Title: Assessment of Resident Decision Making and Patient Safety: A Randomized Trial of Inpatient Medical Attending Supervision of Trainees

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School: Harvard Medical School
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A. Letter of Intent Application. (Cover Sheet)
Letter of Intent

Study Objectives and Research Question/Hypothesis

Graduate physician training is based the apprenticeship model where residents provide care to patients under the supervision of a senior physician. Residents gain increased patient care responsibility, learn critical thinking and make medical decisions with a gradual reduction in supervision as the trainee develops mastery. In this model, performance is increased via explicit instruction from a learned mentor or teacher to allow individualized diagnosis of errors, informative feedback and remedial part training. (1)

Despite the historical legacy of the apprenticeship model and the importance of clinical mentorship, what constitutes “supervision” is not clearly defined. Resident oversight by attending physicians on the general inpatient medical wards varies widely. For example, some attendings independently review all laboratory values and imaging and impose minor changes in treatments, others do not. The right balance between autonomy and supervision to promote both learning and ensure excellent patient care is unknown and difficult to achieve. We propose a study that begins to investigate these questions – what is a reasonable level of resident oversight? What are the consequences, both intended and unintended, of increased resident supervision on the medical wards? What models can we employ to assess these outcomes?

Following the death of Libby Zion, the Bell Commission cited both fatigue and inadequate supervision of residents as contributing factors to her untimely death. (2) As a result, both New York State and the Accreditation Council for Graduate Medical Education (ACGME) focused on resident work hour limitations in an attempt to improve patient safety by reducing medical errors. However, duty-hour reform has not demonstrated the improved patient safety outcomes anticipated, and work hour restriction has raised questions about a decline in educational opportunities. (3, 4) \\

Given the fundamental importance of improving patient safety, the emphasis is now shifting from hours worked to the level of supervision of residents. If improved duty hours have not reduced medical errors and improved patient safety, perhaps increased attending supervision will? In response to these concerns, some residency programs have intensified senior clinician involvement on the medical wards. In these new models, attendings now fully participate in both new patient presentations and old patient work-rounds, are present on the wards for most of the day and are engaged in all details of patient care. Residents’ decision making is monitored, their plans are closely reviewed, and attendings are directly involved with patients and their families.
Deeper attending involvement in patient care and medical decision making seems to be a logical next step to improve patient safety. The underlying assumption is – more supervision, better patient outcomes and resident training. Yet two recent studies comparing increased nighttime Intensive Care Unit supervision to prior more limited staffing models found no difference in mortality or patient safety outcomes. (5, 6) Similarly, heightened attending involvement in medical decision making may be at odds with the way residents learn best. Adult learning theory emphasizes adults are self-directed learners and best discover knowledge for themselves without being told. (7) Many physicians report that independent decision making was crucial for their development as physicians and maturation of clinical thinking. (2) Some would argue closer attending supervision may be detrimental to residents’ education, a theme echoed in a recent perspective piece in the New England Journal of Medicine which raised concerns about the effect of increasing levels of supervision on resident education and critical thinking. (2)

It is within this context that we propose to investigate the hypothesis that increased attending supervision in resident decision making improves patient safety.

**Rationale for Proposed Research**

Massachusetts General Hospital is a 1100 bed tertiary/quaternary medical center. The Internal Medicine Residency Program has 185 residents who rotate through both outpatient clinics and inpatient wards during their tenure. On the inpatient wards the residents interface with 30 core teaching faculty, those who have distinguished themselves as medical teachers and are fluent in inpatient care.

The general medical inpatient service has a mixed model of supervision. For new admissions the attending is deeply involved in initial critical thinking and decision making. Attendings and residents round together for two hours every morning examining and discussing the new admissions. However, resident decisions regarding ongoing management and care of existing patients on the service occur independently of the supervising clinician. After the new patients are presented and discussed with the attending, the residents go on bedside work rounds to evaluate the existing patients without the attending. During these bedside work rounds residents examine all the existing patients, discuss updates, make decisions about plans for the day, call consults and enter orders. The attending for the team briefly provides advice later in the afternoon to help adjust and refine treatment plans on these existing patients.

To investigate whether increased attending supervision in resident decision making improves patient safety, we plan to have these 30 core faculty join bedside work rounds with the residents. Since faculty members will attend on service multiple times during the study period, we will randomize all attendings to both the current system (usual care) and the increased
supervision model – participating in work rounds (intervention). Attendings will serve as their own control. Will this increased supervision improve medical decision making by residents and reduce medical errors?

To better understand the effects of attending input and participation on resident decision making during work rounds we will assess the following:

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Traditionally, resident knowledge has served as a surrogate for overall competency, but knowledge alone provides limited insight into how residents make decisions and the quality of the decisions that are made. It is fundamentally physician decision making that addresses competence. This research study will directly assess resident medical decision making, the consequences of attending participation in this process and the effect on medical education and patient outcomes.
Given there are no prior studies assessing the impact of attending supervision on resident critical decision making and patient outcomes in medicine, we believe this study would be unique. We will utilize novel methods to collect data including time motion studies, direct observation and review of transcripts from work rounds for analysis. This study is of particular import as we strive to better understand what environments drive optimal decision making and resident training. If increased supervision is mandated by the ACGME without research to confirm its value to both patient safety and resident education, the outcome could be increased costs to the health care system and possibly less competent physicians. Alternatively, through better understanding of the inputs to optimal performance and the balance between supervision and autonomy we can focus our efforts and resources on proven interventions.

**Description of Methods**

To understand the effects of attending participation on work rounds (the intervention) we will randomize supervising attendings to two weeks on service with a medical team where they attend work rounds and two weeks on service on the traditional model (attending participation on new attending rounds only with post hoc advice for previous patients). All teams will consist of two attendings, five interns and one junior resident. The study will be done from November to late June 2015 in order to avoid the “July effect” where it is suspected there are more near misses due to resident inexperience. (8) Given that approximately 80 novel patients are admitted to a team per month, over the ensuing eight months over 1200 resident/attending discussions of patient cases will be evaluated.

