PARTNERS HUMAN RESEARCH COMMITTEE
PROTOCOL SUMMARY

Answer all questions accurately and completely in order to provide the PHRC with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.

PRINCIPAL/OVERALL INVESTIGATOR

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PROTOCOL TITLE

A Randomized Trial to Investigate the Impact of Professional Development Coaching Programs in MGH Residency & Fellowship Programs, and in Women Residents in a Professional Surgical Society

FUNDING

Physicians Foundation Grant - Fund #230925; $100,000; 10/31/17-10/31/19

VERSION DATE

April 10, 2018

SPECIFIC AIMS

Concisely state the objectives of the study and the hypothesis being tested.

Goal:

1. Periodic reflection and performance review to allow trainees to visualize their progress and trajectory in training – where are you now and where are you going?
2. Maximize the potential for professional development during residency and/or fellowship.
3. improve burnout and response to stress by reinforcing coping skills and strengths.
4. Ensure 1:1 relationship with core faculty to prevent trainees from going unnoticed in a large academic medical center.

Hypothesis: Residents & Fellows (herein referred to as trainees) will benefit from a Professional Development Coaching Program in the following ways:

1. A Professional Development Coaching Program, based on the principles of positive psychology, will improve trainees well-being, compared to non-coached controls.
2. A Professional Development Coaching Program, based on the principles of positive psychology, will improve trainees workplace satisfaction, compared to non-coached controls.
3. A Professional Development Coaching Program will decrease trainees and faculty coach burnout and improve their resiliency by allowing them to visualize their accomplishments, improve their reponse to stress of uncertainty, and decrease emotional exhaustion, compared to controls.
4. A Professional Development Coaching Program, based on the principles of positive psychology, will improve faculty coach well-being, compared to non-coach controls.

BACKGROUND AND SIGNIFICANCE

Provide a brief paragraph summarizing prior experience important for understanding the proposed study and procedures.

Coaching is used in business and many other career paths to help the individual define and create their own goals and strategies for achieving those goals. The MGH Professional Development Coaching Program applies this model to help our residents in their professional development as physicians. While our housestaff have many evaluators, letter-writers and mentors, our coaching program provides them the opportunity for a non-program director faculty member to review their entire portfolio and development throughout residency in a coaching role. It was successfully developed and rolled out in 2011. This program was evaluated from 2012-present, and based on its success, it has since been adopted by >20 internal medicine residency programs around the country. We have not yet embarked in evaluation in non-internal medicine residencies or internal medicine subspecialty fellowship. Additionally, we have never investigated the impact of coaching compared to non-coached peers in a randomized trial. We would like to pursue a randomized coaching intervention and evaluation across non-internal medicine residency programs and internal medicine subspecialty fellowship to understand the impact of this program and its generalizability. In addition, we would like to investigate the impact of this coaching program delivered remotely for women surgery residents in the Association of Women Surgeons.

The goal of the Professional Development Coaching Program is to allow trainees to understand their development over time, find meaning and

purpose in their work, and identify their strengths and how to use these to overcome challenges and stressors. Additionally, the program connects trainees with a faculty member who will work with them, grow to know them in-depth over time, and provide meaningful guidance throughout the relationship. There is an additional benefit to the coaches themselves, who are able to connect with other faculty coaches in a rewarding way, that provides faculty development in leadership development and positive psychology, and space to interact with a group of like-minded physicians.

The program design will be mirrored on our internal medicine coaching program - Each trainee is assigned a Professional Development Coach, who is a faculty member from a different department than theirs who has volunteered their time as a coach. In the Association of Women Surgeons cohort, the coach will be a faculty member who is a surgeon practicing in another area of the country than the resident. Professional Development Coaches are assigned on average 2 trainees and are responsible for meeting with them quarterly to review evaluations, encourage reflection, provide guidance, and motivate them to set learning goals for the upcoming rotations. Once trainees are matched with their coach, they remain paired with their coach for the duration of the study (3 years). There is a three-year curriculum based on positive psychology and leadership development that is based on quarterly meetings. The faculty coaches receive 2 hours of training in positive psychology coaching annually.

Based on prior program evaluation, residents engage in the coaching program enthusiastically, and those who engage report lower levels of burnout, greater resiliency, greater satisfaction with their training experience, improved responses to stressors at work and in their personal life, and have increased opportunities for reflection and feedback. We would like to continue to study the Professional Development Coaching Program in other specialties and stages of training, and to do so more rigorously than we have in the past, by engaging in a randomized trial comparing coaching to usual mentoring and well-being practices, and if successful, provide an opportunity for crossover in year 3 where all participants receive coaching.

This study would be carried out at MGH, and the AWS cohort would be carried out remotely, with the study team primarily existing at MGH (with one collaborate from AWS at the Cleveland Clinic). All residents from general surgery, OMFS, urology, OB/GYN, and neurosurgery and all internal medicine first year subspecialty fellows will be enrolled in the study. A baseline survey will be obtained to allow for randomization to either coaching, or usual mentoring and well-being practices that exist in the residency and/or fellowship. We will quantitatively surveying the trainees and coaches regarding their experiences with and assessment of the

Professional Development Coaching Program at the end of each year the study period.

