

**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

Barbara Dworetzky, MD

PROTOCOL TITLE

Motivational interviewing to enhance adherence of patients with psychogenic non-epileptic seizures: a model of patient engagement in functional neurological symptom disorders

FUNDING

Practice Research Training Fellowship (American Academy of Neurology, American Brain Foundation)

VERSION DATE

July 8th, 2015

SPECIFIC AIMS

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

NB: Specific Aims 1 and 2 pertain to the first part of this project, detailed under BWH IRB protocol 2013P000133. Specific Aim 3 pertains to the second part of this project, detailed here.

Aim 1: To identify the baseline characteristics which correlate most closely with non-adherence to treatment in patients with PNES.

Hypothesis 1: Factors including low income, low educational achievement, unmarried status, lack of access to transportation, presence of psychiatric comorbidities, high seizure frequency, and long duration since onset of PNES will correlate with non-adherence in patients with PNES.

Aim 2: To identify the factors to which non-adherent patients with PNES attribute lack of adherence.

Hypothesis 2: Patients will most frequently attribute their lack of adherence to external factors including ineffective treatment, lack of empathy on the part of their physicians, and difficulty arranging transportation or time away from work/childcare. Patients will not attribute non-adherence to internal factors such as ambivalence about treatment, avoidance, help-rejection, or psychiatric comorbidities.

Aim 3: To determine whether motivational interviewing improves adherence to treatment (primary outcome), seizure frequency, healthcare usage, and quality of life (secondary outcomes).

Hypothesis 3: A brief in-person interview, using motivational interviewing techniques, will improve adherence, seizure frequency, healthcare usage, and quality of life at 4-month follow-up among patients with PNES when compared to a control group receiving only informational interviewing.

BACKGROUND AND SIGNIFICANCE

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

Psychogenic non-epileptic seizures (PNES) are common, highly disabling, and can be readily diagnosed via the gold standard video-EEG monitoring. Several studies, including two randomized clinical trials have demonstrated the efficacy of psychotherapy (and particularly cognitive behavioral therapy) in treating PNES. However the majority of patients with PNES do not complete psychotherapy and continue to suffer from seizures, disability, social dependence, and increased healthcare resource utilization over the long term. One important barrier to treatment is a high rate of non-adherence with psychotherapy among patients with PNES. This study will entail a randomized trial of motivational interviewing to improve adherence with psychotherapy among patients with PNES. Motivational interviewing is a counseling style that was originally developed to help recovering alcoholics refrain from risky alcohol consumption and has subsequently been extensively studied and used in treating substance abuse, promoting weight loss in obese patients, and improving adherence with treatment among patients with HIV, schizophrenia, and other disorders.

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 study population will be screened from all patients diagnosed with PNES in Brigham and Women’s Hospital by capture of a definitive event on video EEG without EEG correlate. Patients with a mixed diagnosis of both PNES and epileptic seizures will be included. Pediatric patients (under age 18) are not typically evaluated by EEG in our hospital and will therefore be excluded. Patients with estimated IQ<70, inability to speak fluently in English or Spanish, active substance use disorder, pregnancy, or active medical issues which would preclude participation in weekly psychotherapy will be excluded. Patients meeting inclusion criteria will be considered eligible and will be approached for this study whether or not they are also enrolled in PHRC IRB protocol 2013P000133 (we anticipate that most eligible patients will be enrolled in both protocols).

Our goal will be to enroll 60 patients diagnosed with PNES, with 30 randomized to the treatment arm (motivational interview) and 30 randomized to the control arm (informational interview).

Potential subjects will be asked if they are willing to meet with study staff by a member of the clinical team during their inpatient admission. If the patient is willing, they will be approached during their admission by a member of the study staff. The recruiter will not be a member of the treatment team, and in all cases the recruiter will clearly specify that the patient will receive the same standard-of-care treatment for PNES (initial clinical follow-up with neuropsychiatrist and epileptologist and psychotherapy from a licensed therapist) whether or not they participate in the study.

The purpose and structure of the study will be described, and if the individual is interested than the full informed consent process will completed, including detailed review of all potential risks and benefits- Because the informed consent process will be completed during an inpatient admission, time constraints will be minimized and the patient will have ample time to consider his or her consent. If informed consent is obtained, then study procedures will begin.

