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

Sat Bir S. Khalsa

PROTOCOL TITLE

An Evaluation of Changes in Psychological Health to a Yoga Program for Medical Residents

NCT03687450

FUNDING

Partners Centers of Expertise
BWH Osher Center

VERSION DATE

5/4/19

SPECIFIC AIMS

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

We aim to initiate and complete the first investigation of the effect of yoga on resident physicians' psychological health using a randomized controlled trial to measure outcomes across several domains. To meet the goals of the proposed project we have identified three specific aims:

Specific Aim 1: Assess the acceptability and feasibility of the yoga program through measuring participation and conducting standardized interviews with a subset of yoga participants.

Specific Aim 2: Evaluate the effect of the yoga program on resident physicians' stress, burnout, resilience, mindfulness, mood, depression, anxiety, and sleep quality using quantitative self-report measures.

Specific Aim 3. Examine whether outcome measures were perceived as relevant to the participants' work environment and were not burdensome as to the length and content of the program.

BACKGROUND AND SIGNIFICANCE

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

Resident physicians experience high levels of acute and unmanaged chronic stress and burnout, which impairs performance and increases risk for developing psychological and physical health problems. Medical institutions have addressed this problem with limited success with organizational changes, such as schedule reform, and educational wellness curricula. Yoga is a comprehensive system of mind-body practices including physical postures and exercises, breath regulation, deep relaxation, and meditation/mindfulness techniques. Yoga has been demonstrated to reduce stress and burnout across a wide range of populations including frontline medical professionals such as nurses and medical students.

The Kripalu Center for Yoga & Health has developed the standardized RISE (resilience, integration, self-awareness, engagement) yoga program that has been evaluated to improve stress, mood, sleep quality, resilience and mindfulness in workplace populations including medical professionals. Furthermore, previous research from members of our team indicates that yoga-related practices promote beneficial changes in gene expression including up regulation of genes related to energy metabolism and immune function and down regulation of genes related to inflammation and stress.

The proposed study would be the first investigation of a yoga program for medical residents. This is particularly important considering the high level of stress and burnout in this population, and the demonstrated ability of yoga to attenuate both. Also, this proposed project would be the first to investigate the mediating factors of resilience and mindfulness on changes in stress, mood, and burnout in a medical workplace setting.

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."

The project will implement a mixed-methods randomized controlled trial to investigate the impact of the 6-week RISE program on psychological health in Longwood medical area residents. The RISE program is an existing standardized yoga program at Kripalu that will be adapted for residents in a 60-90-minute, once-weekly class for six weeks. Participants will be randomized to either the RISE yoga program or a no treatment control

group. Participants randomized to the RISE program will also be instructed to maintain a short 10-15-minute daily home yoga practice. Sessions will be lead by experienced instructors from Kripalu and will be held in the Longwood medical area. Prior to randomization, all subjects will complete a questionnaire including information on prior yoga experience and demographic data such as gender, age, year in residency, residency program, race, and ethnicity. Additional questions assessing participants' yoga practice after the study will be asked at 2 and 6 months post-program. Participants will complete questionnaires to study the self-report outcomes as described below in "Quantitative Self-Report Measures." These will be assessed at baseline, at program completion (post-program), at 2-month follow-up, and at 6-month follow-up.

Participants will include resident physicians at Longwood medical area hospitals. The only exclusion criterion is having practiced yoga, meditation, tai chi, qigong, or another mind-body practice at least 25 hours or more in the past 6 months. Participants must be willing not to practice mind-body programs other than the treatment protocol during the intervention. Participants must be able to commit to attend at least 4 out of 6 sessions. We plan to enroll up to 200 participants with a goal of at least 60 participants with a 2:1 ratio of participants randomized to yoga to participants randomized to control. The control group will receive a one session of RISE after their participation in the trial is complete.

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.

The RISE program will be delivered as a 6-week yoga-based program on-site at Brigham and Women's Hospital in Boston. The program will consist of six 60-90-minute weekly yoga-based RISE classes. A pre-assessment survey among residents will be conducted to determine the most beneficial location and time. RISE classes will include sitting meditation, mindfulness, breathing techniques, yoga postures, as well as exercises and instruction in mindful communication, mindful sleep preparation, and mindful eating. The program time allocation will be approximately 1/3 yoga instruction and/or practice, 1/3 didactic, and 1/3 experiential. Participants will be provided with tools, skills, and practices that they can use throughout their day.

A member of the study staff will take attendance at each RISE session. Participants will log their home practice via smart phone login, REDcap survey, voicemail line, or paper log to monitor frequency and duration.

Outcome Measures
Primary Outcome Measure:

Feasibility. We will measure the percentage of participants in the intervention group that are able to complete four or more of the six RISE classes.

