Increasing Colorectal Cancer (CRC) Screening among Hispanic Primary Care Patients

NCT02272244

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Thomas Jefferson University—Office of Human Research
Division of Human Subjects Protection

SUMMARY OF NON-BIOMEDICAL RESEARCH WITH HUMAN SUBJECTS

Use this form for social and behavioral research, research on education, questionnaire studies, and other prospective studies not involving drugs, devices or medical/surgical procedures. Please address all applicable points to create a complete and succinct synopsis of the protocol. If a point does not apply to your study, please state "NA." Use language, insofar as is possible, that can be understood by a layperson, and provide meanings for all acronyms used. Attach surveys, discussion/interview guides. **Form must be typewritten.**

PART A- SUMMARY OF STUDY

1. Provide a brief (2-3 sentences) lay language synopsis of the study.

The proposed study is designed to test a standard mailed intervention (SI) versus a novel decision support and navigation intervention (DSNI). Working with patients and stakeholders, we will include 400 consenting Hispanic patients in community based primary care practices who are 50 to 75 years of age and eligible for CRC screening. We will consent, survey, and randomize participants either to the SI Group or the DSNI Group. Study specific aims are to: (1) Assess intervention (DSNI versus SI) impact on overall CRC screening adherence; (2) Assess intervention (DNSI versus SI) impact on CRC screening decision stage; (3) Assess intervention (DNSI versus SI) impact on test-specific CRC screening adherence; and (4) Assess intervention (DNSI versus SI) impact on CRC and knowledge and perceptions.

In order to conduct this study, we will complete preliminary focus groups and convene a Patient and Stakeholder Advisory Committee (PASAC) three times a year. In addition to study data, focus groups and PASAC meetings will also be recorded and analyzed for a multi-level evaluation.

2. Objectives and Significance

a. State the primary objective(s) of the study.

(1) Assess intervention (DSNI versus SI) impact on overall CRC screening adherence
(2) Assess intervention (DNSI versus SI) impact on CRC screening decision stage

b. State the secondary objectives(s) of the study.

(3) Assess intervention (DNSI versus SI) impact on test-specific CRC screening adherence
(4) Assess intervention (DNSI versus SI) impact on CRC and knowledge and perceptions.

c. What benefit or knowledge will be gained?

Potential benefits that might result from participation include increased knowledge about CRC screening and early diagnosis of CRC or adenomatous polyps. The potential benefits for the age-eligible population in general include the development of more effective methods for delivering information about CRC screening and promoting the completion of SBT and screening colonoscopy examination. The potential benefits to

individual participants and for the target population in general are significantly greater than the possible minimal risks.

d. State research question or hypothesis you are testing.

We hypothesize that CRC screening adherence, screening knowledge, and favorable perceptions about screening will be higher in the DSNI Group than the SI Group.

3. **Briefly** describe the background and rationale for the research/evaluative study (whichever is appropriate) in lay language. Please limit response to one paragraph. State the perceived problem and why it is being investigated. *(Do not include references and please do not cut and paste grant application or review article.)*

Colorectal Cancer (CRC) screening rates are rising in the general population, but are low among Hispanics. Unfortunately, Hispanics have a significantly lower CRC screening rate than non-Hispanic whites and African Americans, and, as a consequence, are more likely to be diagnosed with late-stage CRC. Lower CRC screening rates among Hispanics translate into to relatively high mortality and low survival from CRC among Hispanics compared to non-Hispanic whites and African Americans. In fact, CRC is the second leading cause of cancer deaths among Hispanics in this country. The disparities in CRC screening and mortality between Hispanics and non-Hispanic whites persist, even when adjusting for education, income, and insurance status. The potential gains associated with CRC screening can only be realized among Hispanics if screening rates rise in this segment of the population. The proposed study will reach Hispanic who are not up-to-date with CRC screening, are unlikely to have been informed about screening, and are unlikely to have received a physician referral for screening. In addition, we will test the impact of an integrated decision support and patient navigation intervention on CRC screening adherence. This strategy is intended to engage Hispanic primary care patients and their primary care providers in the screening process.

4. **Briefly** describe the research/evaluative study design. ***(Use charts and flow diagrams if applicable****. "See protocol" is not an acceptable response.)*

a. Subjects: State inclusion and exclusion criteria.

Preliminary Focus Group Participants (2 groups, each group n=10):

- Male or Female
- Self-identifies as being Hispanic or Latino
- 50 to 75 years of age
- Patients in the Lehigh Valley Health Network

Patient and Stakeholder Advisory Committee Members (n=12):

Patient Members, Inclusion Criteria:

- Male or Female
- Self-identifies as being Hispanic or Latino
- 50 to 75 years of age

Stakeholder Members, Inclusion Criteria:

- Male or Female
- Stakeholders in the Hispanic community or the Lehigh Valley Health Network

Study Subjects (n=400):

Inclusion Criteria

- Male or Female
- Self-identifies as being Hispanic or Latino
- 50 to 75 years of age
- Patients in the Lehigh Valley Health System

Exclusion Criteria

- Previous diagnosis of CRC
- Up to date with CRC screening guidelines.
- Family history of CRC diagnosed before the age of 60 years

Follow-up Focus Groups (2 groups, each group n=10):

- Previously enrolled study subjects

Evalutaion

- Interviews: ≤14 interviews of research team members and practice administration as related to intervention implementation

b. Procedures: Explain study procedures/methods.

Preliminary Focus Groups:

During the first six months of the proposed study, we will work with the Fox Chase Cancer Center Office of Health Communications & Health Disparities (OHCHD) to develop study materials and conduct two focus groups with Hispanic patients from LVHN primary care practices. The OHCHD has 30 years of experience communicating and disseminating current, evidence-based, culturally-appropriate cancer information. OHCHD staff members have expertise in health communications and cancer control, and bi-lingual, bi-cultural staff members have extensive experience in developing programs for racial and ethnic minorities and in conducting focus groups in Spanish.

In the study, the OHCHD will translate printed English language materials used in prior research into Spanish, and ensure that informational content and visual presentation is culturally-sensitive and is clear and literacy-appropriate. We will also translate the script that will be used in telephone navigation contacts. Study materials and methods will be reviewed in two new focus groups with Hispanic patients (n=10 in each group). The focus groups will be conducted in Spanish or English, as determined by attendees at the time of the group session. Focus groups will be audiorecorded so that the discussion can be captured and analyzed.