Baseline demographic data, psychiatric comorbidities, quality of life, and healthcare resource utilization will be recorded in the EMU and the patient will be randomized to treatment (standard treatment + motivational interviewing) vs. control (standard treatment only). The patient will be scheduled for an initial appointment in the “long-term monitoring clinic” with an epileptologist and a neuropsychiatrist (part of standard care for PNES at BWH). At the end of this clinic appointment the patient will have either a motivational interview (treatment) or informational interview (control) depending on their randomization. They will then be referred for weekly psychotherapy either at BWH or with a local provider (again, part of standard care for PNES at BWH). After 4 months they will be called and have a phone interview regarding their adherence to treatment, their reasons for adherence or non-adherence, seizure frequency, quality of life, and healthcare resource utilization over the prior 3 months.

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.

Baseline demographic data, psychiatric comorbidities, seizure frequency, quality of life, and healthcare resource utilization will be recorded following enrollment during the inpatient stay as part of PHRC IRB protocol 2013P000133. If the patient is not enrolled in protocol 2013P000133, baseline demographic data, seizure data, psychiatric comorbidities, qualities of life and healthcare resource utilization will be collected during the admission at which the patient is diagnosed, as detailed in appendix 1. All enrolled subjects will be scheduled for an initial appointment in the joint psychiatry-neurology clinic with a board certified neuropsychiatrist and board certified neurologists, which is standard of care for newly diagnosed PNES patients at Brigham and Women’s Hospital.

All subjects will attend the initial clinic visit with the neuropsychiatrist and epileptologist. At the end of this visit, those subjects randomized to motivational interviewing will be questioned using standardized motivational interviewing techniques by the study author who is a board certified neurologist and who will have formal training and certification in motivational interviewing. Motivational interviews will include the classical 4 steps of MI: 1) engagement (in which the patient’s goals and interests are elicited and the therapeutic alliance is established); 2) focusing (in which the specific subjects of discussion and intervention are negotiated); 3) strengthening motivation (in which the patients’ reasons for healthcare intervention are made explicit, discussed, and reinforced); and 4) planning (in which actions for healthcare intervention are planned out based on the patients’ own goals and interests).

The initial clinic visit and subsequent interview will be recorded with the patients’ consent, and blinded reviewers hired through the department of psychiatry, trained and certified in motivational interviewing, will score the audio recordings using the Motivational Interviewing Treatment Integrity code (MITI) 4.0 to assess fidelity to standardized motivational interviewing techniques. Recordings and blinded review of interviews are for the sole purpose of ensuring that the interviewer is in fact using proper interviewing techniques (ie motivational interviewing techniques for patients in the motivational interviewing arm and abstinence from motivational interviewing techniques in the control arm). Such recordings and review are recommended in motivational interviewing research.

Those subjects randomized to the control group will also undergo an initial clinic visit with a neuropsychiatrist and neurologists – again recorded with the subjects’ consent and scored using the MITI 4.0 to assess abstinence from motivational interviewing techniques. However they will not undergo any subsequent motivational interview. Following the initial clinic visit, all subjects with ongoing seizures will either be scheduled for ongoing psychotherapy for treatment of PNES at Brigham and Women’s Hospital or referred to a local psychotherapist according to their preference.

All subjects will be contacted by phone at 4 month follow-up. If necessary they will be called 5 times at various times during the day and early evening. If they are not reached, they will receive a letter requesting them to contact the study staff to complete the study. Subjects will be questioned about their adherence to treatment. The primary outcome will be the number of psychotherapy sessions for the treatment of PNES in which they have participated over the past three months. They will also be assessed for secondary outcomes including dichotomous adherence (either seizure freedom or active participation in psychotherapy for the treatment of PNES, with more than 5 sessions over the past 3 months), seizure frequency over the past month, number of hospitalizations and emergency department visits over the past 3 months, and quality of life as measured by the brief QOLIE-10 instrument. For those patients who give permission, their psychotherapists will be contacted by study staff to confirm the exact number of psychotherapy sessions over the past 3 months. A standard Partners clinical records release form with the patient’s signature will be sent to the therapist’s office.