The primary outcome will be medical errors, preventable and avoidable adverse events and near misses per 100-admissions. These will be collected by two clinical research nurses through chart review, review of all orders, daily solicited error reports from residents and attendings and a review of all formal incident reports. Similar to a recent paper assessing rates of medical errors and preventable adverse events during handoffs, all incidents will be classified as adverse events, non-intercepted potential adverse events, intercepted potential adverse events and error with little potential for harm. (8) All recorded events will be blinded and adjudicated by three research physicians as to whether they are real errors, adverse events and near misses. Disagreements will be resolved by discussion.

Secondary outcomes will include changes in medical orders between 12pm and the 7pm (when the team signs out). This should reflect whether the teams had to reverse the orders they wrote during morning bedside work rounds. We will also assess cost per patient. This should reflect whether closer supervision during decision making on work rounds reduces unnecessary orders and helps reduce expensive test ordering. Other patient safety results will be obtained from hospital data including length of stay, pre-noon discharges, transfers to the ICU and readmissions. Additional secondary outcomes include patient and family satisfaction with MD
communication (part of the hospital collected post discharge survey results). We will survey residents about perception of autonomy and satisfaction and perceptions about education. We will also survey faculty about their perception of resident autonomy and education. We will assess both the residents and faculty’s perception of how frequently they believe faculty input changed plans on new and old patient work rounds.

Finally we plan to do a time motion study of work rounds. We will record actual time of work rounds to learn whether the presence of an attending increases the length of rounds. Also recorded will be counts of who is speaking during bedside work rounds and how often the intern is interrupted. We will also evaluate transcripts of the work rounds for resident decision making thought processes.

All of these outcomes will assess and probe resident decision making and its impact on patient safety testing the hypothesis that increased attending supervision in resident decision making improves patient safety.

Key References


B. A Description of Changes to the Proposed Research

We have made the following changes:

1. We now plan to use one research nurse instead of two.
2. The study dates will now be Sept 30, 2015 to June 7, 2016.
3. In the proposal we have clarified many of the outcomes.
4. We will be submitting our IRB application in early February.
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D. Proposal Narrative

An Assessment of Patient Safety in Resident Education: A Randomized Trial of Inpatient Medical Attending Supervision of Trainees.

1. Background Information

Graduate physician training has been based on the apprenticeship model where residents provide care to patients under the supervision of an attending physician. As trainees gain patient care experience they are given increasing responsibility with a gradual reduction in supervision. This model of progressive independence allows clinical oversight as trainees master clinical reasoning and decision making skills. The goal is to develop competent and independent practitioners. [1] This progressive supervision is provided to residents as a mixture of scheduled time with an attending physician and independent work time. In a paper defining degrees of supervision, Kennedy et al call this traditional model “routine oversight.” [2] In most training programs routine oversight consists of scheduled morning attending rounds where cases are presented to the supervising physician for discussion and correction of residents’ plans. Historically, the rest of the time trainees worked independently with the ability to call the supervising physician if needed. [3] Much of the independent time occurred at night and on the weekends when attending physicians were not in the hospital. [4]

In the last decade this independent work time has been scrutinized largely driven by the patient safety movement. This traditional model of supervision was first called into question after the Bell Commission investigation into the death of Libby Zion in a New York teaching hospital. The investigation found both resident fatigue and inadequate clinical supervision as contributing causes in the death. [5]
With pressures from the public, government and patient safety advocates the Accreditation Council for Graduate Medical Education (ACGME) and the Institute of Medicine (IOM) focused new policies on resident duty hours. The goal was to improve patient safety by reducing medical errors through restriction of work hours; less fatigued residents would make fewer mistakes. [3, 6] Starting in 2003, and again in 2011, resident work hours were limited. However, duty-hour reform has not demonstrated the improved patient safety outcomes anticipated. [7-9] A study of Medicare data found no mortality difference in medical or surgical patients after the 2003 work hour change. [7] Following the 2011 changes, a study of 2,323 medical interns noted they worked fewer hours, but did not gain additional sleep and self-reported more medical errors. [9] A second study showed an increase in patient hand-offs and a decrease in both continuity of care and educational opportunities.[8]

Without the patient safety outcomes hoped for, there is now more focus on the second recommendation of the Bell Committee: increased supervision. But will increased clinical supervision improve patient safety? A small body of literature demonstrates benefits from increased supervision or complications from its absence. [2, 10-12] One study found increased resident compliance with emergency room guidelines when residents were supervised.[10] Here supervision was defined by whether the attending wrote a separate note. A study in anesthesia showed a reduction in complications during intubation when an attending was present. A surgical trauma review noted missed radiological diagnoses without attending supervision. [11, 12] Similarly, a study in primary care demonstrated that attendings judged patients to be more seriously ill and reported a change in management for 27% of the cases after having seen the patients.[13]
Survey research looking at the impact of resident supervision from the trainee perspective suggests benefits from a higher degree of supervision. A national survey of residents in multiple specialties asked residents how often they cared for patients without “adequate supervision,” with 21% of 3,604 residents reporting inadequate supervision at least once a week.[14] Better supervision correlated with positive ratings of learning, increased time with attendings and better residency experience. In four studies on increased faculty presence on the wards, either in the afternoon or overnight, residents reported increased satisfaction with both faculty and education. [15-18] These studies conclude that increased supervision would enhance education and assume it would improve patient safety.

The patient safety movement, lead by the IOM with support from the government, medical boards, clinical educators and the public has called for increased supervision. Some policy changes around supervision have already been implemented. The 2011 ACGME work-hour changes included a requirement that “the program must demonstrate that the appropriate level of supervision is in place for all residents who care for patients.”[19] One-third of U.S. hospitals increased nighttime intensive care unit (ICU) supervision. [3] And yet early studies on this new policy have not shown patient safety benefits. [20, 21] A one year ICU study found no change in length of stay or mortality especially for those patients admitted overnight.[20] An accompanying perspective piece in the New England Journal proposes that we should have a better understanding of the clinical and educational tradeoffs between supervision and resident autonomy before blindly implementing policies. [3]

What is known about medicine’s model of clinical education and supervision? In a review of the medical, social science and educational literature, Kennedy notes there is little evidence to demonstrate the efficacy of the current graduate medical model of education.[1] This
progressive supervision model appears to have developed intuitively. In a review of effective supervision in clinical practice settings, Kilminster and Jolly conclude “(clinical supervision) is probably the least investigated, discussed and developed aspect of clinical teaching.” [22] While it is commonly believed supervision is critical in the acquisition of clinical skills and professional development of trainees, it is difficult to know what actual components of supervision matter. The Kilminster review concludes by asking, “In what circumstances is supervision necessary? What sort of supervision should this be? “What is the optimal length and frequency for supervision?” [22] There are indeed the questions that we seek to answer in the proposed study.