Patient and Stakeholder Advisory Committee Meetings:

We have established a patient and stakeholder advisory committee (PASAC) to guide study development, implementation, and evaluation. The PASAC, which is conceived of as an essential part of the research team, includes 5 patient stakeholders and 7 LVHN and community stakeholders. Acting as co-chairs of the committee, Brian Stello, MD (site Principal Investigator)

and a Hispanic primary care patient, will convene meetings three times a year. Minutes from each prior meeting will be reviewed at the beginning of each meeting, and the planned meeting will follow an agenda developed by the co-chairs. PASAC members will receive $50 for attendance at each meeting to defray costs associated with participation. Meetings will be conducted in both English and Spanish, as determined by the members, with assistance provided by bilingual facilitators from the Fox Chase Cancer Center OHCHD. PASAC meetings will be audiorecorded so that the discussion can be captured and analyzed.

At the initial meeting of the study period, members of the PASAC will be provided with a copy of the study protocol and documents that will be used for patient recruitment to the study and data collection. In addition, intervention materials and methods will be shared with participants. All participants will be encouraged to share their perceptions of the research proposal, their roles in the process, expectations, recommendations on methods for foster trust and open communication with other members of the research team. At subsequent PASAC meetings, project staff will present the PASAC with regular study progress reports. These meetings will focus on generating feedback from patients and stakeholders that can facilitate study culturally-sensitive, effective and efficient recruitment intervention implementation, and evaluation. These PASAC meetings will also be audiorecorded so that the discussion can be captured and analyzed.

During the study, the PASAC will work with other members of the research team to (1) plan study development and implementation; (2) review study implementation progress; (3) provide guidance on developments in the community and in the health system that could affect intervention implementation and/or dissemination, (4) review study progress reports, and (5) contribute to manuscript development and preparation.

In addition to PASAC meetings, in order to complete a RE-AIM analysis, PASAC members will be interviewed at the close of the study. The research team will develop an interview guide to assess organizational factors that influenced the screening process (i.e., participant recruitment, contact, appointment scheduling, test performance, and results reporting). The guide will be used by Drs. Myers and Sifri to conduct interviews to obtain insights into response to study interventions, factors that may influence the dissemination of research findings, and future intervention implementation and maintenance

Research Study Procedures

Participant Recruitment, Baseline Survey Administration, and Randomization. Initially, Hispanic patients who are 50 to 75 years of age, have not been diagnosed with CRC, and have not had a recent CRC screening test will be identified via LVHN electronic records. These individuals will be mailed a study invitation letter in English and Spanish. The letter will describe the proposed research and provide information about ways to opt out of or register to participate in the study (i.e., complete and return a study registration card in an addressed postage-paid return envelope, or call a toll-free telephone number.) The letter will also inform recipients that a research staff member will call non-respondents.

A trained bilingual research assistant will call patients within 15 days after the invitation letter mailing. The research assistant will conduct the call in the language preferred by the respondent. The research assistant will verify patient eligibility, describe the study, ascertain patient willingness to participate, obtain verbal consent, and administer a brief baseline survey to a total

of 400 participants. As part of the survey, the research assistant will describe SBT and colonoscopy screening, and will ascertain the participant's overall and test-specific screening decision stage. We will use this information to determine the participant's overall CRC screening decision stage and preferred CRC screening test. Data on sociodemographic background will also be collected. At the end of the baseline survey, the interviewer will ask participants to indicate a day(s) of the week and time(s) of the day when research staff can most conveniently speak to the participant by telephone. The interviewer will also ask for a telephone number and email address for use in making contact. Finally, the research assistant will inform the participants that they will receive CRC screening materials in the mail, will determine whether the participant wants to receive study materials in English or Spanish, and will mention that the research team may contact them by telephone to discuss screening and will contact them to complete two follow-up surveys. As shown in **Figure 1**, research staff will randomly assign all consented participants either to a SI Group or a DSNI Group. Random assignment will be stratified by participant primary care practice.

Figure 1. Study Design

Baseline Survey	Randomization	Intervention Delivery		Records Review (6,12 month)	6-Month Survey
Complete (N = 400)	Stratify random assignment by primary practice	Standard Intervention (SI) (n = 200)	Mailed contacts*	Complete (n = 190)	Complete (n = 160)
		Decision Support and Navigation Intervention (DSNI) (n = 200)	Mailed contacts, Support/Navigation contacts**	Complete (n = 190)	Complete (n =160)

* Mailed Contacts: Screening letter, informational booklet, colonoscopy instructions, SBT kit, and reminder letter.

**Mailed Contacts: Screening letter, informational booklet, colonoscopy instructions, SBT kit, and reminder letter; Support/Navigation contacts: navigator calls to provide decision counseling, develop screening plans, support plan implementation, and deliver screening plan and status reports.

Intervention Implementation. Following randomization, **SI Group** participants will be mailed a set of standard materials. The materials will include a letter from the participant's primary care practice encouraging selection and performance of either (1) colonoscopy screening, or (2) stool blood test (SBT). Accompanying the letter will be instructions for arranging a colonoscopy appointment and instructions for completing an enclosed immunochemical SBT kit. Print materials and contacts will be provided in the language the participant as preferred (English or Spanish) at the time of the baseline survey. At 45 days following random assignment, research staff will send participants a reminder letter from the participant's primary care provider that endorses and encourages screening. Study participants assigned to the **DSNI Group** will also be

mailed print materials, including a letter from the practice on CRC screening, an informational booklet, and instructions for arranging a colonoscopy appointment and instructions for completing an enclosed immunochemical SBT kit. Again, print materials will be provided in the language specified by the participant at baseline. Within 7 days after this mailing, DSNI Group participants will also receive a telephone call from a trained bilingual study navigator. In the call, the navigator initially will review the CRC screening materials and verify the participant's preferred CRC screening test. During this encounter, the navigator will also use an online Decision Counseling Program© (DCP) to identify barriers to and facilitators of preferred test performance, determine the likelihood of test performance, and develop a personal screening plan.

The online DCP includes a script that guides the navigator and participant through a structured telephone encounter with participants. Following the script, the navigator will elicit major factors that would influence the participant to or not to (pros and cons) screen, determine the level of importance the patient assigns to each factor (not important to overwhelmingly important), enter the reported factors and factor weights into the DCP, and compute a screening likelihood score (low to high). The navigator will then review the result with the patient, and will use a Motivational Interviewing approach to develop a plan to reinforce facilitators and overcome barriers to performing the individual's preferred test. For participants who prefer colonoscopy screening, the navigator will be authorized to obtain appropriate referral approvals, and will help to schedule a colonoscopy appointment at the time of the navigation call. For those who prefer SBT screening, the navigator will explain steps for performing the test, and offer to be available to answer questions that arise about SBT completion. For colonoscopy and SBT screening, the navigator will follow up with the participant to address emergent questions or concerns.