Secondary Outcome Measures:
Quantitative Self-Report Measures
Some or all of the following measures will be used:
Resilience. The 14-item Resilience Scale (RS-14; Wagnild & Young, 1993) aims to evaluate whether individuals in the face of adversity are able to adapt and restore equilibrium. Resilience is considered a positive 4 personality characteristic that enhances individual adaptation. The RS displays high levels of reliability and validity (Wagnild 2009).
Mindfulness. The Five Facet Mindfulness Questionnaire (FFMQ) is a well-established 39-item scale for the assessment of mindfulness (Baer et al., 2006). The 15-item FFMQ is a validated short-form of the 39-item FFMQ (Baer et al., 2006; Baer et al., 2012; Gu et al., 2016). The FFMQ measures five aspects of mindfulness: observing, describing, awareness, non-judgment of experience, and non-reactivity to inner experience (Baer et al., 2006; 2012).
Stress. The 10-item Perceived Stress Scale (PSS) is the most widely used psychological instrument for measuring the perception of stress. Items are designed to tap how unpredictable, uncontrollable, and overloaded respondents find their lives (Cohen et al., 1983).
Burnout and Professional Fulfillment. The Maslach Burnout Inventory (MBI) is a 22-item instrument that has been widely used to evaluate three domains of burnout, including emotional exhaustion, depersonalization, and sense of personal accomplishment, in health care professionals and trainees. The scale is rated on a 7-point Likert scale. A two-question screen based on the MBI developed to evaluate emotional exhaustion and depersonalization has shown strong, consistent associations with the full MBI evaluation for EE and DP and has been validated in internal medicine resident physicians (West CP, et al., 2009; 2012). The 16-item Professional Fulfillment Index (PFI) measures physician professional fulfillment and burnout across three scales; professional fulfillment, interpersonal disengagement, and work exhaustion (Trockel et al., 2018). The PFI has been validated in practicing and resident physicians (Trockel et al., 2018).
Depression and Anxiety. The Depression Anxiety and Stress Scale (DASS; Henry & Crawford, 2005) is a set of three self-report scales that are designed to measure the negative emotional states of depression, anxiety, and stress. The shorter 21-item scale will be used to limit the number of questions for busy trainees. The Patient Reported Outcomes Measurement Information System (PROMIS) Depression and Anxiety 8-item short-form (Pilkonis et al., 2014) measures symptoms of depression (negative mood, views of self, and social cognition, as well as decreased positive affect and engagement) and anxiety (fear, anxious misery, hyperarousal, and somatic symptoms related to arousal).

Affect. The Positive and Negative Affect Schedule (PANAS; Watson et al., 1988) is a commonly used, well validated, reliable measure of positive and negative mood, and is composed of 10 positive mood terms (i.e. interested, enthusiastic, proud), and 10 negative mood terms (i.e. distressed, guilty, hostile).
Sleep Quality. The Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance item bank assesses qualitative aspects of sleep and wake function. Short forms containing 4 and 8 items has been developed from the original 27-item question bank and correlates strongly with the longer form (Yu et al., 2011; 2012). Questions regarding sleep quality, latency, and other sleep qualities are rated on a 5-point Likert scale ranging from "not at all" to "very much."
Well-Being: The 7-item Resident Physician Well-Being Index has been used in resident physicians to evaluate overall well-being (Dyrbye et al., 2014). This has been studied in resident physicians previously and residents with scores greater than or equal to 5 were at a greater risk of adverse events including burnout, suicidal ideation, and reporting a recent medical error.

Exploratory outcome measures:
Relevance Questionnaire. We have developed and will administer a relevance questionnaire as a means to understand the participants' perception of the outcome measures employed in the study, including whether the measures were relevant to the participants' work environment, level of burden if any, the length and content of the battery.

Qualitative Interviews. A block-randomized sample of 35% of the resident physicians in the RISE group will participate in 20-30 minute interviews after the RISE intervention is complete and the end program quantitative measures have been taken. We will use standard qualitative research methods in the form of structured interviews to gather information about each participant's experience of the yoga program with regard to feasibility, any barriers to practice that were encountered, intention to continue using the yoga-based skills and practices learned in the program, and any changes in their psychosocial and physical health and wellbeing as a result of the program.

References:

1. Wagnild G, Young H. Development and psychometric. J Nurs Measure, 1993;1(2):165-178.
2. Wagnild GM. (2009). The resilience scale user's guide. *Worden, MT: The Resilience Centre*.
3. Baer RA, Smith GT, Hopkins J, Krietemeyer J, Toney L. Using self-report assessment methods to explore facets of mindfulness. Assessment, 2006;13(1):27-45.