RESEARCH DESIGN AND METHODS

Briefly describe study design and anticipated enrollment, i.e., number of subjects to be enrolled by researchers study-wide and by Partners researchers. Provide a brief summary of the eligibility criteria (for example, age range, gender, medical condition). Include any local site restrictions, for example, "Enrollment at Partners will be limited to adults although the sponsor's protocol is open to both children and adults."

- All residents from general surgery, OMFS, urology, OB/GYN, and neurosurgery and all internal medicine first year subspecialty fellows will be enrolled in the study.
- All residents in the Association of Women's Surgeons will be invited to participate in the study.
- Control group – 50% of the study trainee population will be randomized to control in a 1:1 manner after baseline burnout data is obtained. 50% of the coaches who volunteer will be randomized to control in a 1:1 manner after baseline burnout data is obtained. In year 3, these trainees and coaches will crossover into the coaching intervention.
- Study group – 50% of the study population will be randomized to coaching in a 1:1 manner after baseline burnout data is obtained. 50% of the coaches who volunteer will be randomized to coaching in a 1:1 manner after baseline burnout data is obtained.
- Faculty and trainees will be surveyed at beginning and end of each academic year. Surveys will be administered by a researcher not affiliated with the residency program, who has been involved in coaching research since 2011. This researcher will collect the data centrally, which will be de-identified when shared with study staff or the training programs.
- Training programs and the Association of Women Surgeons will be given access to the aggregate data, as well as the de-identified data from their training program.

Briefly describe study procedures. Include any local site restrictions, for example, "Subjects enrolled at Partners will not participate in the pharmacokinetic portion of the study." Describe study endpoints.

- Coaches are recruited via email to all teaching faculty within the representative training programs, and volunteer their time to serve as a faculty coach. In the AWS cohort, they will be invited by email in advance of the annual meeting in October 2018. They participate in 2 hours of mandatory faculty development coach training per academic year. There is also an annual coach faculty development retreat that is not mandatory.

- Trainees will be assigned to a professional development coach who is not likely to be a mentor, evaluator or letter-writer for the trainee
- All trainees are oriented to the coaching program during a mandatory orientation session and informed about the study. All incoming interns and fellows will be sent an email in advance to inform them of the study.
- All AWS trainees will be oriented during an informational session at the 2018 AWS Annual Meeting.
- All trainees and faculty (interventions and controls) will be asked to complete a baseline survey.
- Intervention trainees and coaches will be expected to meet quarterly to review performance and establish learning goals for subsequent rotations. There is no consequence or repercussion for not meeting.
- All trainees enrolled (interventions and controls) will be asked to complete a survey at the end of each academic year inquiring about their workplace experiences, workplace relationships, burnout, resiliency, response to stress, hardiness, happiness, and gratitude. This will serve as their baseline for the following academic year.
- All coaches (interventions and controls) will be asked to complete a survey at baseline enrollment in the program and the end of each academic year about their workplace experiences, workplace relationships, burnout, resiliency, response to stress, hardiness, happiness, and gratitude. This will serve as their baseline for the following academic year.

For studies involving treatment or diagnosis, provide information about standard of care at Partners (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

This study does not involve treatment or diagnoses.

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

This study does not involve treatment, diagnoses, or procedures

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

The only potential harm that could be anticipated from this study is if there is a large difference in experience in interventions and controls. We have

seen from our experience with internal medicine coaching that those who do not engage in coaching (people who chose to opt-out of regular coaching) do have higher burnout, but it is not clear if coaching is the correlation, or if in fact these people are avoiding coaching due to their burnout. This study will help determine if there is a difference.

Confidentiality will be required of the coaches. Specifically, they will be required not to share the details of confidential evaluations with other faculty. Coaches are not asked to report back on their meetings to the training program, unless they are concerned about the safety and well-being of the trainees, patients, or others. The usual potential harms that these physicians may encounter in the course of their work in patient care are expected and their health and safety will be safeguarded as per the usual hospital policies at MGH.

Since there are no treatment plans or procedures involved, there is no risk to the safety of the subjects.

FORESEEABLE RISKS AND DISCOMFORTS

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

The only potential harm that could be anticipated from this study is if there is a large difference in experience in interventions and controls. The usual potential harms that these physicians may encounter in the course of their work in patient care are expected and their health and safety will be safeguarded as per the usual hospital policies at MGH.

The coaching program was agreed upon by the training programs involved in this study and leadership of AWS. All trainees will be randomized but coaching program and survey participation is voluntary. In the study there is risk of discomfort for the trainees and coaches in filling out surveys about burnout and their program experience. This risk will be minimized by surveys which are de-identified and only viewed by research staff not affiliated with the training program. There will be no consequence if trainees do not complete the survey and this will be explained before completing the survey.

EXPECTED BENEFITS

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, “It is hoped that the

treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects." Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.