The navigator will enter a description of each participant's screening plan into the DCP, will print out a 1-page summary of the decision counseling session and screening plan, and will send to a copy this form to the participant. Importantly, primary care practices included in this study share an electronic medical record that includes a "progress note" feature, to which the navigator will have access. The navigator will use this feature to enter the participant's CRC screening plan directly into the electronic medical record, along with information on scheduled appointments and test performance. When the plan is entered, it will be routed to both the patient's primary physician and the practice office manager to authorize any necessary insurance referral(s), and send the referral(s) directly to the navigator and participant. The navigator will contact the office manager to verify provider receipt of the screening plan and obtain any needed referrals. At 45 days after random assignment, research staff will send participants a reminder that includes a provider endorsement and encouragement of screening. Note: the grant will cover the cost of the mailed SBT kit and, LVHN will help participants with limited or no insurance coverage by providing colonoscopy and follow-up, including treatment, at little or no cost via Medical Assistance applications and an established Charity Care program.

At 6 months after randomization, the navigator will use the same progress note feature in Centricity to provide the provider and office manager of the participant's primary care practice a participant CRC screening status report. This report will be based on screening data obtained by project staff from the 6-month survey and medical records review described below. The report will indicate whether the participant adhered to screening, and if the participant is in need of diagnostic follow-up for an abnormal SBT result. For those participants who are nonadherent to

CRC screening, the report will advise providers and the office manager to contact the participant and encourage screening. For those screenees who require follow-up of an abnormal SBT result, the report will also encourage providers to arrange a diagnostic colonoscopy. For patients who had a normal SBT result, the report will encourage providers to contact patients in a year to offer screening. Finally, 30 days after the screening status report is mailed, the navigator will contact the office manager to verify provider receipt of the screening status report and to record follow-up action(s) taken.

Six-Month Survey and Medical Records Review. Six months after randomization, a survey interviewer from Survey Technology and Research (STR), a professional survey company, will contact each participant by telephone and administer a 6-month Survey. The survey will include items that assess participant sociodemographic characteristics. In addition, items will be included on the survey to assess CRC screening decision stage and screening test preference. In terms of actual screening adherence, survey respondents will also be asked to report any CRC screening tests performed during the 6 months. For all reported tests, participants will be asked to provide a date of testing. Following prior studies, we will allow for 20% missing survey data.

A 6-month medical records review for DSNI Group participants will be completed by a study research assistant. Screening adherence data collected on the 6-month survey and 6-month medical records review will be used to prepare the DSNI Group screening status report described earlier, and to assess the CRC screening outcome. Participant insurance status will also be ascertained on medical records review. CRC screening adherence will reflect performance of any ACS or USPSTF guidelines-recommended CRC screening test recorded in the chart or self-reported on the survey, if the survey report is accompanied by a procedure date that falls within the 6-month study period following randomization.

Twelve-Month Medical Records Review. At 12 months after randomization, an endpoint medical records review will be performed on all study participants to assess CRC screening adherence. The medical records review will be conducted by a study research assistant who will be blinded to each participant's study group assignment. Any ACS or USPSTF guidelines-recommended CRC screening test will be accepted. Following prior studies, we will allow for 5% missing endpoint medical records data. As part of the records review, we will review electronic medical records for all participants in the last year of the study to characterize patterns of screening use among participants after the study observation period. This information will be combined with self-reported CRC screening from the 6-month survey and 6-month medical records review to determine the main study outcome in the analyses.

<u>Follow-up Focus Groups:</u>

In the last year of the study, the research team will also work with the OHCHD to conduct two focus groups with DSNI Group participants. The two focus groups will include screenees (n=10) and nonscreeners (n=10). We will develop discussion guides for use in eliciting participant perceptions about intervention contacts, and barriers to and facilitators of screening. Focus groups will be conducted in Spanish or English, as needed, and will be audio recorded.

<u>Evaluation:</u>

The research team will apply the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework. We will complete an assessment of RE-AIM dimensions at different levels of the LVHN for the interim and final reports to the sponsor.

c. Data analysis: *Provide the methods by which the study objectives/aims will be assessed or measured, i.e., statistical analysis plan, qualitative research methods such as procedures for conducting theme analysis and enhancing validity, program evaluation methods and analysis plan, or mixed methods analysis plan. For a quantitative study include what statistical tools will be applied and how the study is powered, if appropriate. Pilot studies do not require a statistical plan.*

Preliminary Focus Groups

Both focus groups will be audio recorded and will be transcribed prior to initiating the coding process. Fox Chase Cancer Center OHCHD staff will develop a coding scheme using MaxQDA professional text analysis and content analysis software; and will review data output to identify the most common themes and responses voiced by participants. Basic descriptive statistics (frequencies) will reveal key themes, which will be presented in a formal report.

Patient and Stakeholder Advisory Committee Meetings

The initial meeting and all subsequent meetings of the PASAC will be audio recorded. OHCHD staff will transcribe and analyze the audio recordings to create an objective record of PASAC meeting discussions, recommendations made by participants, and research team responses to those recommendations. This level of reporting is likely to improve balanced participation, ensure that the patient voice is represented in study operations, and contribute to the patient-centeredness of the study.

Research Study Procedures

The study will rely on a randomized design to assess the two interventions. Because of this design, we expect the two intervention groups to be comparable with respect to all participant and practice characteristics. However, if there is substantial imbalance in any of the baseline variables, the analyses will control for them. Some of the planned analyses will rely solely on endpoint survey data (Aims 2 and 4) and survey non-response might negatively impact study group comparability. In our prior research, we have found that overall non-response rates and the characteristics of non-respondents (i.e., non-response patterns) do not differ substantially across different types of CRC screening interventions, suggesting little missing data bias. Nevertheless, we plan to control for all baseline characteristics to account for any differential missing data patterns. In addition, we will also explore multiple imputation analyses, particularly if the endpoint survey non-response is higher than expected. Research data will be described for each study group using both graphical methods (boxplots for continuous variables, and bar graphs for categorical variables) and summary statistics (mean and standard deviation for continuous variables, frequency counts and percentages for categorical variables). Main analyses will follow the intent-to-treat principle and will control for practice (stratification variable at randomization).

Aim 1 (DSNI versus SI on overall CRC screening adherence). The two study groups will be compared in terms of the fraction of participants who undergo CRC screening (through SBT, colonoscopy, flexible sigmoidoscopy, etc.) within 12 months of the randomization date. Screening status will be determined using both the 6-month survey and 12-month medical records review data. We hypothesize that DSNI Group participants will have higher overall screening than SI Group participants. We will analyze screening (yes vs. no) via logistic regression, using study group (DSNI versus SI) as the main predictor. As mentioned above, we expect the two study groups to be comparable at baseline due to randomization. So, the model will control only for practice and participant gender and age (the latter two variables will be included to allow addition of interaction between study group and gender or age in secondary analyses). If, however, substantial baseline imbalances occur, the model will include for those additional variables.