An evaluation of models of supervision needs to consider not only the impact on patient outcomes but also the impact on physician skill development. Is there harm in too much supervision? Many physicians recall their independent work time as formative in their development as clinicians. The expertise literature supports this idea. Learners must be engaged in active decision making and take responsibility for the results of their actions in order to integrate new information into their understanding of situations. [1] There needs to be some degree of independence in order to progress to expertise. Educational theory notes that learning takes place when learners are challenged to work beyond the level at which they comfortable and self directed learning occurs when there is appropriate space between teacher and learner. [4] And sociology literature has illustrated the limitations when learning and evaluation occur at the same time; a common practice in clinical supervision. Studies in medical students reveal they disguise their lack of knowledge and do not ask questions in order to portray competence. [23] In Kennedy’s review she notes excessive supervision without progressive independence may hamper progression to competent practitioner. [1] A balance between supervision and autonomy
is required to facilitate resident’s development. In the short term limiting autonomy might improve patient safety, but in the long term could have unintended consequences of creating physicians who are not ready for independent practice. The question is what is the right amount autonomy without compromising patient safety?

The growth of hospitalists over the last decade has provided more faculty presence on the wards expanding supervision beyond “routine oversight”. Hospitalists are now more involved in patient care details and double check residents’ work. This is defined as “responsive oversight” in the framework of supervision created by Kennedy et al. [2] Hospitalists also provide direct patient care without involvement of the resident and practice more “backstage oversight” defined as reviewing all the patient’s care details without the trainee’s awareness. A study on the introduction of hospitalists in a pediatric hospital, where attendings gave more “responsive oversight” and did direct patient care, found the interns reported learning more and still felt they could make decisions independently, but upper level residents reported a decrease in their knowledge and supervisory skills and a loss in their ability to make independent decisions. [18] This study raises questions about the optimal type of supervision and when it should be applied.

In this context it is clear that there is limited evidence as to the appropriate balance of clinical supervision and autonomy for both patient safety and educational purposes. Multiple medical educators have expressed the need for studies evaluating types of supervision and its related outcomes. [3, 4, 22] With this in mind, we propose to study the effect of additional attending “responsive oversight” on resident medical teams in terms of both patient safety and resident learning. Given that the mission of the National Board of Medical Examiners is to “protect the health of the public through the state of art assessment of health professions”, clinical supervision clearly falls under this domain. Traditionally, resident knowledge has
served as a surrogate for overall competency, but knowledge alone provides limited insight into how residents make decisions and the quality of the decisions that are made. It is fundamentally physician decision making that addresses competence. This research study will directly assess resident medical decision making, the consequences of attending participation in this process and the effect on medical education and patient outcomes.

2. Hypothesis or Research Question

Background: Currently our general medical inpatient service employs the model of “routine oversight”. During the scheduled daily two-hour morning attending rounds new admissions are presented at the bedside. These rounds focus only on new admissions to the medical team. After attending rounds, a resident leads team rounds on all of the previously admitted patients without the presence of the attending, identifying new medical issues, discussing ongoing problems and reviewing the management and care of these existing patients. This is frequently referred to as “work rounds”. The attending for the team independently sees and evaluates the previously admitted patients and briefly provide advice to the supervising resident later in the afternoon to help adjust and refine treatment plans. With this background, our research aims are:

Specific Aims:

1. To investigate whether a rounding model of increased resident supervision by including attending physicians on work rounds (responsive oversight) in addition to new patient rounds (routine oversight) compared to attending physicians on new patient rounds only (routine oversight) result in improved patient safety? This will be measured by a reduction in medical errors (primary outcome) and reductions in length of stay, intensive care unit transfers, inpatient mortality and costs (secondary outcomes). Our hypothesis is that the increased supervision model will improve patient outcomes.
2. To investigate whether a rounding model of increased resident supervision by including attending physicians on work rounds (responsive oversight) in addition to new patient rounds (routine oversight) compared to attending physicians on new patient rounds only (routine oversight) affect resident autonomy, decision making and learning? This will be assessed by the percentage of time of resident communication on work rounds and length of work rounds (primary outcome). Secondary outcomes will include resident, attending and nurse perception of education and autonomy and a qualitative analysis of content of discussion on work rounds and reason for attending interruptions.

*Our hypothesis is that increased supervision will not affect educational outcomes for residents.*

**Outcomes:**

To better understand the effects of attending input and participation on patient safety and resident education and autonomy during work rounds we will assess multiple aspects of the supervisor-resident-patient triad. (Table 1) Each aim, (1) patient safety and (2) education and autonomy, will have its own primary and secondary outcomes. Given the complexity of the relationship between supervision, resident education and patient safety, we believe it is necessary to evaluate both aims and their outcomes during this study. The results of one aim cannot be interpreted without the results of the other.

**Patient Outcomes:**

Our primary outcome of patient safety which will be assessed by recording medical errors using the standard definition that medical errors are preventable failures in the process of care. Medical errors will include preventable adverse events, near misses and errors with little or
no potential for harm. Using an established surveillance process developed in several studies evaluating medical errors in residency programs, we will measure the rate of medical errors per 100 admissions. [24-26] We will also collect mortality, length of stay, transfers to the intensive care unit (ICU) and total costs, including the number of radiology studies as secondary outcomes. Our hypothesis is “responsive oversight” will reduce medical errors, mortality, length of stay, transfers to the ICU, costs and number of radiology studies as residents are supervised in decision making.