4. Baer RA, Carmody J, Hunsinger M. Weekly change in mindfulness and perceived stress in a mindfulness-based stress reduction program. *J Clil Psychol*. 2012;68(7):755-65.
5. Gu J, Strauss C, Crane C, Barnhofer T, Karl A, Cavanagh K, Kuyken W. Examining the factor structure of the 39-item and 15-item versions of the Five Facet Mindfulness Questionnaire before and after mindfulness-based cognitive therapy for people with recurrent depression. *Psychological Assessment*, 2016;28(7):791.
6. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. J Health Soc Behav, 1983, 385-396.
7. West CP, Dyrbye LN, Sloan, JA, Shanafelt TD. Single item measures of emotional exhaustion and depersonalization are useful for assessing burnout in medical professionals. J Gen Intern Med, 2009;24(12):1318-1321.
8. West CP, Dyrbye LN, Satele D, Sloan J, Shanafelt TD. Concurrent validity of single-item measures of emotional exhaustion and depersonalization in burnout assessment. J Gen Intern Med 2012;27:1445-52.
9. Trockel M, Bohman B, Lesure E, Hamidi MS, Welle D, Roberts L, Shanafelt T. A brief instrument to assess both burnout and professional fulfillment in physicians: reliability and validity, including correlation with self-reported medical errors, in a sample of resident and practicing physicians. Acad Psychiatry, 2018;42(1):11-24.
10. Henry JD, Crawford JR. The short-form version of the Depression Anxiety Stress Scales (DASS-21): Construct validity and normative data in a large non-clinical sample. Brit J Clin Psychol, 2005;44(2):227-239.
11. Pilkonis PA, Yu L, Dodds NE, Johnston KL, Maihoefer CC, Lawrence SM. Validation of the depression item bank from the Patient-Reported Outcomes Measurement Information System (PROMIS®) in a three-month observational study. J Psychiat Res, 2014;56:112-9.
12. Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: the PANAS scales. Journal of personality and social psychology, 1988;54(6):1063.
13. Yu L, Buysse DJ, Germain A, Moul DE, Stover A, Dodds NE, Johnston KL, Pilkonis PA. Development of short forms from the PROMIS™ sleep disturbance and sleep-related impairment item banks. Behavioral Sleep Medicine, 2012;10(1):6-24.
14. Dyrbye, LN, Satele, D, Sloan, J, Shanafelt, TD (2014). "Ability of the Physician Well-Being Index to identify residents in distress." J Grad Med Educ 6(1): 78-84.

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.

Not applicable

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.

There are minimal risks of injury during yoga. The practice of the physical exercises and postures, breathing exercises, relaxation techniques, and meditation in the yoga treatment involve little risk, although at times subjects may find them challenging and difficult to complete. Overexertion on the physical exercises may lead to temporary muscle soreness for up to a week. However, subjects will be instructed to gradually increase their effort on any physical exercises or breathing exercises so as not to overexert themselves, and to stop if they experience unexpected unpleasant symptoms. The control of mental activity aims at controlling the participant's thinking process. There are no known risks for controlling thought processes. There may be risks and side effects that are currently unknown and/or unanticipated.

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.

Not applicable

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.

There is a minimal risk of loss of privacy with respect to the data collected although confidentiality will be maintained according to standard procedures. The study staff will take all appropriate precautions and keep this information fully controlled.

Emotional distress may be experienced when subjects complete the outcome measures. For example, rumination on the existence and severity of negative psychological characteristics may pose limited risks to subjects during or following questionnaire administration.

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.

It is hoped that those in the RISE yoga program will show improvements in psychological health outcomes.

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.

The study is restricted to individuals enrolled in residency programs in the Longwood medical area. Though residents in other programs may also benefit, the study excludes these programs to impose a size limit on yoga classes and offer a convenient location for residents.

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.

Physicians practicing in the United States must be proficient in English. Therefore, no subjects will be excluded on the basis of language.

For guidance, refer to the following Partners policy:
Obtaining and Documenting Informed Consent of Subjects who do not Speak English
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Non-English_Speaking_Subjects.1.10.pdf

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.

An e-mail containing study information will be distributed to all BWH Internal Medicine residents. If the recruitment goal of at least 60 participants is not

met, an e-mail containing study information will be distributed to all BWH residents. Recruitment flyers will also be posted in common areas and workspaces used by residents. If more subjects are necessary, recruitment will be extended to other Longwood medical area hospitals. E-mails will be sent to residents via institutional e-mails.

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

As described above, participants will receive a $25.00 gift card for the purchase of a yoga mat as incentive for enrolling in the study.