Aim 2 (DSNI versus SI on change in CRC screening decision stage). CRC screening decision stage will be assessed in both the baseline and 6-month surveys. Forward change (between baseline and endpoint) will encompass any movement from a lower to a higher decision stage. We hypothesize that DSNI Group participants will have greater forward movement in screening decision stage than SI Group participants. We will analyze forward change in screening decision stage (yes vs. no) via logistic regression. These analyses will be based on 6-month survey data. Prior research suggests that survey response will be comparable in both study groups. The model will include practice and participant baseline characteristics.

Aim 3 (DSNI versus SI on test-specific CRC screening adherence). The two study groups will be compared in terms of the fraction of participants who undergo a SBT or a colonoscopy within 12 months. Due to current screening practices in primary care, we expect very few, if any, instances of screening via other modalities. We hypothesize that DSNI Group participants will have higher SBT and colonoscopy screening than SI Group participants. The main analysis of test-specific screening (no screening, SBT screening, colonoscopy screening) will be based on polytomous (multinomial) logistic regression. The analysis strategy will be similar to that for Aim 1 (i.e., control for practice, as well as participant gender and age).

Aim 4 (DSNI versus SI on CRC and screening knowledge and perceptions). Knowledge and perceptions (PHM scales) about CRC and screening will be assessed at the 6-month survey. We hypothesize that DSNI Group participants will have higher knowledge and more favorable perceptions than SI Group participants. The analyses of knowledge and perception scales will be based on linear regression. However, if some of the scales are skewed, some transformation will be needed prior to the analyses (e.g., log). Alternatively, some of the outcomes might be used as dichotomous or categorical, in which case the analyses will rely on logistic regression. The analysis strategy will be similar to that for Aim 2 (i.e., control for practice, as well as all participant baseline characteristics).

Additional Analyses. Data on tailored navigation and support delivery (e.g., number and timing of navigator call attempts, time from randomization to initiation and completion of contact, validation of test preference, assessment of screening likelihood, reasons for incomplete delivery of the navigation call, and mailing of the screening plan and screening status report) will also be collected and summarized. We will also assess the potential interaction between study group and sex and age, by the addition of corresponding interaction terms to the main logistic regression

model of Aim 1. Using electronic medical records data for SBT screenees, we will also describe patterns of screening beyond the initial 12-month observation period for SBT-negative patients and patterns of diagnostic follow-up for SBT-positive patients.

Sample Size and Power. As shown in Figure 1 above, we will randomize 400 LVHN Hispanic patients (200 per study group). We expect to have CRC screening data for at least 95% of the participants, given access to patient electronic medical records, and direct reports from a centralized SBT laboratory (N~380). Given our prior experience in similar research studies, we also expect an 80% completion rate for the endpoint survey (N~320).

> **Power for Aim 1**. Based on our previous research and given the planned enhancements in the decision support and navigation intervention, we expect overall CRC screening rates to be about 30% in the SI Group and at least 45% in the DSNI Group (odds ratio, OR = 1.9). Given a projected total sample size of 380 and a two-sided alpha of 0.05. the study has 85% power for Aim 1.
>
> **Power for Aim 2**. We expect a similar magnitude of difference between the two study groups on forward change in CRC decision stage (e.g., 35% in SI vs. 51% in DSNI, OR = 1.9). Thus, the study has 82% power (projected N~320, two-sided alpha = 0.05).
>
> **Power for Aim 3.** Finally, with respect to test-specific CRC screening, we expect SBT screening rates to be 20% in the SI Group versus 30% in the DSNI Group, and colonoscopy rates to be 10% versus 15% for the two groups, respectively. Thus, the study has 78% power (projected N~380, two-sided alpha = 0.05).
>
> As described in Section 3.3.2., we will also monitor the intervention fidelity. Given our prior research, we expect more than 95% of the mailed materials to be received by study participants. Furthermore, we expect that navigation will be actually delivered to about 85% of the DSNI Group participants. However, if the intervention completion rate turns out to be lower, we will carry out additional analyses to explore the differences between DSNI Group participants who received versus those who did not receive navigation

Follow-up Focus Groups

As in Year 1, the focus group audio recordings will be transcribed and prior to initiating the coding process, a coding scheme will be developed using MaxQDA professional text analysis and content analysis software. Output will be reviewed to identify the most common themes and responses. Basic descriptive statistics (frequencies) will be used to identify key themes, which will be presented in a final report. The PASAC and the rest of the research team will review focus group results, and will make recommendations to advance intervention implementation and dissemination in LVHN and other health care systems.

Evaluation

Specifically, we will assess intervention **reach** at the patient level in terms of the number/percentage of study participants who receive planned intervention contacts as compared to those who are eligible to receive such contacts. We will also determine the number/percentage of providers who receive participant screening plans and reports. In addition, navigators will be asked about their experiences in delivering intervention contacts to participants and providers. Mail and telephone records, along with navigator logs, will be used

to obtain data to measure this dimension. We will measure intervention **efficacy/effectiveness** at the patient level in terms of impact on defined primary outcomes (i.e., screening adherence, screening decision stage, and test-specific adherence). Here, we will use data from the 6-month survey, 6-month medical records review, and 12-month medical records review to evaluate this dimension. In terms of intervention **adoption,** we will determine the number and percentage of providers and office managers who acknowledge receipt of screening plans and reports by study navigators and provide feedback on provider review of this documentation. We will assess intervention **implementation** by determining the number and timing of attempted and completed navigator calls, time from call initiation to call completion, length of calls, and reasons for incomplete calls. We will also track navigator contacts with provider practices in a similar manner. In addition, qualitative data will be collected from the navigators about their experience implementing the intervention: what worked well and what didn't, whether patients utilized their assistance, and what were the key services that they offered that they believe contributed to completion of screening. We will also interview selected lead physicians and office managers from participating practices in order to obtain information on their experience receiving and acting on intervention-related contacts, including feedback from patients, study navigator contacts, and their receipt of participant screening plans and reports.

5. Delineate procedures that are standard of care from those that are being performed specifically for the research.

There are national guidelines for CRC screening, but how they are implemented in specific practices with specific patients varies widely. At this time, in most primary care practices, systematic approaches to screening recommendations and follow-up are not being implemented. Throughout the course of this study participants may receive mailed educational materials, an SBT kit and a call from a trained patient navigator in order to encourage screening.

6. How will accuracy of data be assessed?

The PASAC committee will review surveys so that the questions are relevant to patients. In addition, data will be double-entered and verified in the database in order to assure accuracy. Finally, all analyses will be done by or with the assistance of biostatisticians so that results and conclusions are accurate.

7. Identify the sources of data obtained about human subjects in the form of specimens, records, survey instruments, interviews, focus groups, observation, or other sources.