Biostatistical Analysis:

A) Motivational Interviewing Treatment Integrity

Fidelity to motivational interviewing techniques during motivational interviewing sessions (intervention arm) will be assessed by blinded reviewers using the Motivational Interviewing Treatment Integrity code (MITI) 4.0. Relational scores and technical scores of ≥ 4 will be taken as indicating adherence to motivational interviewing techniques. Conversely abstinence from motivational interviewing techniques during informational interviews (control arm) will also be assessed by blinded reviewers using the MITI 4.0. Relational scores and technical scores of ≤ 2 will be taken as indicating abstinence from motivational interviewing techniques.

B) Outcome data

Outcome data collected during study, collected at 4 month follow-up, includes seizure frequency over the past 3 months, number of emergency department visits over the past 3 months, QOLIE-10 score (see attached instrument), and participation in psychotherapy for the treatment of PNES (and number of sessions over the past 3 months). The primary outcome will be adherence, defined as attending 8 or more psychotherapy sessions over the past 3 months. Secondary outcomes will include decrease in PNES frequency, seizure freedom, change in QOLIE-10 score, and change in monthly ED visits.

Intergroup comparisons will be made between the treatment arm (motivational interviewing) and control arm (informational interviewing) using the t-test or Wilcoxon rank-sum test depending on normality of distributions.

C) Power analysis:

Sample size of 30-per-arm was calculated to detect a difference in adherence of 25% vs. 60% with power of 0.80 and alpha of 0.05.

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.

All patients enrolled in study will still receive standard of care for patients diagnosed with PNES at Brigham and Women's Hospital: initial clinical follow-up with neuropsychiatrist and epileptologist and psychotherapy from a licensed therapist. Study patients will additionally receive either an informational interview (control arm) or a motivational interview (treatment arm) following their initial clinic follow-up.

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.

Research procedures (motivational interviewing vs. informational interview) are consistent with sound research design. Motivational interviewing has been studied and used for years in promoting abstinence from substance abuse and adherence with treatment in other disorders (HIV, schizophrenia, etc.), and is thought to be associated with minimal risk.

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.

We will also continuously review any adverse reactions to motivational interviews or informational interviews, and will stop the study if there is any indication of repeated adverse reactions. The study author and principal investigator will be responsible for continuous review of adverse reactions.

Individuals will be dropped from the study in cases where PNES is significantly worsening (>100% increase in frequency) or where psychiatric symptoms are otherwise significantly worsening, and where the principal investigator and/or the treating psychiatrist feels that study participation is contributing to psychiatric decompensation.

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.

Psychosocial risks include potential embarrassment or sense of stigmatization due to motivational interviewing or informational interviewing, or to the 6 month follow-up phone calls. Additionally there is a potential loss of privacy associated with audio recording of the motivational interviewing and informational interviewing sessions.

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.

Individual subjects in both the treatment arm and control arm of this study may benefit from additional time with a board certified neurologist, and the opportunity to ask questions about their diagnosis and treatment, which are often points of confusion following a new diagnosis of PNES. If our intervention of motivational interviewing is successful in improving adherence and outcomes in patients with PNES, then subjects randomized to the treatment arm may experience these benefits.

Potential social benefits include the test of a promising intervention to improve adherence with psychotherapy among a large, significantly disabled, and difficult to treat patient population (see background and significance). Evidence based treatments (such as cognitive behavioral therapy) exist for PNES, but are currently rarely completed, in part because adherence rates are ~50% under the best circumstances. It is hoped that motivational interviewing will provide an improvement in adherence with psychotherapy of at least 25%. If motivational interviewing is successful in improving adherence and seizure control among patients with PNES, this may benefit not only those patients, but also the healthcare system and society as a whole. Untreated or incompletely treated patients with PNES are economically and socially dependent, have frequent emergency department visits and hospital admissions, and incur high medical care costs.

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.

Patients will not be excluded from study participation on the basis of gender, pregnancy, or ethnicity. Pediatric patients (<18 years of age) will not be included because such patients are not typically evaluated with video EEG at Brigham and Women’s Hospital. Otherwise, patients will not be excluded on the basis of age.

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.

Patients will not be excluded from study participation 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.

Potential subjects will be asked if they are willing to meet with study staff by a member of the clinical team during their inpatient admission. If the patient is willing, they will be approached during their admission by a member of the study staff. The recruiter will not be a member of the treatment team, and in all cases the recruiter will clearly specify that the patient will receive the same standard-of-care treatment for PNES (initial clinical follow-up with neuropsychiatrist and epileptologist and psychotherapy from a licensed therapist) whether or not they participate in the study.

