11 million Americans with a diagnosis of cancer in January 2004, and this number continues to rise each year, with 437,180 new cancer cases expected in 2008. In 2008, approximately 565,650 Americans are expected to die of cancer, more than 1,500 people a day, making it the second leading cause of death in the US. The National Institutes of Health estimate the overall costs of cancer in 2007 at $89.0 billion for direct medical costs (total of all health expenditures), with an additional $18.2 billion for indirect morbidity costs (cost of lost productivity due to illness) and $112.0 billion for indirect mortality costs (cost of lost productivity due to premature death). In 2002, over a million Americans were hospitalized with cancer, a figure expected to rise in association with the growth in numbers and needs of the elderly with cancer and other chronic conditions.

A.3. Non-Hospice Palliative Care: Palliative care utilizes an interdisciplinary, collaborative team-based approach to decrease pain and suffering for patients with advanced illness. The goal is to achieve the best possible quality of life, including physical, psychological, social and spiritual aspects, for patients and families through specific knowledge and skills. These include the assessment and treatment of pain and other burdensome symptoms, aid with complex medical decision-making, mobilization of practical, spiritual, and psychosocial support, care coordination (especially during transitions of care), and bereavement services. The National Quality Forum Framework for Preferred Practices in Palliative Care recommends palliative care be delivered through an interdisciplinary team consisting of appropriately trained physicians, nurses, and social workers with support and contributions from chaplains, rehabilitative and mental health experts. Palliative care developed as a subspecialty to support other clinicians in the care of seriously ill patients by providing intensive symptom management, helping with time-consuming and difficult interactions with distressed patients and family members, and attempting to ensure safe, and well-communicated care transitions.

Palliative care, as distinct from hospice, is not limited to end of life care and is offered simultaneously with life prolonging therapies for persons living with serious chronic illness. A substantial portion of the chronically ill suffer from mostly preventable, burdensome symptoms that affect their quality of life while pursuing marginally effective therapies, many of which could be avoided with better matching of risks and benefits and use of only cost-effective therapies. Modern palliative care combines decision-making support for effective curative or life-prolonging therapies, if desired, and ongoing palliation of symptoms, while simultaneously providing support to caregivers and family members. Within the US, outside of hospice, palliative care is delivered predominantly by hospital consultation teams. While there is likely a large outpatient need as well, current reimbursement mechanisms are not conducive to supporting a fiscally responsible business model for the development of ambulatory palliative care outside of hospice.

A.4. Does Palliative Care Improve Outcomes? Palliative care has been shown to significantly improve patient and family member quality of life, while at the same time reducing health care costs, improving patient and caregiver satisfaction, and reducing distressing symptoms, such as pain or dyspnea, improving quality of care, and reducing hospital length-of-stay and cost per day. Therefore reducing overall health care expenditures. Although over seventy percent of hospitals with more than 250 beds now have palliative care services and their availability continues to increase, hospital-based consultation typically occurs over a week into a patient’s hospital stay. Due to their demonstrated effectiveness, hospital-based palliative programs have grown quickly in number and now more than half of hospitals with 50 or more beds have a palliative care service.

A.5. Cancer and Palliative Care: Unmet Needs: Half a million people now die of cancer each year in the United States, and this number will continue to grow as the population ages and more people develop cancer. Despite the fact that many patients will eventually die of their disease, the focus of much research has been on cure rather than palliation of symptoms and end of life care. The National Cancer Institute spends less than one percent of its budget on any aspect of palliative care, symptom control, or end of life care research or training. The American Cancer Society (ACS), on the other hand, has attempted to fill this gap by providing dedicated grants and a study section for palliative care, as well as co-sponsorship of the National Palliative Care Research Center retreat. In addition, ACS plans to make measurable improvements in quality of life (physical, psychological, social, and spiritual) for cancer patients by 2015, showing a clear commitment to relief of pain and suffering in a broad sense. At least half of those dying of cancer suffer considerably at the end of life, with burdensome symptoms such as nausea, vomiting, pain, dyspnea, confusion, and anxiety, most of which are under-assessed and under-treated. We know that patients’ main concerns at the end of life include: 1) to avoid inappropriate prolongation of dying; 2) maintaining control; and 3) relieving burdens and strengthening relationships, all of which are core aspects of palliative care. We also know that these meaningful aspects of patients’ experience can be represented in valid
constructs that are stable over time and measurable. Nonetheless, medical providers often fail to initiate these discussions, even though evidence shows they are well received by patients and cause minimal stress. Besides relief of pain and suffering and respite for caregivers, there are also economic reasons to consider palliative care for patients with advanced cancer. Costs at the end of life are high, and cancer patients in particular have even higher costs than those who die from other chronic diseases, twenty percent greater than average. For those who died of cancer in 2000, an average $32,000 was spent in the last year of life. In addition to the high costs of care, large amounts of money have also been put into research. The budget for the National Cancer Institute is higher than any other institute within the NIH. Despite this substantial investment, the quality of care for dying cancer patients is still greatly lacking. That said, cancer continues to be the gold standard disease for palliative care, partly because oncology had been a leader in palliative care and also because cancer has a more predictable trajectory and more consistent symptoms by cancer type compared to other chronic diseases.