Data Type	Data Elements	Data Source
Demographic data	Name, telephone number(s), mailing address, insurance status	LVHN IDX administrative database
Demographic data	Age, ethnicity, race, education, income and marital status. E-mail address and cell telephone number. Language preference.	Baseline survey
Medical Records data	Colorectal cancer related screening and diagnostic history	LVHN IDX administrative database
Data collected for the study	Decision stage related to screening SBT and colonoscopy	Baseline & 6-month survey
	Decision factors, factor weights, screening likelihood score	Decision counseling session (DSNI Group only)
	Factors that influence screening, barriers to screen and steps in the screening plan.	Navigation log
	SBT (FIT or some other SBT) and colonoscopy screening use. Flexible sigmoidoscopy and barium enema x-ray use. Test-specific decision stage, acculturation, fatalism, and perceptions regarding CRC screening and CRC screening knowledge	6-month survey
	SBT(FIT or some other SBT) and colonoscopy Screening use. Flexible sigmoidoscopy and barium enema x-ray use.	6- and 12-month medical records review/EMR

8. Please check off those steps noted below that you intend to implement to ensure confidentiality of Subject data and to protect the identifiers or codes that can be linked to identifiers from improper use or disclosure. (Note: Non-Jefferson sanctioned "covered devices" may **not** be used for the storage of identifiable Subject data. See **Jefferson Policy #122.35, "Wireless and Portable Device Security Policy."**)

_____ List of identifiers will be kept in a separate location from the coded Subject data that can be linked to identifiers.
_X_ Subject data will be kept in a locked filing cabinet or desk and in a locked office.
_____ Subject data will be kept on a password-protected, encrypted on-site computer.
_X_ Subject data will be kept on a Jefferson server. Provide specific physical and/or electronic location:
_____ Subject data will be kept on a Jefferson-issued or –approved "covered device" as per Jefferson Policy #122.35. Specify type of "covered device" to be used:
_____ Other (please describe):
_____ Not Applicable – No PHI being collected.

PART B- SUBJECTS AND FACILITIES

1. What is the expected number of subjects to be enrolled?

No. subjects per year at TJU	Total No. subjects at TJU	No. Subjects Nationally or Internationally (if applicable)	No. subjects at collaborating Institutions (if applicable)
Up to: 0	Up to: 0		400 (recruited at LVHN)

2. Are sufficient numbers of potential subjects available in the PI's practice (or group practice) or through community study partners to meet recruitment goals for this study?
_X_ YES ____NO

a). If NO, identify other sources of potential subjects.

3. Identify where the research will be conducted and describe the adequacy of facilities.

TJU/KCC Department of Medical Oncology, Division of Population Science, Center for Health Decisions. The Department consists of 41 university salaried faculty members. At the present time, the university faculty members are organized into three clinical divisions based on predominant disease interests and sites of practice as well as a Population Science Division. Jefferson's Medical Oncology cancer care happens throughout the City of Philadelphia. In center city we are located within the Jefferson campus, in South Philadelphia at both Methodist Hospital and The Navy Yard, and in the Northeast at Nazareth Hospital. The department evaluates over 2,000 newly-diagnosed cancer patients each year. Our experts have helped prepare roadmaps for care incorporating both novel, leading-edge treatments as well as tried and true therapies as appropriate for the particular clinical circumstances. These roadmaps help to ensure that every patient receives the same high level of care throughout our department. At any given time, there are more than 120 clinical trials for promising new cancer treatments and diagnostic methods being conducted at Jefferson. Innovative therapies are being evaluated through collaboration with the National Cancer Institute, various pharmaceutical companies and programs developed at the Kimmel Cancer Center at Jefferson. Vaccine development and other forms of immunotherapy are also under active investigation.

4. Please identify any facilities to be used for research other than those assigned to Department or division.

Lehigh Valley Health Network (LVHN) is a private, non-profit healthcare organization located in the Lehigh Valley of Eastern Pennsylvania. The Lehigh Valley is the third most populous and the fastest growing region in the state of Pennsylvania with a population of

821,623 residents as of the 2010 U.S. Census. It is eclipsed in total population only by the metropolitan areas of Philadelphia and Pittsburgh in Pennsylvania. Founded as the Allentown Hospital in 1899LVHN is a multi-facility, multi-organizational, non-profit healthcare delivery system and a National Community Cancer Center Program site. The Lehigh Valley Health Network (LVHN) is a multi-center, non-profit healthcare delivery system in Lehigh Valley of Eastern Pennsylvania, and an academic affiliate of the University of South Florida (USF). The Lehigh Valley is the third most populous and the fastest growing region in the state of Pennsylvania with a population of 821,623 residents as of the 2010 U.S. Census. The primary service area of LVHN is the greater Lehigh Valley of Eastern Pennsylvania, which includes Lehigh, Northampton, and surrounding counties. Lehigh and Northampton counties include over 645,000 residents, of whom 96,967 are Hispanic (population statistics U.S. Census 2010). LVHN is the home of the regions only NCI-selected Community Cancer Center, the John & Dorothy Morgan Cancer Center, an affiliate of USF's Moffit Cancer Center and Research Institute in Tampa, FL. The largest academic community hospital in PA, LVHN has 9,656 employees, a 1,100+ member medical staff including more than 800 board-certified providers in 95 specialties and 2,334 nurses. LVHN is the largest Level 1 Trauma Center in PA, a certified stroke center and a Nursing Magnet Hospital. In 2010, Lehigh Valley Health Network recorded 154,792 ED visits. A teaching affiliate of the University of South Florida, LVHN provides education and clinical training for 227 residents and fellows in 20 programs. A new program in medical education has been jointly created by the University of South Florida (USF) College of Medicine and LVHN. This program is called SELECT, The Scholarly Excellence, Leadership Experiences, Collaborative Training program. Students admitted to SELECT will spend their first two years taking classes at the USF College of Medicine, and then go to Lehigh Valley Health Network for two years to focus on clinical education.

Fox Chase Cancer Center, The Office of Health Communications and Health Disparities (OHCHD), where the subcontract would be housed, is the community outreach arm of Fox Chase. The Office includes three key programs: community outreach and education; community screening; and cancer education for patients and their families. These programs help people better understand cancer risks, diagnoses, treatment options and prevention; provide opportunities to obtain screening; and help patients and families find supportive resources. OHCHD also undertakes research related to decreasing the impact of cancer on minority and ethnic communities. For example, currently we are educating minority and ethnic populations about the importance and benefits of participating in cancer research while trying to better understand barriers and facilitators, with the ultimate goal being the inclusion of more minority members in research trials. The multidisciplinary OHCHD staff is skilled in such areas as program development and management, training, interviewing, data analysis and evaluation skills as they relate to cancer control and prevention activities. They also conduct research into diverse health communications and health disparities topics, including patient navigation and health literacy. Community Based Participatory Research is a key part of the OHCHD vision. The OHCHD reports to Fox Chase's Office of Academic Affairs, which provides additional scientific oversight through senior scientific leadership. The OHCHD office consists of 5,500 square feet in an off-site building directly across the street from the main campus. The space includes 22 offices for

professional staff, support staff workstations, publication storage and conference rooms. All FCCC computers are integrated within a LAN system that provides access to needed data management/analysis and word-processing software as well as to graphics programs, email and the Internet. OHCHD has 22 computers and three printers.