The purpose and structure of the study will be described, and if the patient is interested then the full informed consent process will be completed by a physician investigator once the diagnosis of PNES is made. The informed consent process will include detailed review of the consent form and all potential risks and benefits. The patient will be encouraged to ask questions. If the patient is unsure about participation, they will be encouraged to take the consent form and review it further during the course of the admission. In that case the physician investigator will return at a later time during the admission, and will again review the consent form and answer any questions. Because the informed consent process will be completed during an inpatient admission, time constraints will be minimized and the patient will have ample time (>12 hours) to consider his or her consent.

At that time the patient will be randomized to treatment (motivational interviewing) vs. control (informational interviewing).

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

There are no extra hospital or clinic visits necessitated by this study, beyond the usual standard of care at Brigham and Women's Hospital. Therefore it is expected that there will be no additional expenses for study participants and no travel or other significant inconveniences.

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](https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Guidelines%20For%20Advertisements.1.11.pdf)

Remuneration for Research Subjects

[https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Remuneration for Research Subjects.pdf](https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Remuneration%20for%20Research%20Subjects.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.

Study staff will initially discuss the study with patients during the inpatient admission. If the patient is interested, informed consent will then be obtained by a licensed physician investigator. The consent process will begin with a review of the consent form. The patient will be encouraged to ask questions. If the patient is still unsure if he wants to participate, he will be encouraged to take the consent form and review it further during the course of the admission. In that case the physician investigator will return at a later time during the admission, and will again review the consent form and answer any questions. If the patient agrees to participation and signs the consent, then the new subject will be randomized and study procedures will be performed.

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](https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Informed%20Consent%20of%20Research%20Subjects.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.

No serious safety issues are anticipated in this study. Nonetheless, study staff will continuously review any adverse reactions to motivational interviews or informational interviews. Any unanticipated problems, including adverse events involving risks to subjects or others will be reported to the principal investigator weekly. Any serious adverse events will be reported within 24 hours. Any unanticipated problems, including adverse events involving risks to subjects or others that are serious, unexpected, and related or possibly related to the research study will be reported to the IRB within 5 working days/ 7 calendar days of the date the investigator first becomes aware of the event.

The principal investigator will stop the study if there is any indication of repeated adverse reactions. The principal investigator will be responsible for review of adverse reactions and for overseeing the safety of study subjects.

Individuals will be dropped from the study in cases where PNES is significantly worsening (>100% increase in frequency) or where psychiatric symptoms are otherwise significantly worsening, and where the principal investigator and/or the treating psychiatrist feels that study participation is contributing to psychiatric decompensation. Subjects may also choose to leave the study at any time. In the event that a subject is dropped from the study or chooses to leave, the study staff will document the reason for their leaving the study and the principal investigator will ensure that they withdraw in the safest manner possible, in coordination with their treating psychiatrist. In the event that the subject does not have a treating psychiatrist or psychotherapist at the time of their withdrawal, a study physician investigator will provide a referral. The principal investigator will be responsible for the safe withdrawal of patients from the trial.

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

No serious safety issues are anticipated in this study. Nonetheless, study staff will continuously review any adverse reactions to motivational interviews or informational interviews. Any unanticipated problems, including adverse events involving risks to subjects or others will be reported to the principal investigator weekly. Any serious adverse events will be reported within 24 hours. Any unanticipated problems, including adverse events involving risks to subjects or others that are serious, unexpected, and related or possibly related to the research study will be reported to the IRB within 5 working days/ 7 calendar days of the date the investigator first becomes aware of the event.

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.

The study staff will be responsible for accurate entry of all data into a password protected electronic database on the Partners network. The principal investigator will be ultimately responsible for data integrity and quality assurance and will review entered data at least once monthly.

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.

Subjects will immediately be given a unique code after signing the consent form. There will be one form with contact information that will contain the subject's name and medical record number, but all other data forms will only contain the subject id. The data collection forms and signed informed consent will be stored in binders in locked cabinets in the locked offices of the epilepsy division. Audio recordings will be stored in the same locked cabinets. Only IRB-approved study staff will have access to keys. The electronic database will be housed in a limited-access server on the Partners network and will be password protected. Only the IRB-approved study staff will know the password. All study staff will be trained in the critical importance of data confidentiality.

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.

There are no outside research collaborators.

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.

There are no collaborating sites.

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.

There are no outside research collaborators.