A.6. Cancer: Symptom Burden: Symptom burden is not limited to the end of life for cancer patients, but is a continuum that can begin with initial diagnosis and often continues even in long-term survivors. It includes physical, psychological, social and spiritual symptoms, and involves not only patients but caregivers and other family members as well. Symptoms can lead to the diagnosis of cancer (e.g., dyspnea), be caused by it (e.g., anxiety), be a side effect of its treatment, or result from progressing illness. Whatever the cause, symptoms are often moderate to severe and clearly reduce quality of life for patients and caregivers.

Pain is one of the most common symptoms in patients with cancer and is often inadequately treated when measured by patient or staff perceptions, particularly in vulnerable subgroups. Cancer pain can stem from many causes: primary tumor or metastasis, including bone and neurological pain; diagnostic or therapeutic interventions; and as a side effect of chemotherapy or radiation therapy. About half of terminally ill patients experience moderate to severe pain, and it is the most frequent and unrelieved symptom in advanced cancer. Chronic pain can also be a component of cancer survivorship, and patients with cancer may also have pain due to unrelated causes. Many studies have documented that pain is often inadequately treated, and the quality of treatment varies widely among centers. Racial/ethnic disparities in pain assessment and management have also been described.

Other physical symptoms (e.g., shortness of breath), as well as psychological symptoms (e.g., anxiety or depression), have recently received increased attention as burdensome symptoms for cancer patients that have effective treatments. Depression is common and occurs in about a quarter of cancer patients during the course of their care. Its symptoms often accompany the diagnosis of cancer, and are strongly correlated with physical symptoms (e.g., pain) that fluctuate over time and treatment course. Evidence has demonstrated an important relationship between intrinsic religiosity or spiritual well being and mood, especially related to how patients and caregivers maintain hope throughout their cancer course.

Shortness of breath, or dyspnea, is an unpleasant and distressing symptom that occurs in over half of cancer patients at some point. For those with cancer at the end of life, from 60% to 90% experience shortness of breath, with the symptom especially prominent in those with lung cancer. Dyspnea can result from pulmonary or pleural processes, such as metastasis or pulmonary embolism, as well as other systemic processes, including anemia and muscle weakness. Despite the high frequency of dyspnea among cancer patients, most dyspnea research has been conducted in patients with chronic pulmonary conditions. However, there is now increasing evidence that interventions can decrease suffering for cancer patients with dyspnea.