Survey Techonolgy and Research Center (STR). STR is located in Allentown, PA. The STR mission is to develop and implement state of the art data collection technologies and study designs to promote research. Facilities and resources available to the proposed project include:

* Physical Call Center – 60 Seat Site In Allentown, Pennsylvania
* CATI – Multiple CATI System Support
* Remote Interviewing Support / At-Home Staff Network
* PRO-T-S Predictive Dialing Equipment From Marketing Systems Group
* Digital Sound Management / Full Interview Recording
* Automation of Interviewer Productivity and Quality Control Metrics
* Inbound/Outbound Call Support
* IVR Call Transfer and Web Hosting
* DSF / Address Based Sampling
* Seamless Multi-Mode Project Execution

5. Describe provisions to protect the privacy of subjects during the course of the study. (Privacy can be defined as the subject's desire to control the ways in which s/he is approached and/or the ways in which his/her private information is shared with others.)

Data management. Identification numbers are assigned to patients from draws from the IDX systems of the participating practices. This identification number links data in the operational and study databases. This number is also used to track and exclude patients from future samples who opt out, refuse when contacted, or withdraw from the study.

Study data. Survey data is entered, verified, and stored electronically with only numeric identifiers attached to the records. A research assistant completes the endpoint chart audits, using chart audit forms developed specifically for the study. Information from completed chart audit forms will be entered, verified, and checked for consistency by the research assistant. The printed copies of completed data collection instruments will be kept in locked cabinets in the office suite of the principal investigator at LVHN.

Operations data (e.g., patient names and contact information, assignment of participants to study groups, delivery of intervention components, etc.). The project managers at both sites will maintain an operational data and EMR data in a central secure database with specific safeguards to ensure that only authorized study personnel have access to the information. Periodic updates regarding accrual and key information regarding intervention delivery

6. How has the research staff been trained regarding study procedures/methods and their duties (in-service, investigator meeting, etc.)?

Staff	Training/ experience
Project manager	Had similar responsibilities in previous related research. Participates in regular study operations meetings. Prepares study specific procedures that are reviewed by investigators.
Programmer/ analyst	Had similar responsibilities in previous related research. Participates in regular study operations meetings. Prepares study specific procedures that are reviewed by investigators.
TJU Research Assistant	Had similar responsibilities in previous related research. Participates in regular study operations meetings.
LVHN Research Assistant	Has previous experience with the LVHN cancer center and colorectal clinic, coordinating services on behalf of patients, working with registries. In addition, will be provided a self-study manual re: CRC, CRC screening, and study protocol and operations. Practice calls to potential participants using surrogate patients and various scenarios have been completed. Project manager or investigator will observe sample of 10 contact calls per year
LVHN Patient navigator	Has previous experience with the LVHN cancer center and colorectal clinic, coordinating services on behalf of patients, working with registries. In addition, Will be provided a self-study manual re: CRC, CRC screening, and study protocol and operations. Practice navigation calls with surrogate patients using various scenarios have been completed. Project manager and navigation consultant will observe sample of 10 navigation calls per year.

7. Which of the following groups are eligible to be subjects?

Decisionally-impaired (*include only if research targets this population or if there is potential benefit to individual or decisionally-impaired in general*)		Yes		No X
Women of reproductive potential		Yes X		No
Pregnant women/fetuses./neonates (*if yes, include OHR-27 as an addendum to the OHR-2*)		Yes X		No
Men of reproductive potential		Yes X		No
Minorities		Yes X		No
Prisoners (*if yes, notify the IRB in advance of the meeting*)		Yes		No X
Vulnerable populations (*trauma victims, students, aged infirm, substance abusers, impoverished, terminally ill, etc.*)		Yes X		No

8. If applicable, what additional protective mechanisms are in place to protect the rights and welfare of vulnerable populations?

It is possible and likely that persons who are members of vulnerable populations may be approached for enrollment in this study, focus groups or to be a member of the PASAC. The research team is sensitive to the possible reluctance of some people to participate in a publically-funded study. In describing the study to prospective participants, we will explain that information related to their participation will be known only by members of the research team, and information related to screening will be shared only by with their health care provider

9. Explanation of Exclusion. (If groups of subjects are excluded, explain why)

NA

NIH policy requires that minorities and women be adequately represented as research subjects. If this is an NIH-funded study and you checked "no" to either of these categories in the above table, you must provide a scientific reason for such exclusion.

PART C - RISKS, BENEFITS, AND ALTERNATIVES

1. What are the risks of the research? Address this at the individual and/or community level as appropriate.

Risks to participants from identification, recruitment and consent, randomization and exposure to the study interventions include anxiety and loss of confidentiality.

2. Discuss measures taken to minimize risks and maximize benefits associated with this research.

In terms of confidentiality, a file linking participant names to numeric identifiers will be kept in a secure data file in the principal investigator's office. When survey data are obtained from the study participants, only numeric identifiers will be attached to the records. Names and telephone numbers of consented participants will be shared with the professional survey company (STR) for administration of the baseline survey. All research staff with access to study data will be certified by the TJU Office of Human Research/ Division of Human Subjects Protection.

3. What are the potential benefits of participation?

Potential benefits that might result from participation by age-eligible patients include increased knowledge about CRC screening and early diagnosis of CRC or adenomatous polyps. The potential benefits for the age-eligible population in general include the development of more effective methods for delivering information about CRC screening and promoting the completion of SBT and screening colonoscopy examination. The potential benefits to individual participants and for the target population in general are significantly greater than the possible minimal risks.

4. Explain how the risks of the research are justified by potential benefit to the subject or society.

Results from the study will not only be implemented by the LVHN, but also will be disseminated for use by other healthcare delivery systems. Colorectal cancer screening programs in various populations have demonstrated a positive impact on colon cancer morbidity and mortality. Widespread implementation of effective screening programs has a great potential benefit to individual patients as well as the medical care system.