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Recruitment_Of_Research_Subjects.pdf

Guidelines for Advertisements for Recruiting Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Guidelines_For_Advertisements.1.11.pdf

Remuneration for Research Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Remuneration_for_Research_Subjects.pdf

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.

Potential subjects who respond to recruitment e-mails and/or fliers will be provided with information about the study along with a link to the consent form via their unique Partners e-mail address. Informed consent will be performed electronically via REDCap survey software. Participants will have an opportunity to review the consent form and indicate via REDCap that they would like more information about the study. A member of the study staff will then contact the potential subject. If the potential subject elects to proceed, they will provide informed consent with an electronic signature via REDCap survey. This consent must be signed prior to completion of the pre-intervention questionnaires. The consent form is included separately for IRB review. The REDCap consent process was discussed with Lynn Simpson.

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:
https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb

For guidance, refer to the following Partners policy:
Informed Consent of Research Subjects:
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Informed_Consent_of_Research_Subjects.pdf

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.

The Principal Investigator, Dr. Sat Bir Khalsa, will be responsible for the oversight of data and safety issues, and will be ultimately responsible for determining whether the research should be altered or stopped. The efficacy data to be reviewed will include subject's responses to self-report questionnaires and interviews. As data from each planned assessment becomes available, analyses will be conducted to screen for adverse effects on subjects' mental health (only non-clinical indicators are assessed) and behavioral outcomes from the questionnaires or interviews.

Research staff conducting interim analyses of efficacy data will immediately inform Dr. Khalsa if any evidence of adverse events, including data breaches, is found. All project staff and yoga instructors will be fully instructed in the maintenance of confidentiality required for this study, will be trained to observe for potential adverse events and report to the PI if one occurs as soon as an event is observed (staff are instructed that the PI and post-doctoral fellow/project leader are available by cell phone at all times), and will meet on a regular basis for ongoing training, supervision, and problem solving. See the section on "Privacy and Confidentiality" below for a description of procedures that will be followed to prevent potential data breaches.

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

Adverse events (AEs) will be reported by Dr. Khalsa to the IRB at least once per year and will be reported as part of the annual progress report. Specifically, the PI compiles an annual report to the IRB as part of the recertification process. This report includes a summary of data collection activities, certifications on human subjects training and conflict of interest issues, and a report of AEs if any. AEs will be described in this annual report. Serious adverse events (SAEs) will be reported to the IRB within 24 hours of the event by email, including a brief explanation of the SAE and when it occurred. A written follow-up will be submitted within 72 hours of the event and will include information on the date of the event, what occurred, actions taken by the project staff, planned follow up (if any), whether the event appears to be related to completing the outcome measures, and whether the affected participant will continue in the study. Following any AEs or SAEs, Dr. Khalsa will consult with study staff to determine a course of corrective action, and will report these corrective actions to the IRB. Study staff will immediately report any breaches of data security directly to Dr. Khalsa who will report these incidents to the IRB as described above. (See the section on "Privacy and Confidentiality" below for a description of procedures that will be followed to prevent potential data breaches.)

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.

Procedures will be used at several points to ensure the integrity of the data. The measures used in the study were selected on the basis of previous research which indicates that the scales have good reliability and strong evidence of construct validity. In addition, data transferred from paper questionnaires will be double-checked by blinded staff members to ensure integrity of the data entry. Questionnaires are edited before data entry by research assistants who are trained to code any ambiguous responses (e.g., subject circles two numbers on a single response scale) and to flag protocols that show evidence of obvious invalidity using standardized criteria (e.g., zig-zag patterns).

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/DSMP_in_Human_Subjects_Research.pdf

Reporting Unanticipated Problems (including Adverse Events)
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Reporting_Unanticipated_Problems_including_Adverse_Events.pdf

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.

The majority of data will be collected via REDcap, which is consistent with privacy and confidentiality requirements for research protocols. If there are paper forms, they will be stored in a locked file cabinet. All electronic data files will be stored in a password-protected computerized database. The only people with access to these files will be IRB approved study staff. Subjects will be assigned a study ID number that will be used to identify data sets. No identifiable information, such as name or date of birth, will be on any primary source data documents. A master enrollment log will be maintained, and will be used to match subject's names and study ID numbers. This enrollment log will be encrypted with a password and will only be accessible by approved study staff.

No identifiable data will be shared or published outside of the study staff. Once all of the data from the study have been fully verified and baseline data matched with end-program data, all paper data information will be entered into electronic data files in which only subject codes are associated with the data; no identifiable information will be associated with these files. All personal identifiers such as name and birth date will not appear in the electronic data. All research staff will be trained on the importance of confidentiality of data.

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.

N/A