**Educational Outcomes:**

To assess the effect on resident autonomy, decision making and learning, we plan to use a mix methods approach during work rounds for both the intervention period (responsive oversight) and the control period (routine oversight). Our primary outcome will be assessed by the length of work rounds and the amount of time the resident is communicating during these rounds. Using a time motion study of work rounds, both on the intervention and usual care teams; we will measure length of work rounds and quantity of conversation by the resident, attending and interns. Who is actually talking during the work rounds? Our secondary outcomes will include both quantitative and qualitative components. At the conclusion of each 2 week block, we will survey of residents, attendings and nurses about their perception of the learning environment, autonomy and decision making and patient care. Given nursing also participate in resident work rounds, their unique perspective as the patient advocate will be valuable. The qualitative data collection will include content analysis of the conversations occurring during work rounds. We will assess the conversational interactions around the following clinical areas: (1) interpretation of the data (labs, vital signs, and physical exam), (2) identifying problems, (3) generating differentials, (4) decision making or (5) teaching points. Which area is the attending
participating in? These analyses will be conducted comparing conversations with and without an attending present, to explore which areas the supervising resident participates. We will also assess the reasons for attending interruptions on work rounds.

Table 1 Outcomes

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<td>Patient outcomes</td>
<td>Mortality, # ICU transfers, LOS, cost of hospitalization and number of radiology studies.</td>
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<td>Educational Outcomes</td>
<td>Length of work rounds and time/percentage of resident communication during rounds.</td>
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3. Study Design and Methodology

**Study Design:** Our intervention is to expand supervision from “routine oversight” (attending rounds on new patient only) to “responsive oversight” (attending rounds on new patients and established patient work rounds). Since faculty members attend on service multiple times during the study period, we will randomize all attendings to both the current system of “routine oversight” (usual care) and the increased supervision model or “responsive oversight” (intervention). In the intervention phase, the supervising physician will more actively participate in work rounds, overseeing detailed resident discussions and decision making about existing patients on the medical team.

We will conduct a randomized cross-over study, with each attending serving as his or her own control. Faculty rotations are two weeks and they work with the same resident team for that entire time. Faculty will be randomized to start with either the intervention or usual care for the
duration of the two weeks for their first rotation during the study period and then “cross-over” to
the other study arm for their next two week rotation. (Figure 1).

**Figure 1**

**Study Settings**: Massachusetts General Hospital (MGH) is a 1100 bed tertiary/quaternary
medical center. The study will take place on the MGH general medical service which consists of
5 identical teams on similar nursing floors. Patients are randomly assigned to teams by the
admitting department based on bed availability. The study will occur September 30, 2015 to June
7, 2016. We plan to start in late September to avoid the “July Effect” of new trainees, a time
when we would expect more medical errors.[27]

**Participants**: The Internal Medicine Residency Program has 185 residents who rotate through
both outpatient clinics and inpatient wards during their training. Inpatient resident teams consist
of one resident, 5 interns and two attendings and care for 20-24 patients. Resident teams rotate
every 2-4 weeks, with upper level residents working on this service 6-8 weeks a year and interns working about 4 months a year. We anticipate the study will involve 30 upper level residents and nearly all 85 interns. On the inpatient wards the residents interface with 20 core teaching faculty, who have distinguished themselves as medical teachers and are fluent in inpatient care. These 20 experienced clinician educators have a background in inpatient medicine and frequently attend on service.

Attendings participating in this study will receive a one-hour training session on “responsive oversight” with a discussion of expectations for joining work hours. Residents and interns will receive an orientation to this process and will receive reassurances that the measurement of medical errors will be blinded and there will be no consequences to their reporting such errors. Nursing on the floors will receive the same orientation and reassurance.

Data Collection and Analysis:

Patient Outcomes: For the primary outcome of medical errors we will apply standard definitions. [24, 25] Medical errors, as noted previously, are preventable failures in the process of care and include: (1) preventable adverse events, (2) near misses (where the error was caught before anything could happen) and (3) errors with little or no potential for harm. We will also collect non-preventable adverse events, and since these events cannot be prevented, this event rate should be similar in both arms. Using an established surveillance process, one trained research nurse will review all medical records and orders on the medical teams, 5 days a week, with Mondays review to include a review of the weekends. [24, 25] There will be a locked-box on each floor where nurses and residents can anonymously submit possible medical errors and near misses. The nurse will also ask the team each day about possible errors, as well as pharmacy, and will check the hospital reporting system for events. All possible medical errors
will be reviewed by two blinded physician investigators. They will independently classify each event as a preventable adverse event, near miss, error with little potential for harm, non-preventable adverse event or exclusion (not a medical error). The preventability of the adverse event will be rated on a 4-point Likert scale: (definitely preventable, probably preventable, probably not preventable, or definitely not preventable) which will be dichotomized into preventable versus non-preventable before analysis. We will be following the methodology of the IPASS study looking at medical errors in hand offs. [24] We will also collect severity of harm using the National Coordination Council for Medication Error Reporting and Prevention Index for Categorizing Errors. (MCC MERP). [28] Any disagreements in error assessment will be summarized using a kappa statistic and resolved by discussion between the physician reviewers. Secondary patient outcomes (morality, number of ICU transfers, length of stay, cost of hospitalization and number of radiology studies) will be obtained from the hospital data base.

In the primary analysis, we will use an intention-to-treat approach for each patient. That is, patients’ group assignment will be determined by the status of the first responding clinician they encounter during the study period. We will compare the patient characteristics between patients under routine oversight and patients under responsive oversight. The potential confounding factors will be included in the regression model if any imbalance exists. We will compare between the two groups using Poisson regression models for medical error rate, number of ICU transfers, and number of radiology studies and quantile regression models for length of stay and cost of hospitalization. We will use the mixed effects model approach to take into account the clustering of patients within each responding attending and model the care team (residents, interns and nurses) as random effects.
In a secondary analysis, we will determine patient’s group assignment on a daily basis according to the status of the assigned attending since patients’ hospitalization might span across faculty rotations. Poisson regression models will be used to compare medical error rate between the two groups with group considered as a time-varying variable.