A.7. Insurance and Cost-Related Barriers to Cancer Care: Though problems are more severe for the uninsured and underinsured, even patients with health insurance can face significant financial barriers to cancer care. Co-payments, deductibles and annual or lifetime caps can result in financial burden for patients and families. Patients facing economic barriers to appropriate care often choose to use the ED, not because it is appropriate, but because it is the only setting in which providers are required by law to care for patients regardless of their ability to pay. For our most vulnerable, this may even be the setting in which cancer is first diagnosed. The American Cancer Society has documented the circumstances of over 13,000 uninsured and underinsured patients with cancer since 2005 through the Health Insurance Assistance Service. While they suggest options for dealing with the costs of cancer treatment, there are no options for about 30 percent of callers, and if options were available, 7 out of 10 people found them either unaffordable or inadequate. Many states have policies that allow patients with serious illnesses such as cancer to qualify for Medicaid, but only if their medical expenses exceed their income after they “spend down” their assets, including family savings and often the family residence. Even if patients qualify for Medicaid or Medicare, they may still face significant barriers to care. A national survey of private physicians found that although 96% were accepting new patients, 40% did not accept charity cases, 26% did not accept Medicaid and 14% did not accept Medicare. These patients may have no other option than to use the ED for care. Callers stating they had private insurance after an ED visit for a serious medical condition were twice as likely to receive prompt appointments as those who stated they had Medicaid. Lack of access to health care can affect all aspects of cancer care, including disease prevention, early detection and treatment, mortality, and palliative care.
A.8. Racial and Ethnic Disparities in Cancer: The incidence of cancer is not only higher in African-Americans than whites, but is increasing at a higher rate, 1.2 percent versus 0.8 percent each year. In addition, mortality rates are higher, 222 per 100,000 for African-Americans versus 167 per 100,000 for whites. Opportunities to decrease disparities exist across the spectrum of cancer care, from primary prevention to initial diagnosis and early treatment to end of life care. Racial and ethnic minorities face numerous obstacles to cancer care and receive lower quality health care even after controlling for insurance status, income, age, and illness severity.

Despite the higher incidence of cancer and death rates for cancer, minority groups are less likely to use palliative care services. In one study, African-American cancer patients wanted more life-sustaining treatments and were less likely to want to complete advance directives than were white patients. Mistrust due to historical factors (i.e., slavery), medical experimentation (such as the US Public Health Service Syphilis Study), and persistent reports of unequal treatment contribute to decreased utilization of palliative care services by African-Americans. In 1996, 93% of enrollees in the Medicare hospice benefit were white. The National Hospice and Palliative Care Program has similarly concluded that less than 10% of all hospice patients were African-American. In its report Improving Palliative Care for Cancer, the Institute of Medicine called for end of life care for the poor in inner-city locations in addition to training to understand palliative and end of life care across different medical settings. ED-based palliative care consultation is one way to increase access to palliative care services for racial and ethnic minorities, who disproportionately seek care in EDs.

A.9. Palliative Care and Emergency Medicine: Unmet Need for Cancer Patients: In their report, Improving Palliative Care for Cancer, the Institute of Medicine delineated many of the barriers to improving cancer care at the end of life, including the historical separation of palliative or hospice care from potentially life-prolonging therapies. Bringing palliative care into the ED, a place designed more to intervene than to comfort, is one important place to begin to make improvements in this area. In addition, from a quality and cost-benefit perspective, offering palliative care services in the ED, at the beginning of the hospital course, might provide even greater benefit to patients, families and hospitals than inpatient consultation, which often occurs late in a patient’s hospital course. As of 2008, palliative care is an official sub-specialty of Emergency Medicine. In response to the growing numbers of patients with advanced illness cared for in the ED, several medical centers have recently initiated pilot programs to deliver ED-based palliative care consultation. Preliminary data from Virginia Commonwealth University Medical Center show that ED-based consultation decreased hospital length of stay and costs for those who are admitted to and die in the hospital. The palliative care service at Montefiore Medical Center also established a program to identify chronically ill older adults in need of palliative care, homecare, and hospice services and to link such patients with these services. Pilot programs thus far have focused on implementing services, and little attention has been paid thus far to formative efforts to determine barriers and facilitators or formal evaluation.

A.10. Palliative Care and Cancer: Barriers to Quality Research: The Institute of Medicine cited the lack of trained investigators as a major impediment to the conduct of quality palliative care research for patients with cancer. As of January 2009, there are 68 active fellowship programs, 60 of which have been accredited by the Accreditation Council for Graduate Medical Education (ACGME). Many of the research issues faced by palliative care researchers are relatively unique to this field. For example, the problem of missing or distorted data is considerable in palliative care research. Data can be missing because patients with advanced disease die during studies or are unable to report directly about their symptoms, concerns, or attitudes because their illness or treatment have left them confused, weak, or unconscious. Although some research questions in palliative care may be addressed using the gold standard of clinical research - the randomized controlled trial - many others may only be feasibly addressed through observational data, quasi-experimental designs, and qualitative research methods. Thus, junior palliative care investigators require, in addition to more traditional research training, considerable mentorship and training in the areas of palliative care content, careful and innovative use of non-randomized trials and mixed-methods, sophisticated statistical approaches to non-random missing data, and training in analytic techniques that strengthen the inferences that can be made from non-randomized trials.