All trainees participating in the Professional Development Coaching Program are expected to receive the same benefit, regardless of participation in the surveys; which is increased increased awareness of their accomplishments, increased opportunity for reflection, decreased burnout, improved well-being, increased resiliency, and increased opportunity to set self-directed learning goals. Additional benefits which are likely, but may be harder to capture in a survey, are increased awareness of where to turn in the event that they are struggling with work, life or professional issues.

EQUITABLE SELECTION OF SUBJECTS

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

All residents from general surgery, OMFS, urology, OB/GYN, and neurosurgery and all internal medicine first year subspecialty fellows will be enrolled in the study. All residents who are members of AWS will be invited to participate. Randomization will be carefully done to ensure gender and other demographics are balanced between groups, with the exception of the AWS cohort, which is all women, and in that cohort, we will focus on balancing the remaining demographics.

When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and to have an interpreter present.

All trainees have exhibited English proficiency at the time of enrollment in the training program.

For guidance, refer to the following Partners policy:
Obtaining and Documenting Informed Consent of Subjects who do not Speak English
http://healthcare.partners.org/phsirb/nonengco.htm

RECRUITMENT PROCEDURES

Explain in detail the specific methodology that will be used to recruit subjects. Specifically address how, when, where and by whom subjects will be identified and approached about participation. Include any specific recruitment methods used to enhance recruitment of women and minorities.

Trainees will be asked to complete a de-identified survey in August of their training year. All trainees and faculty will be asked to complete de-identified surveys at the end of each academic year. These surveys will serve no evaluative purpose in the training program. It will be clearly described that their participation is not mandatory.

Provide details of remuneration, when applicable. Even when subjects may derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital, parking fees or other inconveniences will result in additional out-of-pocket expenses related to study participation. Investigators may wish to consider providing reimbursement for such expenses when funding is available

None

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects
http://healthcare.partners.org/phsirb/recruit.htm

Guidelines for Advertisements for Recruiting Subjects
http://healthcare.partners.org/phsirb/advert.htm

Remuneration for Research Subjects
http://healthcare.partners.org/phsirb/remun.htm

CONSENT PROCEDURES

Explain in detail how, when, where, and by whom consent is obtained, and the timing of consent (i.e., how long subjects will be given to consider participation). For most studies involving more than minimal risk and all studies involving investigational drugs/devices, a licensed physician investigator must obtain informed consent. When subjects are to be enrolled from among the investigators' own patients, describe how the potential for coercion will be avoided.

Consent will be obtained during the orientation following an overview of the study, as well as in emails when surveys are sent out.

NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research

and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the PHRC website:
http://healthcare.partners.org/phsirb/newapp.htm#Newapp

For guidance, refer to the following Partners policy:
Informed Consent of Research Subjects
http://healthcare.partners.org/phsirb/infcons.htm

DATA AND SAFETY MONITORING

Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping rules for the study, when appropriate. Depending upon the risk, size and complexity of the study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

NOTE: Regardless of data and safety monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under his/her care.

Survey data will be reviewed quarterly using on-line, de-identified survey tools. The data will be reviewed by study researcher within the MGH Department of Medicine. Anonymous, de-identified data will then be reviewed by study investigators. Training programs will receive the aggregate de-identified data, as well as their de-identified individual program data.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor safety reports and DSMB reports. Describe the plan for reporting adverse events to the sponsor and the Partners' IRB and, when applicable, for submitting sponsor safety reports and DSMB reports to the Partners' IRBs. When the investigator is also the sponsor of the IND/IDE, include the plan for reporting of adverse events to the FDA and, when applicable, to investigators at other sites.

NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Partners Human Research Committee guidelines for Adverse Event Reporting

There are no anticipated adverse or safety events in this study. Any adverse events that might occur will be directly reported to the IRB.

MONITORING AND QUALITY ASSURANCE

Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, specify who will review the accuracy and completeness of case report form entries, source documents, and informed consent.

NOTE: Regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

Online survey data will be used to assure validity and integrity of the data. The surveys will be submitted to the IRB as well, to assure adherence to IRB-approved protocol. Study researchers will review the accuracy and completeness of all data and consent.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance
http://healthcare.partners.org/phsirb/datasafe.htm

Adverse Event Reporting Guidelines
http://healthcare.partners.org/phsirb/adverse_events.htm

PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed surveys/questionnaires; proper disposal of printed computer data; limited access to study data; use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.

NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

Trainees and faculty will be asked to enter their names on any online survey data tools, for matching purposes (match their response to their coach/coachee response). There will be no written surveys. This information will only be viewed by study researchers and not anyone affiliated with the training program.

Information gathered from the surveys will not be published or shared with individual identifying information. Individual data will not be traceable. All data will be stored in a secure Partners electronic folder protected by a password on a network drive. All survey related papers will be disposed of properly.

SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS

Specimens or data collected by Partners investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects.

n/a

Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

n/a

RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS

When specimens or data collected by research collaborators outside Partners will be sent to Partners investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Partners investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.