PART D - CHILDREN

1. Will this study involve children (age 17 or under)?

___ **YES - Submit form OHR-26, "Research Involving Children."**
_X_ **NO - Delete questions 2-8, address question 9 below and then go to next Part.**

9. If this proposal is a Type I NIH application/proposal, you must include children, defined as individuals under the age of 21, as subjects unless there are scientific or ethical reasons for excluding them. If excluding children, please justify your exclusion by choosing one or more of the following exclusionary circumstances, as per NIH policy:

- ☒ Not a Type 1 NIH study
- ☒ The research topic is irrelevant for children
- ☐ Children are barred by law from participation because of the risk
- ☐ Study is redundant; knowledge is being obtained in another study or is already available
- ☐ Separate age-specific children study is preferable
- ☐ Rarity of disorder makes inclusion of children extremely difficult
- ☐ The limited number of available children are already enrolled in a nation-wide pediatric disease network
- ☐ Study design precludes direct applicability to children
- ☐ Insufficient adult data to judge potential risk for children
- ☐ Study design is a follow-up of an adult study

PART E – RECRUITMENT, EQUITABLE SELECTION, AND CONSENT PROCESS

1. Discuss the recruitment plan and describe recruitment methods and materials (e.g., physician referral, newspaper ad, radio, TV spot, e-mail, membership lists, flyers, social networks, etc.) *Pleasse attach all relevant materials for IRB review and approval.*

Hispanic patients who are 50 to 75 years of age, have not been diagnosed with CRC, and have not had a recent CRC screening test will be identified via LVHN electronic records. These individuals will be mailed a study invitation letter in English and Spanish. The letter will describe the proposed research and provide information about ways to opt out of or register to participate in the study (i.e., complete and return a study registration card in an addressed

postage-paid return envelope, or call a toll-free telephone number.) The letter will also inform recipients that a research staff member will call non-respondents.

Advertising and recruitment materials using the TJU or TJUH logo must be submitted to the Trademark Committee for approval. Call the Office of University Counsel at 955-8585 for information.

2. Will all qualified potential subjects populations have adequate access to recruitment materials? Please explain.

Preliminary Focus Groups

Qualified potential subjects will receive recruitment materials directly, these materials will also include a toll free number for additional information.

Patient and Stakeholder Advisory Committee

Patients and stakeholders have been approached based on involvement in the community and willingness to participate in three meetings per year.

Research Study

Qualified potential subjects will receive recruitment materials directly, these materials will also include a toll free number for additional information.

Follow-up Focus Groups

Qualified potential subjects will receive recruitment materials directly, these materials will also include a toll free number for additional information.

3. Is the location and cultural setting of the research equally accessible to all qualified potential subject populations? If not, what can be done to make the location and setting more accessible?

Yes**.** The LVHN has been selected because they include a high proportion of age-eligible Hispanic patients.

4. If you are requesting a waiver of written consent, describe the information that will be provided to subjects.

Waiver of a written consent is being requested for the research study portion of this protocol. Written consent will be obtained for the Preliminary Focus Group, PASAC, and Follow-up Focus Groups.

A request for consent to be obtained orally is being made as all study contacts occur through the mail and over the telephone. After patients are consented, a form including the patient's contact information and instructions withdrawing from the study as well as the signature of the LVHN PI and the research assistant who obtained the oral consent will be sent the to study participant.

5. Who will conduct the consent interview?

LVHN Research Assistant

6. Who will provide consent or permission (e.g., subject, legally authorized representative, parent, caregiver, etc.)?

Subject.

7. Where will the consent interview take place?

Preliminary Focus Groups

In-person, prior to the focus group.

Patient and Stakeholder Advisory Committee

In-person, prior to the initial PASAC meeting.

Research Study

Oral consent will be obtained over the telephone, prior to the completion of the baseline survey.

Follow-up Focus Groups

In-person, prior to the focus group.

8. Provide a step-by-step description of the consent process.

Preliminary Focus Groups and Follow-up Focus Groups

Potential participants will be mailed a focus group invitation letter signed by the lead physician in their primary care practice. The will describe the proposed focus group and invite participation. The letter will also states that patients who do not want to participate can stop all further contacts related to the study by calling a toll free number.

At 10 days after the initial mailing, the research assistant will call individuals who have not opted out. During these telephone contacts, the research assistant will verify eligibility for the focus group and schedule the potential participant a focus group. The research assistant will inform the potential participant that an informed consent document will be reviewed and will require signature prior to their participation.

On the day of the focus group, potential participants will be asked to arrive 30 minutes prior to the start of the group. The research staff will review consent forms with each potential participant individually. Signed consents will be signed by the Principle Investigator, copies will be provided back to the participant for their records.

Patient and Stakeholder Advisory Committee

Potential PASAC members will receive a telephone call from the LVHN Project Manager. During this call, the LVHN Project Manager will review the requirements of participating in the PASAC and inform the potential participant that an informed consent document will be reviewed and will require signature prior to their participation.

On the day of the first PASAC meeting, members will be asked to arrive 30 minutes prior to the start of the meeting. The research staff will review consent forms with each

potential participant individually. Signed consents will be signed by the Principle Investigator, copies will be provided back to the participants for their records.

Research Study

The Research Assistant obtains verbal consent from potential participants at the time of initial telephone call, prior to completion of the baseline survey. NOTE: Included with this submission is a waiver of written consent and an **OHR-8H** for the verbal consent interview.

Potential participants have will receive a study invitation letter signed by the lead physician in their primary care practice. The letter describes the proposed research, invites study participation, and states that patients who do not want to participate can stop all further contacts related to the study. Recipients will be able to stop further contacts by returning the card by mail in an enclosed envelope, calling a toll-free study number, or visiting the study website.

At 21 days after the initial mailing, the research assistant will call individuals who have not opted out. During these telephone contacts, the research assistant will verify eligibility for the study, obtain consent for study participation, and update contact information. The interviewer then administers the baseline survey. After participants are verbally consented, they are mailed the first page of the OHR-8H (that is, the verbal consent interviewer script). On this page are the signatures of the research assistant who conducted the consent process and the principal investigator of the subcontract (or a co-investigator). The page also includes names, titles, departments, and telephone numbers of the principal investigator and contact persons involved in the study

9. Describe your plan to assess a person's capacity to consent.

The research assistant is trained to be alert if the responses of potential participants suggest that they do **not** understand that they are being asked to participate in a research study and that participation is voluntary, The interviewer will (1) terminate the call; (2) record the responses and/or behavior suggesting that the patient did not understand key aspects of consent; and (3) notify the project manager and the principal investigator within five (5) business days about the details of the call

10. Will you seek assent from decisionally-impaired individuals? If so, describe your plan for obtaining assent.

    No.

11. Will the potential subject be informed of the research or be provided a copy of the consent to review prior to the actual time of consent? If so, how much time in advance? How much time will be available for the consent process?

Preliminary Focus Groups and Follow-up Focus Groups

No copy of the consent will be sent prior to the consent interview. Potential participants will be asked to arrive 30 minutes prior to the group to ensure enough time for consent review.

Patient and Stakeholder Advisory Committee

No copy of the consent will be sent prior to the consent interview. Potential participants will be asked to arrive 30 minutes prior to the meeting to ensure enough time for consent review.