A.11. Summary: Despite cancer’s high prevalence and major contribution to morbidity and mortality in the US, cancer-related suffering continues to be widespread. While palliative care consultation has been shown to reduce burdensome symptoms, increase patient and family member satisfaction, and decrease costs, consultation occurs very late in the illness trajectory. It is even less common in ethnic and racial minorities, who disproportionately present to the ED for care. While some EDs are pilot testing palliative care programs, there has not been a structured and rigorous approach to the development and testing of such interventions to assure their success and test their effect on predetermined outcomes.

3) Setting of the Human Research

Mount Sinai Hospital (MSH) is a tertiary care academic referral center in New York City and the MSH ED is an active, urban emergency department. The ED provides care for a socio-economically and racially diverse patient population. It serves as both the primary source of regular care for the surrounding community, including the
medically indigent East Harlem, and as an academic tertiary care referral center. Annually, approximately 80,000 patient visits are seen in the ED’s Adult and Pediatrics divisions. Approximately 27% of all ED patients are admitted to the hospital, and nearly 40% of Mount Sinai’s hospitalized patients originate from the ED. The ED provides excellent patient care twenty-four hours per day, seven days per week, to all who seek care, regardless of ability to pay. The racial/ethnic distribution of the ED patient population is 35% Hispanic, 29% African-American, 19% White, 1% Asian, and 16% other. Approximately 67% of patients are adults and 33% are pediatric patients (age 20 and under). Last year, 46% of adult patients had no insurance, 22% had Medicaid, 20% had private insurance and 13% had Medicare. It was also the first “paperless” ED in NYC and one of few in the nation with a fully implemented comprehensive ED Information System (IBEX Pulsecheck version 6.70, a product of Picis) that provides triage, patient tracking, electronic physician and nurse charting, electronic order entry, discharge instructions and prescription writing. Documents of particular importance (e.g., advance directives) are scanned and maintained in electronic format as part of the ED chart. All data points are time-stamped, beginning with time of arrival in the ED and ending with the patient encounter.

The Hertzberg Palliative Care Institute is one of the leading palliative care programs in the country encompassing a broad array of clinical, educational and research activities aimed at improving the care of persons with serious, complex, and terminal illnesses. The Palliative Care Consult Service has cared for over 10,000 patients since its establishment in 1997. Services are delivered in a consultative model in collaboration and close communication with patients’ primary care physicians and nurses. Over 80% report pain and are actively treated for this symptom. Of patients seen by the service to date, the average age is 68, 53% were female, and over 50% were ethnic minorities. Approximately 65% of patients are discharged to home, home hospice, or to a long term care facility, depending upon their needs and preferences.

4) Resources Available to Conduct the Human Research

B.1. Preliminary Studies: Members of the palliative care research team at Mount Sinai (Drs. Diane E. Meier and R. Sean Morrison) have an ongoing multi-site R01 study funded by the National Cancer Institute to examine palliative care consultation for hospitalized cancer patients. Because their study does not include an ED component, this project would link well to this larger funded project.

B.1.i. ED Patients with Cancer at Mount Sinai Hospital (MSH): The Mount Sinai Hospital (MSH) ED saw approximately 7,500 patients in August of 2008, 25% of whom were admitted. To obtain estimates of how many patients with advanced cancer were seen in the ED, patients with a final ED diagnosis of cancer and all ED admissions to the oncology service were reviewed. Twenty-seven patients had a final ED visit diagnosis of cancer and their mean length of stay in the ED was 8.2 hours (range 2.3 - 30.2 hours). Because the chief complaint and final ED diagnosis may not list cancer, we also determined how many oncology patients were admitted, hypothesizing it would be greater than those with a final diagnosis of cancer. Approximately 780 ED patients are admitted to the oncology service each year, and over 95% of those admitted present to the ED with a chief complaint of shortness of breath, dizziness or lightheadedness, pain, vomiting, or weakness.