We will conduct two pre-specified exploratory analyses. The first is looking at error rates comparing the first 4 months to the last 4 months of the study. Studies on residents are complicated by the fact they gain knowledge and improve through time. Our faculty will be randomized throughout the year to try and mitigate this, but we plan to evaluate error rates based on time of year. We will also compare error rates looking at the order in which attendings are randomized. If an attending does the “responsive oversight” arm first, will this affect their ability to return to “routine oversight”?

**Educational Outcomes:** For the primary educational outcome we will have a research assistant join resident work rounds both on the intervention team and usual care team. For this time-motion study, we anticipate they will join rounds approximately 5 times during a two-week block. They will record rounds with permission granted by the resident team, nurse, attending and patients. Using an iPad device, they will record the number of times and length each individual speaks. The total length of these work rounds will be recorded. We plan to collect the length of work rounds on all teams on weekdays. On the days the research assistant cannot join rounds, they will ask the team for the start and stop time of work rounds. We will first examine the distribution of the length of work rounds and time/percentage of resident communication during rounds and perform variable transformations if necessary. These outcomes will be then compared using a linear regression model with the Generalized Estimating Equations method to take into account of the clustering within each attending.
For perceptions, we will email surveys to the residents, attendings and nurses at the end of every two week rotation to evaluate their perception of autonomy, the learning environment, decision making and quality of care of patients. Survey responses will be compared between the two groups using regression models taking into account of the individual responder effect.

**Qualitative Data Analysis:** Using purposive sampling, a random selection of recorded work rounds with and without attending participation will be transcribed. We will transcribe both the intervention work rounds and usual care work rounds. Each transcript will be coded by the physician investigators and will explore the content of the discussion, including: (1) interpretation of data, (2) identification of active medical problems, (3) the generation of differential diagnoses for the active medical problems, (4) decision making regarding plans for each problem and (5) teaching points around active or theoretical problems. We will initially review a subset of transcripts and develop preliminary codes. We will then apply these final codes to our random sampling using NVivo 10 qualitative data analysis software. Coding will continue until level of agreement (kappa > 0.80) is reached. We will resolve discrepancies by reviewing the transcript data for context. We will evaluate which areas the attendings are involved in, how often they speak and who makes the final decision for each problem. All analyses will be conducted comparing findings on rounds with attendings and without attendings.

In a prior study looking at attending interruptions on new patient presentations, the researchers used the following 5 categories to classify interruptions by the attendings: (1) Probing for further data, (2) prompting for expected sequence, (3) teaching around the case, (4) thinking out loud and (5) providing direction. [29] We will use these categories for analyzing attending interruptions.
Finally, we will explore whether there is a relationship between percentage of time communicating on rounds, the content areas discussed, number of interruptions by the attending and if any of these are related to medical error rates.

**Sample Size:** Given that each attending sees approximately 25 new admissions during each two-week block, and all 20 attendings will be attending both in the usual arm and intervention arm, we anticipate to enroll 500 patients in each arm. Since patients are clustered within each attending, the inflation factor is 2.7 in an intra-class correlation coefficient of 0.07 and the effective sample is 187 per group. Based on prior studies using the same surveillance methods we anticipate 55 errors per 100 admissions from the routine oversight group and 33 errors per 100 admissions from the responsive oversight group, which only requires 178 patients per group for 80% power and a 0.05 two-sided significance level. ([24, 26]

**Conclusion:** Given the limited number of studies assessing the impact of attending supervision on resident decision making, autonomy and patient outcomes, we believe this study would be unique. We will utilize a well established surveillance process to assess medical errors, a time motion study, direct observation and a qualitative analysis of transcripts from work rounds. This study is of particular import as we strive to better understand different aspects of supervision and their affect on the development of independent and competence physicians. If increased supervision is mandated by the ACGME without research to confirm its value to both patient safety and resident education, the outcome could be increased costs to the health care system and possibly less competent physicians. In order to ensure to the general public both short term and long term patient safety, we need to find the right balance of supervision and autonomy through proven interventions.
E. Project Budget Form

<table>
<thead>
<tr>
<th>Personnel - Direct Costs</th>
<th>Year 1</th>
<th>Year 2</th>
<th>TOTAL</th>
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</thead>
<tbody>
<tr>
<td>Compensation (Not including fringe benefits.)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>A. Kathleen Finn, MD, Principal Investigator</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>B. Research RN</td>
<td>$73,873</td>
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<td>$73,873</td>
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<tr>
<td>B. Research Asst</td>
<td>$23,400</td>
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<td>$23,400</td>
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<td>C. Fringe Benefits</td>
<td>$35,991</td>
<td>$0</td>
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</table>

<table>
<thead>
<tr>
<th>Other - Direct Costs</th>
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<tr>
<td>A. iPad</td>
<td>$600</td>
<td>$0</td>
<td>$600</td>
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<tr>
<td>B. Travel</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>C. Materials and Supplies</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
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<tr>
<td>D. Consultants/Contractual (Include both honorarium and travel costs for consultants. Provide a breakdown in the Budget Narrative)</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
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<tr>
<td>E. NVivo Software - 10</td>
<td>$2,500</td>
<td>$0</td>
<td>$2,500</td>
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</table>

<table>
<thead>
<tr>
<th>Project Administrative Charges</th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(Limited to 10% of the amount of Total Direct Costs)</td>
<td>$13,636</td>
<td>$0</td>
<td>$13,636</td>
</tr>
</tbody>
</table>

| Total Project Budget         | $150,000| $0     | $150,000|
F. Budget Narrative

Research Nurse Investigator: The clinical research nurse must be experienced in inpatient medicine and clinical medicine. He or she will be reviewing charts and medical orders searching for medical errors. He or she will also need to speak regularly with team members, nursing and pharmacy and review medical error reports. Given the identification of medical errors is a primary outcome for this study we anticipate hiring a more advanced clinical nurse investigator. At our institution the top rate is $70/hour. We anticipate he or she will need to work 8 hours per day. This person will be hired for 8-9 months.