Research Study

No copy of the consent is sent prior to the verbal consent interview. A study invitation letter will be sent with a brief (one-paragraph) description of the study before contacting the potential participant for verbal consent interview. Research Assistants do not impose a time limit on the consent process. Research Assistants are trained to reread sections of the script, if necessary; to pause periodically and ask patients if they have questions about the preceding information; and to answer questions, as needed. If they cannot answer potential participants' questions, either the interviewers encourage potential participants to call an investigator with their question, or the interviewers find out the requested information and call back potential participants with their answer.

12. What provisions will be made if the potential subject does not wish to proceed with the consent interview?

If potential participants indicate either at the beginning of the interview or at any time during the interview that they do not wish to participate in the study (a clear refusal), the Research Assistants will accept their refusal and closes the interview.

If potential participants do not clearly refuse but wish to end a telephone call for other reasons, the Research Assistants will offer to call back at a time that is convenient for the potential participant. The names and birthdates of refusers are noted in the operational database so that they can be excluded from future lists drawn of potential participants

13. If the potential subject does not understand spoken English, will an interpreter be present?
YES _X__NO _____

This study will include both English and Spanish speaking participants. All Research Assistants and Patient Navigators will be bilingual in order to handle each situation.

14. Is surrogate consent involved? YES _____ NO __X__

15. Will subjects be paid or receive any other inducements for participating? If yes, please explain. *Please note that payment of subjects must be on a pro-rated basis unless there are compelling reasons not to prorate. There cannot be a requirement to finish all study components in order for subjects to be paid, as this is considered coercive.*

Preliminary Focus Groups and Follow-up Focus Groups

Focus group participants will receive $50 at the completion of the Focus Group in order to defray the cost of their time spent during the group and travel.

Patient and Stakeholder Advisory Committee

PASAC members will receive $50 at the completion of each committee meeting order to defray the cost of their time spent during the meeting and travel.

Research Study

Study subjects will receive a gift card a $25 gift card the completion of both the Baseline and Endpoint Surveys in order to compensate them for their time spent completing surveys related to their CRC screening preference.

16. Describe any steps taken to minimize the possibility of coercion or undue influence.

Participants will not be paid too much money such that they would participate only for the compensation. In addition, participants can and will be informed that they can drop out at any time without repercussions from the study team or their physicians at LVHN. Participants will also be informed that not participating will not change the type or quality of care they receive at LVHN.

PART F - LOCATION/COLLABORATION

1. This study involves research to be performed at/in/with *(check appropriate entries)*:
   - ☐ TJU only
   - ☐ TJU as part of a multi-center, commercially sponsored study
   - ☐ TJU and JKCCN Network sites
   - ☐ Rothman Institute Center City
   - ☐ Rothman Institute Center City and other Rothman Sites
   - ☐ TJU and Methodist
   - ☐ Methodist only
   - ☒ TJU and Other Institution(s): Lehigh Valley Health Network and Fox Chase Cancer Center, TJU will act as the IRB of record.

     Please name institutions only for investigator-initiated and federally funded studies where data will be shared between institutions. Please provide copy of collaborating institution IRB approval letter if applicable. The DHSP will effect IRB Authorization Agreements with collaborating institutions as required.
   - ☐ Collaboration with City Services *(City of Philadelphia IRB must approve study. For more information, go to http://www.phila.gov/health/irb/.) Please list collaborating city services.*
   - ☐ Unaffiliated investigators. *Please specify by name and role in study.*

2. This question is not applicable if research is a commercially sponsored multi-center trial.

   Will research be conducted in states other than Pennsylvania? ☐ YES ☒ NO

   If YES, does research involve subjects age 17 or younger? ☐ YES ☒ NO

   If YES to either or both, in what state(s) will research be conducted? _____

   Below please (a) verify the age at which subjects in such state(s) have the ability to consent to participation in research, including any medical treatments or procedures, if applicable and/or (b) verify the requirements for determining who may serve as a Legally Authorized Representative, including a guardian for a child to participate in research. You must also provide information on any state specific regulations on privacy requirements and genetic research if applicable. Please contact the Office of University Counsel for information, as needed.

   Age at which subjects have the ability to consent to participate in research: _____

   State specific requirements: _____

3. If the investigator is the lead investigator or TJU is the lead site in a multi-site study, please address the following:

   a. Where is the repository for adverse events and unanticipated problems and how will information be disseminated to other sites?

      The repository for adverse events and unanticipated problems will be held at TJU. Information will be disseminated through a secure, HIPPA Compliant SharePoint site developed by TJU IT.

   b. Who will tabulate and disseminate interim results?

      The TJU Data Analyst and TJU Project Manager will tabulate interim results. These results will be disseminated by the TJU Project Manager.

   c. Who will provide information to other sites concerning methods/procedures modifications?

      Weekly operations meetings will occur with all sites in order to discuss progress, methods and procedures. TJU Project Manager will record all decisions made and distribute minutes to the entire study team.

   d. Describe how information that is relevant to subject safety will be managed (i.e., notifying site investigators of SAEs and Unanticipated Problems Involving Risks to Subjects or Others, communicating DSMB or Interim Reports, etc.)

      During weekly operations meetings unanticipated problem will be discussed. In addition, ad hoc meetings will be convened as necessary to deal with any adverse events. TJU Project Manager will record all decisions made and distribute minutes to the entire study team.

Collaborative Studies: For investigator-initiated studies that are collaborative or multi-center, or for federally funded studies where TJU is the lead site, please provide IRB approvals for each collaborating institution. If the institution does not have its own IRB, then the institution must first obtain a Federal-Wide Assurance (FWA) from the Office of Human Research Protection (OHRP). This registers the institution with the federal government for conducting human subjects research. The institution should then fill out an IRB Authorization Agreement (IAA) that ties the institution to the TJU IRB for this study. For more information, go to http://www.jefferson.edu/osa/irb/forms/.

Unaffiliated investigators involved with this study should fill out an Unaffiliated Investigator Agreement, also available at the above Website address.

PART G - CERTIFICATION

Federal Regulations require the following responsibilities of the Principal Investigator. Please check those items to which you have conformed, and sign.

As Principal Investigator, I certify that: *(check appropriate boxes)*

- ☐ I have read the IRB Policy and Procedures Manual.
- ☐ I understand the federally-mandated responsibilities of a research investigator in conducting research or evaluation involving human subjects.
- ☐ I will conduct this research in accordance with these responsibilities.
- ☐ I will consent all subjects with an IRB-approved consent form, if applicable to the project, and store the consent forms in a safe repository.
- ☐ I will provide all subjects with a copy of their signed and dated consent form.
- ☐ All personnel have been appropriately trained for their assigned roles in this research.

_____ _____

Signature of Principal Investigator **Date**