B.2. ED Wait Times at MSH: For all ED patients admitted to MSH between April 2007 and March 2008, mean length of ED stay was 10.4 hours and median was 8.2 hours. Time from nurse triage to the decision to admit was 3.6 hours on average though patients waited an additional mean 6.8 hours to be transferred to their bed. Time to transfer to an inpatient bed varied depending on bed type. Patients assigned a monitored bed waited an average of 40 minutes longer. This unpublished data shows that the majority of the ED wait time for admitted patients is spent waiting for a bed, rather than getting a work-up or treatment from ED staff. Palliative care consultation based on set triage criteria might better be able to understand patient and family goals of care, thereby averting unwanted admissions and testing and possibly decreasing ED length of stay.

B.2.i. ED Patients and Palliative Care Consultation at MSH: Data on palliative care consultation was also reviewed. Although the palliative care service at MSH saw 1,600 patients in 2007, only seventeen of these were ED patients at the time of consultation. Preliminary unpublished data show that 65% (45 of 70) of patients seen by the palliative care service at MSH in January 2005 were admitted through the ED. Mean number of days from ED arrival to palliative care consultation was 9 (SD 12). The primary reasons for admission in these 45 patients were cancer (22%), neurological or cognitive dysfunction (22%, including stroke, altered mental status and dementia), and pulmonary disease (20%, including COPD exacerbation, pneumonia, and pleural effusion). Based on a study of patients presenting with hip fracture to our ED, we know that pain is not adequately assessed, is rarely reassessed, and that there are long delays to analgesic medication.

B.2.iii. Prior Research on Palliative Care in the ED: Dr. Grudzen led the qualitative phase of a prospective, randomized trial of an ED-based palliative care intervention called ED-HELP under the guidance of the trial’s PI, Dr. Susan C. Stone. Dr. Grudzen designed and conducted the semi-structured interviews used in this trial, which was conducted in the ED of a large public hospital. Preliminary, unpublished data from thirteen qualitative interviews with ED patients in the intervention group suggests that they are highly satisfied with the palliative care services,
Despite the lack of private space for sensitive discussions. Interestingly, emergency physicians considered less than half of patients appropriate for palliative care that were identified by research staff. During this trial, 390 patients were approached in the ED and offered participation in a study of palliative care. The majority of patients (n = 251) had cancer. Of the 390 patients approached, 193 met the inclusion criteria (which included a cognitive screen and the requirement of speaking Spanish or English) and agreed to participate. Inability to pass the cognitive screen was the most common reason for patients not to participate (n = 74), followed by concerns about signing the consent form (n = 49) and transfer to home or an inpatient bed prior to completion of enrollment (n = 16). These data have been published in the *Journal of Palliative Medicine*. Analysis of the outcome data is underway. This preliminary study establishes that it is feasible to deliver palliative care in the ED and conduct research on its acceptance and effectiveness. This proposal makes important changes based on what was learned from this trial. First, we will blind research staff to condition throughout all phases of the study.

Pilot testing of the survey instrument in the Mount Sinai Hospital (MSH) ED was conducted with 20 oncology patients in July and August of 2009, which demonstrated feasibility of recruitment and data collection. All 20 patients who met inclusion criteria completed the face-to-face interview. Of the 35 patients approached for participation, four did not meet inclusion criteria based on their functional status, two declined participation, and nine were excluded because of cognitive deficits. The pilot interviews show that their palliative care needs are substantial. The majority of patients exceeded intra-test severity of needs cutoffs for financial difficulty, access to care, and suffering from physical symptoms. The most prevalent bothersome symptoms were anxiety, pain, fatigue, and shortness of breath.

### B.2.4. Prior Research on End of Life Care

Dr. Grudzen has developed content expertise pertinent to this project in end of life care, terminal illness, ethics, and decision-making regarding emergent interventions. She trained under and collaborated with health services researchers in emergency medicine, palliative care, and public health at the University of California, Los Angeles (UCLA) and the RAND Corporation to help Los Angeles County Emergency Medicine Services Agency design a new resuscitation policy that would better match patient preferences. In preparation for this work, Dr. Grudzen wrote a policy paper on this topic which was published in *Prehospital and Disaster Medicine*.