Research Assistant: This person will need to record work rounds for the qualitative component of the study, as well as measure the speaking time of each team member and total length of rounds. They will be transcribing the recordings in the afternoon. We will need someone with a college degree who can transcribe. At our institutions the lowest rate for a research assistant is $15/hour. This person will be hired for 8-9 months.

iPad: This device will be used by the research assistant for both recording rounds and for counting speaking time. We will be searching or programming an App to help us with both the recording and counting components.

NVivo software: This commercial software is needed to qualitative analysis of content of work rounds.

Physician Investigators: The investigators’ time will be supported by Massachusetts General Hospital
G. Project Timeline

January 14, 2015  Submission of the Invited Proposal

February 3, 2015  IRB Submission to Harvard Medical School and Partners Healthcare

Summer, 2015  Hiring of Research Nurse and Research Assistant

Purchase of iPad and programming data collection application

Randomization of Faculty

September 2015  Training of Research Nurse and Research Assistant

Training of Clinical Faculty who will be attending on service

Orientation sessions for resident teams and floor nursing

September 30, 2015  Start of first 2 week block and beginning of study

October 2015 – September 2016: Physician investigators’ will start blinded reviews of potential medical errors and coding of content of transcribed work rounds.

June 7, 2016  End of data collection. Completion of last randomized 2 week block
H. Primary Qualifications of Research Team

Principal Investigator:

Dr. Kathleen Finn is an Assistant Professor of Medicine at Harvard Medical School and the Inpatient Associate Program Director for Internal Medicine at Massachusetts General Hospital. She is actively involved in the training and evaluation of medical residents. She was the PI for a $100,000 Partners Reengineering Grant and led a team evaluating discharge facilitators embedded in resident teams. The study was published in the Journal of Hospital Medicine. She has also led several quality improvement projects and is actively involved in residency education redesign.

Research Team:

Dr. Christiana Iyasere is an Instructor at Harvard Medical School and a member of the Inpatient Clinician Educator Service at Massachusetts General Hospital. She is actively involved in the training and evaluation of medical residents in addition to development of novel curricula in medical leadership. Dr. Iyasere attended Columbia Medical School and Harvard Business School. She has been actively involved in research projects looking at novel ways to promote ongoing clinical mentorship of junior hospitalists, and the role of discharge facilitators on resident teams. She will be co-lead investigator in this project.

Dr. Joshua Metlay is Professor of Medicine at Harvard Medical School and Chief of the Division of General Internal Medicine at Massachusetts General Hospital. He has led numerous multi-institutional clinical studies, including cluster randomized trials, and has specific expertise in developing methods for primary and secondary data collection, outcome measurement and analysis. He has also led several training programs, including serving as the PI of two federally funded institutional Career Development studies. He is serving as lead advisor.

Dr. Hasan Bazari is Associate Professor of Medicine at Harvard Medical School and the Emeritus Residency Program Director for Internal Medicine at Massachusetts General Hospital. He has participated in numerous research projects evaluating resident education, work structure and sleep deprivation and well being. He is serving as one of the physician Investigator to the project.
Dr. Jatin M. Vyas is Associate Professor of Medicine at Harvard Medical School and the Residency Program Director for Internal Medicine at Massachusetts General Hospital. He is an NIH-funded investigator in the area of fungal immunology. He served as the Chief Resident in Medicine after training and actively participates in resident education and direct observation of housestaff for over 15 years. He is serving as one of the physician investigators.

Dr. Yuchiao Chang is Assistant Professor of Medicine at Harvard Medical School and Statistician at Massachusetts General Hospital. She is currently supporting all research activities for Emergency Department and the Division of General Internal Medicine at Massachusetts General Hospital. Dr. Chang has been the principal statistician for more than 50 federally/industrially funded grants, including cluster randomized trials. She has extensive experience with various types of clinical data and advanced statistical methodology as reflected by her list of more than 250 publications. She will be the primary statistician.

Dr. Elyse Park is Associate Professor of Psychiatry at Harvard Medical School and Director of Behavioral Health Research at the Benson-Henry Institute for Mind Body Medicine at Massachusetts General Hospital. Dr. Park is an expert if mix-methods approach and qualitative research. She has been on numerous grants and studies involving qualitative research around smoking cessation, palliative care and relaxation response. She will be serving as advisor and statistician for the qualitative component of this study.
I. Biographical Data Form

**BIOGRAPHICAL DATA FORM**

1. **Name/Position in Project:** Kathleen Finn  
   **Principal Investigator**

2. **Education/Training:**

<table>
<thead>
<tr>
<th>Institution and Location</th>
<th>Degree</th>
<th>Year(s)</th>
<th>Field of Study</th>
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<tbody>
<tr>
<td>University of Pennsylvania</td>
<td>BA</td>
<td>1987</td>
<td>Anthropology</td>
</tr>
<tr>
<td>Oxford University</td>
<td>M.Phil</td>
<td>1989</td>
<td>Social Anthropology</td>
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<tr>
<td>Bryn Mawr College</td>
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<td>1990</td>
<td>Post-Baccalaureate</td>
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<tr>
<td>Harvard Medical School</td>
<td>M.D.</td>
<td>1995</td>
<td>Medicine</td>
</tr>
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3. **Research and Professional Experience:**

- 1998-2009 Instructor in Medicine  
- Harvard Medical School
- 2004-2006 Medical Director of the General Medical Service  
- Brigham & Women’s Hosp
- 2008-present Inpatient Associate Program Director, Internal Medicine Residency Program  
- MGH
- 2008-present Director of MGH Annual Teaching Retreat  
- Department of Medicine
- 2008-2009 Principal Investigator Partners Physician Education Care Delivery Reengineering Innovation Grant.
- 2009 Harvard MACY program Educators in Health Professions
- 2009 – present Assistant and Associate Editor  
- Journal of Hospital Medicine
- 2010 Assistant Professor of Medicine  
- Harvard Medical School
- 2012 Kranes Award for Excellence in Clinical Teaching  
- MGH
- 2014 Charles Burnett Special Recognition Award  
- MGH
- 2014 ACP Top Hospitalist’s for 2014

4. **Publications:**


7. Dankers, C and Finn, K. Non-Invasive Mechanical Ventilation. In: Decision Support in Medicine, Hospital Medicine. Decision Support in Medicine, LLC. 2013