The first phase of her work involved formation of a UCLA/RAND appropriateness panel composed of academic and community emergency physicians, paramedics, an ethicist, a palliative care physician, and a chaplain to rate the appropriateness and feasibility of new criteria for resuscitation in prehospital cardiac arrest. This resulted in a change in resuscitation policy in Los Angeles County, in which paramedics forgo resuscitation based on a verbal request from a family member or if they meet certain clinical criteria. Dr. Grudzen and her collaborators are conducting an evaluation of this policy, which helped her further refine skills in data collection and analysis for observational studies, policy evaluation using pre-post design, and qualitative methods. More recently, Dr. Grudzen has served as the liaison and site director for a palliative care improvement project under the direction of Dr. Knox Todd of Beth Israel. The ED Palliative Care Champions Project, funded by the Fox Samuels Foundation, utilizes a group of multidisciplinary emergency providers (nursing, social work, physicians) to champion palliative care efforts in the ED. The MSSM team designed a death audit tool to review processes of care for the imminently dying patient. The audit tool is now being incorporated into our normal workflow, so that it is imbedded in the electronic medical records and reviewed for all deaths by the quality assurance committee.

### 5) Study Design

#### a) Recruitment Methods

**Patient:** EPIC, the ED electronic medical record, has a surveillance module that is used to screen for potential research subjects at triage. In the Adult ED, the triage nurse routinely takes initial vital signs and records the chief complaint and medical history for each patient in EPIC. Between 9am and 9pm Sunday through Friday, the research assistant will periodically check the tracking system in the electronic medical record for patients with a history of cancer. The RA will first speak with the ED attending physician caring for the patient to see if they can approach the patient and invite them to participate. If the attending agrees, the RA or PI will then approach and ask the patient if s/he is interested in participating in this study and proceed with the cognitive screen. Enrollment and the survey itself will never interfere with medical care and the interview will be stopped if the patient needs a medical intervention, to speak with a nurse or physician, or for any reason related to their care. The interview will continue when the patient is again ready and the interview will not interfere with any medical care.

Since the PI is an emergency medicine physician, the targeted study population is part of her patient population. However, the PI will not recruit, consent or enroll any patients she is providing direct care for, and will not enroll any patients during her clinical shifts.

#### b) Inclusion and Exclusion Criteria
English or Spanish speaking adults 18 years of age or older who pass a cognitive screen, have active cancer, will meet inclusion criteria. Because this is a study of adult patients seen in the ED, no differentiation will be made distinguishing adult vulnerable subjects from enrollment. The cognitive screen will be administered to assess whether a patient is able to give informed consent and participate. Patients will only be interviewed if they pass this cognitive screen. Potential subjects do not have to have a caregiver in order to be eligible. There is no minimum amount of time that potential participants need to be in the ED in order to be eligible to participate.

To that end, no specific gender or ethnic groups will be excluded from participation in this study. The study will exclude children because its focus is on adults with advanced cancer.

c) Number of Subjects
We will be enrolling 200 patients.

d) Study Timelines
Participants will be contacted by phone at 6 and 12 weeks after baseline for follow-up, wherein we will administer components of the baseline survey again.

e) Outcomes
Independent variables will be collected via a baseline interview with the patient. Primary outcomes include ED length of stay, time to palliative care consultation, and disposition (admission, hospice, nursing home or home) along with measure of change score of quality of life. Secondary outcomes will include health care utilization, survival and symptom assessment.

f) Procedures Involved in the Human Research
In partnership with The Mount Sinai Medical Center (MSMC), the Center to Advance Palliative Care (Director DE Meier, Advisory Board Member), the National Palliative Care Research Center (Director RS Morrison, Primary Mentor) and the Department of Emergency Medicine at MSMC, we aim to decrease the pain and suffering of ED patients with advanced cancer by developing a sustainable and effective model for ED-based palliative care delivery that is linked to hospital priorities and goals and tailored to maximize the use of community resources.

To determine what effect an ED-based palliative care consultation has on symptom burden and utilization for patients with advanced cancer, we will then randomize 200 ED patients with advanced cancer to a targeted palliative care consultation versus regular care and compare their ED length of stay and time to palliative care consultation (as well as other measures of utilization and symptom assessment).

To assess the effect of a targeted palliative care consultation compared to usual care, we will randomize 200 ED patients with advanced cancer. Patients will be enrolled and complete the baseline survey, and will be subsequently randomized to the intervention or control group used balanced block randomization to ensure perfect balance between the two groups at the end of blocks. The research team will be unaware of the varying block sizes and therefore unable to predict patient assignment. The nature of the intervention makes it impossible to blind the patient, emergency provider, or palliative care team to patient assignment, but all study staff participating in data collection, chart abstraction, and analysis will be blinded to decrease investigator bias. Continuous systematic monitoring of the intervention will continue throughout the randomized control trial process. Weekly meetings between the palliative care and research team will occur to resolve any discrepancies and discuss complex cases.

At MSM, inpatient comprehensive palliative care consultation consists of three components: 1) Symptom assessment and treatment; 2) Establishment of goals of care and advance care plans; and 3) Transition planning. These areas comprise the core elements of palliative care as detailed in the National Quality Forum.46 The palliative care team is composed of an MD, an NP, a social worker, and a chaplain. The team uses validated symptom assessments makes recommendations for symptom management using National Comprehensive Cancer Network (NCCN) guidelines.196 They communicate these recommendations to consulting physicians using standardized palliative care team chart notes and in person or by telephone. The palliative care team meets with patients, families, and care teams to identify goals of care, complete advance directives, and communicate bad news (if requested) using standardized communication protocols. If admitted, the team sees patients daily to monitor implementation and results of treatment recommendations and to assess for new and ongoing symptoms. Reassessment and treatment modifications occur as needed to achieve goals of care. The palliative care team conducts or assists with discussions about new or changing goals of care, communicating bad news, and associated treatment adjustments. The team also works with the patients’ social workers and family to facilitate transition management consistent with goals of care.
An emergency department-targeted palliative care consultation will be developed based on the results obtained from interviews with patients regarding palliative care needs. We hypothesize that while symptom assessment and treatment will be important, establishing goals of care and transition planning are skills that emergency providers will find require more advanced knowledge and skills than they are able to provide, and which will likely need to be addressed emergently. For example, complex decisions regarding the use of advance technologies are often required in the ED. Our pilot data suggest that palliative care consultation may be able to facilitate this decision making process. The targeted consultation would therefore address one or two of the three components of a comprehensive consultation, that are found to be high on the hierarchy of needs for ED patients with advanced cancer.

Prior to randomization, the initial screen and baseline interview will proceed as described previously. Six months after the ED visit, outcome data will be collected via an electronic medical record and administrative data review using the Mount Sinai Data Warehouse. The Data Warehouse gives researchers access to comprehensive patient care and administrative data to support clinical and translational research. Anonymized data are available to all researchers within Mount Sinai School of Medicine. Identified data (i.e., including patient identifiers) are available for Program for the Protection of Human Subjects (PPHS)-approved research studies. It provides content such as registration data, lab results, medications, radiology reports, procedures, and billing information. For the chart and administrative data review, a codebook will be developed, inter-rater reliability will be measured, and the research assistant performing chart abstraction will be blinded to patient assignment. We will follow patients using the medical record system from time of enrollment to time of death or to the time of censoring data (to be determined). Patients lost to follow up will be searched using the National Death Index.

Specimen Banking
N/A

Data Management and Confidentiality

All electronic data will be entered into and stored in a secure, password protected computer connected to the Mount Sinai Medical Center server that will remain in the PI's locked office (3 East 101st Street, room 216) and will be accessible only by the PI and research assistant. ALL data will be kept on the MSSM/MSH secure server maintained by Mount Sinai’s IT department and protected by the Medical Center firewall.

Each study participant will be assigned a random number as a study ID. The list that connects the study ID to the MRN will be kept in a secure, password protected computer connected to the Mount Sinai Medical Center server that will remain in the PI’s locked office (3 East 101st Street, room 216) and will be accessible only by the PI and research assistant. This list will be destroyed as soon as data collection is complete. The MRN is needed temporarily in order to collect data from the participant’s electronic medical record and match it to the surveys that are part of this project.

All paper data will be stored in a locked cabinet in the locked office of the PI that is accessible only by the PI and research assistant.

While it is necessary to collect the MRN of each participant in order to collect medical data and link it to the participant, the main study database will NOT include the participant’s MRN. Each participant will be assigned a unique, random study ID number. A list that matches the study ID to the MRN will be destroyed as soon as data collection and analysis is complete.

The list that links the MRN of each participant to their unique ID will be stored separately from all other data, including personal health information and responses to surveys. The data will not contain any personal identifiers.