**BIOGRAPHICAL DATA FORM**

**Name/Position in Project:** Christiana Iyasere, Co-Lead Investigator

**Education/Training:**

<table>
<thead>
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<th>Institution and Location</th>
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<th>Field of Study</th>
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<tr>
<td>Columbia University, College of Physicians and Surgeons</td>
<td>MD</td>
<td>2002</td>
<td>Medicine</td>
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<tr>
<td>Harvard Business School</td>
<td>MBA</td>
<td>2008</td>
<td>Business</td>
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</table>

**Research and Professional Experience:**

Instructor in Medicine, Harvard Medical School 2006-current

Clinician Educator Service, Massachusetts General Hospital 2008-current

Associate Director, MGH Innovation Support Center 2008-current

**Publications:**

BIOGRAPHICAL DATA FORM

Name/Position in Project:  Joshua Metlay  Senior Advisor – Physician Investigator

Education/Training:

<table>
<thead>
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<th>Institution and Location</th>
<th>Degree</th>
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<th>Field of Study</th>
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<tr>
<td>Yale University, New Haven, CT</td>
<td>B.A.</td>
<td>05/84</td>
<td>Biology</td>
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<tr>
<td>Rockefeller University, New York, NY</td>
<td>Ph.D.</td>
<td>06/90</td>
<td>Immunology</td>
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<tr>
<td>Cornell University, New York, NY</td>
<td>M.D.</td>
<td>05/91</td>
<td>Medicine</td>
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<tr>
<td>Harvard School of Public Health, Boston, MA</td>
<td>M.Sc.</td>
<td>06/97</td>
<td>Health</td>
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<td></td>
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<td>Policy/Management</td>
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</table>

Research and Professional Experience:

1995-97  Clinical and Research Fellow in Medicine, Massachusetts General Hospital, Boston
1997-2006  Assistant Professor of Medicine and Epidemiology, University of Pennsylvania
1997-2013  Senior Scholar, Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania
1997-2009  Staff Physician, Veterans Affairs Medical Center, Philadelphia, PA
1997-2013  Senior Fellow, Leonard Davis Institute of Health Economics, University of Penn
2006-2010  Associate Professor of Medicine and Epidemiology (Tenure), University of Penn
2006-2010  Program Leader, Doris Duke Clinical Research Fellowship, University of Penn
2006-2013  Co-Director, Robert Wood Johnson Foundation Clinical Scholars Program
                  University of Pennsylvania School of Medicine
2009-2013  Chief, Section of Hospital Medicine, University of Pennsylvania School of Med
2009-2013  Director, Center for Healthcare Improvement and Patient Safety, University of Pennsylvania School of Medicine
2010-2013  Professor of Medicine, Emergency Medicine and Epidemiology, University of Pennsylvania
2013-2013  Chief, Division of General Medicine, Massachusetts General Hospital, Boston
2013-2013  Professor of Medicine, Harvard Medical School

Honors
1982 Phi Beta Kappa, Yale University
1989 Alpha Omega Alpha, Cornell University Medical College
1995 National Associates Award for Outstanding Research, Society of General Internal Medicine
1999 Robert Wood Johnson Foundation Generalist Physician Faculty Scholar
2003 Robert Austrian Faculty Research Award. Department of Medicine. University of Pennsylvania
2005 Penn Pearls Teaching Award, University of Pennsylvania School of Medicine
2008 Christian and Mary Lindback Foundation Award for Distinguished Teaching
2009 Samuel Martin Health Evaluation Sciences Research Award, University of Penn
2010 Mid-Career Research and Mentorship Award, Society of General Internal Med
2011 Arthur Asbury Outstanding Faculty Mentor Award, University of Pennsylvania
2012 American Epidemiological Society
2014 Award for Excellence in Research, Society of Hospital Medicine

Publications:

2. Soneji S, Metlay J. Mortality reductions for older adults differ by race/ethnicity and gender since the introduction of adult and pediatric pneumococcal vaccines. Public Health Reports. 2011;126:259-269. PMCID: PMC3056039
BIOGRAPHICAL DATA FORM

Name/Position in Project: Hasan Bazari Physician Investor

Education/Training:

<table>
<thead>
<tr>
<th>Institution and Location</th>
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<th>Field of Study</th>
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<tbody>
<tr>
<td>Columbia College, New</td>
<td>B.A</td>
<td>1976</td>
<td>Biology</td>
</tr>
<tr>
<td>York</td>
<td>M.A.</td>
<td>1978</td>
<td>Biology</td>
</tr>
<tr>
<td>Columbia University</td>
<td>M.Ph</td>
<td>1979</td>
<td>Biology( Dr.Cyrus Levinthal)</td>
</tr>
<tr>
<td>New York</td>
<td>M.D.</td>
<td>1983</td>
<td>Medicine</td>
</tr>
<tr>
<td>Columbia University,</td>
<td></td>
<td></td>
<td>Albert Einstein College of Medicine, New York.</td>
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<tr>
<td>New York</td>
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</table>

Research and Professional Experience:

Program Director emeritus
Director, Swartz Initiative
Associate Professor of Medicine

2010 Winner of the Alfred Krane Award
2011 Honor Roll for the Partners Program Director Award
2011 Principal Clinical Experience Teaching Award
2011 Gold Humanism Award
2012 Excellence in Clinical Teaching
2013  Outstanding Program
    Director Award

Publications:


**BIOGRAPHICAL DATA FORM**

**Name/Position in Project:** Jatin M. Vyas, MD, PhD - Residency Program Director
Physician Investigator

**Education/Training:**

<table>
<thead>
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<th>Institution and Location</th>
<th>Degree</th>
<th>Year(s)</th>
<th>Field of Study</th>
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<tr>
<td>University of Texas at Austin</td>
<td>B.A. (plan II)</td>
<td>1985-1989</td>
<td>Liberal Arts Honors Program</td>
</tr>
<tr>
<td>Baylor College of Medicine</td>
<td>Ph.D.</td>
<td>1989-1994</td>
<td>Microbiology and Immunology</td>
</tr>
<tr>
<td>Baylor College of Medicine</td>
<td>M.D.</td>
<td>1989-1996</td>
<td>Medicine</td>
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**Research and Professional Experience:**

2007-present  Faculty, Division of Infectious Disease, Department of Medicine, Massachusetts General Hospital, Harvard Medical School

2011-present  PI on 2 NIH R01 to fund basic investigations in the Innate Immune Responses to Fungal Pathogens

2014-present  Residency Program Director for the Department of Medicine, Massachusetts General Hospital

**Publications:**


Name/Position in Project:  Yuchiao Chang, Statistician

Education/Training:

<table>
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<th>Degree</th>
<th>Year(s)</th>
<th>Field of Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Taiwan University, Taipei, Taiwan</td>
<td>BS</td>
<td>06/86</td>
<td>Agronomy</td>
</tr>
<tr>
<td>Yale University, New Haven, Connecticut</td>
<td>MA</td>
<td>05/89</td>
<td>Statistics</td>
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<tr>
<td>Carnegie Mellon University, Pittsburgh, PA</td>
<td>PhD</td>
<td>12/93</td>
<td>Statistics</td>
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</tbody>
</table>

Research and Professional Experience:

Positions:

1986-1987    Research Assistant, Biometry Laboratory, National Taiwan University
1991-1992    Summer Lecturer, Department of Statistics, Carnegie Mellon University
1989-1993    Teaching Assistant, Department of Statistics, Carnegie Mellon University
1998-2001    Statistical Consultant, Gastroenterology
1993-2005    Instructor in Medicine, Department of Medicine, Harvard Medical School
1998-2006    Assistant Biostatistician, Massachusetts General Hospital, Boston, MA
2005-current Assistant Professor in Medicine, Department of Medicine, Harvard Medical School
2006-2012    Associate Biostatistician, Massachusetts General Hospital, Boston, MA
2012-current Biostatistician, Massachusetts General Hospital, Boston, MA

Honors:

1993         Biometric Society Student Award
1995         American Cancer Society Institutional Research Grant Award

Publications:


BIOGRAPHICAL DATA FORM

Name/Position in Project: Elyse R. Park Qualitative Researcher

Education/Training:

<table>
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<th>Institution and Location</th>
<th>Degree</th>
<th>Year(s)</th>
<th>Field of Study</th>
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<tr>
<td>Tufts University, Medford, MA</td>
<td>B.A.</td>
<td>1988</td>
<td>Social Psychology</td>
</tr>
<tr>
<td>Yeshiva University, Bronx, NY</td>
<td>Ph.D.</td>
<td>1997</td>
<td>Clinical Health</td>
</tr>
<tr>
<td>Harvard School of Public Health, Boston, MA</td>
<td>MPH</td>
<td>2007</td>
<td>Behavioral Medicine Public Health</td>
</tr>
</tbody>
</table>

Research and Professional Experience:

1990-1991 Research Intern, Memorial Sloan Kettering Cancer Center, New York, NY.
1993-1995 Graduate Research Assistant, Albert Einstein College of Medicine, Bronx,
1995-1996 Psychology Intern, APA approved Clinical Psychology/Behavioral Medicine Program. Union Memorial Hospital, Baltimore, MD.
1998-2000 Research Associate, Dana-Farber Cancer Institute, Boston, MA.
2001-2006 Instructor, Department of Psychiatry, Harvard Medical School, Boston, M.
2006-2011 Assistant Professor, Department of Psychiatry, Harvard Medical School, B
2007-2010 Chief of Behavioral Health Research, Benson-Henry Institute for Mind
2009- Director of Behavioral Sciences, MGH Center for Psychiatric Oncology and Behavioral Sciences at the Cancer Center
2009- Director of Behavioral Science Research, MGH Tobacco Research & Treatment Center
2010- Director of Behavioral Health Research, Benson-Henry Institute for Mind Body Med
2011- Associate Professor, Department of Psychiatry, Harvard Medical School

Honors

1991-1994 Academic Scholarship (Yeshiva University, Bronx, NY)
1993-1994 Jewish Foundation for Education of Women Award
2005 Author of top 25 most read articles of 2005 (Health Affairs)
2006 Behavioral Medicine Excellence in Mentorship Award (MGH, Boston, MA)
2008 4th Biennial Survivorship Research Conference Meritorious Presentation
2010 Clinical Innovator Award, MGH Cancer Center’s Psychiatric Oncology and Behavioral Sciences Center
2014 Mentor: Best poster, 11th annual American Psychosocial Oncology Society

5. Publications:


J. Appendices

References – Literature Cited

Institutional Review Board (IRB) Certification Status

Our application will be submitted February 2015. We are completing our data collection documents and surveys.
Applicant's Non Profit Status

Employer Identification Number: 06-2103580
Person to Contact: Jeffery Cordell
Toll Free Telephone Number: 1-877-829-5500

Dear Taxpayer:

This is in response to your Dec. 16, 2011, request for information regarding your tax-exempt status.

Our records indicate that you were recognized as exempt under section 501(c)(3) of the Internal Revenue Code in a determination letter issued in December, 1967.

Our records also indicate that you are not a private foundation within the meaning of section 509(a) of the Code because you are described in section(s) 509(a)(1) and 170(b)(1)(A)(ii).

Donors may deduct contributions to you as provided in section 170 of the Code. Bequests, legacies, devises, transfers, or gifts to you or for your use are deductible for Federal estate and gift tax purposes if they meet the applicable provisions of sections 2055, 2106, and 2522 of the Code.

Please refer to our website www.irs.gov/eo for information regarding filing requirements. Specifically, section 6033(j) of the Code provides that failure to file an annual information return for three consecutive years results in revocation of tax-exempt status as of the filing due date of the third return for organizations required to file. We will publish a list of organizations whose tax-exempt status was revoked under section 6033(j) of the Code on our website beginning in early 2011.
PRESIDENT AND FELLOWS OF HARVARD COLLEGE
1033 MASSACHUSETTS AVE STE 3
CAMBRIDGE MA 02138-5366

If you have any questions, please call us at the telephone number shown in the heading of this letter.

Sincerely yours,

S. A. Martin, Operations Manager
Accounts Management Operations