Only the PI and research assistants will have access to information about the subjects that is identifiable during data collection. This will be destroyed immediately once data collection is completed.

Provisions to Monitor the Data to Ensure the Safety of Subjects

It is our assessment that there is a minimal risk for participation in this study. The only foreseeable risk is the potential loss of personal information. For this reason, the benefit of information gained on palliative care for patients with advanced cancer is greater than the risk of the research.

Withdrawal of Subjects

We do not foresee any anticipated circumstance which would lead to participant termination.

6) Risks to Subjects
Emanuel, et al concluded that the risks of discussing death, dying and bereavement with terminally ill patients and their caregivers is minimally stressful, and often helpful. In this case, the benefits outweigh the risks of the research, which have shown to be minimal.

7) **Provisions for Research Related Harm/Injury**
The interview will be immediately stopped if it interferes with any medical care then restarted when the patient is again available. If patients have suicidal ideation or homicidal ideation, the Emergency Department attending of record will be notified immediately.

8) **Potential Benefits to Subjects**
If the research participant is randomized to the intervention arm of the study, there is the benefit of a palliative care intervention. If they are randomized to care as usual, they will still be provided quality emergency care in our ED.

9) **Provisions to Protect the Privacy Interests of Subjects**
The RA will first speak with the ED attending physician caring for the patient to see if they can approach the patient and invite them to participate. If the attending agrees, the RA or PI will then approach and ask the patient if s/he is interested in participating in this study and proceed with the cognitive screen. Participants will be assured from the onset of participation that they can refuse any question that may make them uncomfortable.

Research participants will be informed before the consent process of the follow-up phone call at 6 and 12 weeks after baseline. Participants then provide us with their primary contact number, along with 2-3 contact numbers that they feel comfortable sharing. For the follow-up interview, if the research coordinator is not initially able to come in contact with the participant, she will then attempt communication with second and third contact people. If this is the case, however, she will not divulge that the phone call is in reference to a palliative care research study.

Since the PI is an emergency medicine physician, the targeted study population is part of her patient population. However, the PI will not recruit, consent or enroll any patients she is providing direct care for, and will not enroll any patients during her clinical shifts.

10) **Economic Impact on Subjects**
There will be no economic impact on patients.

11) **Payments to Subjects**
Subjects will be reimbursed a $20 electronic gift card immediately upon completion of the survey.

12) **Consent Process**
We will be requiring signed consent from our patient participants, and while we will not consent patients or caregivers in a private room, it is common practice to discuss information with patients and caregivers in as private a space as possible and we will ask family members to leave if the patient desires.

Once identified and it is determined that inclusion criteria have been met, potential participants will be informed of the study and asked if they are interested in participating in the study while they are in the ED. The RA that is recruiting the participant will use a consent form to explain the study to the potential participant and will be available to answer any questions that arise and/or discuss any concerns the potential participant may have. Adequate time will be spent responding to participant questions and discussing their participation in the study. The patient will be interviewed in their assigned area. They will be not moved to a private room (of which there are only a few in the ED, and they are needed for patients who can transmit infections)- moving the patient to a different area would disrupt their medical care.

If the interview takes place in the patient’s assigned area (as a normal medical interview in the ED would take place), then the interview could be interrupted as needed so that medical providers can continue to provide needed care.

Potential participants in the structured survey will complete a cognitive screen to assess ability to give informed consent and participate. Additionally, they will be asked to paraphrase the purpose of the research, what their participation entails, and what the risks, benefits and alternatives to participation are.

13) **Process to Document Consent in Writing**
We will be using the standard PPHS consent template.

14) **Vulnerable Populations**

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<thead>
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<th>Include</th>
<th>Exclude</th>
<th>Vulnerable Population Type</th>
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Revised 8/16/10
| X | Adults unable to consent |
| X | Individuals who are not yet adults (e.g. infants, children, teenagers) |
| X | Wards of the State (e.g. foster children) |
| X | Pregnant women |
| X | Prisoners |

15) Multi-Site Human Research (Coordinating Center): N/A  
16) Community-Based Participatory Research: N/A  
17) Sharing of Results with Subjects: N/A  
18) External IRB Review History: N/A

References


55. Center to Advance Palliative Care. A Guide to Developing a Hospital-Based Palliative Care Program. New York: Center to Advance Palliative Care; 2004.


