Protocol with Statistical Analysis Plan

Comparing Interventions to Increase Colorectal Cancer Screening among Low-Income and Minority Patients

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PCORI RESEARCH PLAN TEMPLATE

FINAL RESEARCH STRATEGY / IRB PROTOCOL

A. Background ***(RQ-3, RQ-4, RQ-6)***

Colorectal cancer (CRC), a preventable cancer, is the third most common cause of cancer deaths in Americans with an estimated 132,700 new cases in 2015.[1] Approximately half of the 49,700 deaths from CRC this year could be prevented if appropriate colon cancer screening was widely implemented. Unfortunately, CRC screening rates in Indiana are well below the national average; only 61.5% of Indiana residents are up-to-date with CRC screening. The American Cancer Society and the U.S. Preventive Services Task Force recommends screening beginning at age 50 years and continuing until age 75 years.[1,2] For people at average risk for CRC – those who have no risk factors other than age – guidelines recommend several test options including: annual stool testing with fecal occult blood tests (FOBT) or fecal immunochemical tests (FIT), sigmoidoscopy every 5 years, or colonoscopy every 10 years.[2,3] For people who have a strong family history of CRC or polyps, colonoscopy is the most appropriate test. Which CRC screening test is recommended to patients, therefore, should be based on assessment of each individual's risk factors.[4,5]

Failure to screen for CRC leads to people being diagnosed with late-stage disease causing unnecessary deaths from this preventable cancer. The current level of screening reduces CRC mortality by 44% compared to no screening. If it were possible to increase compliance with CRC screening tests by 20%, an additional 9.3% reduction in mortality would be realized.[6] To further reduce CRC incidence and mortality, provider referral and timely completion of CRC screening tests that include, but are not limited to, colonoscopy are imperative.

Although there are several test options available for screening people at average risk, providers almost universally recommend colonoscopy and do not offer alternative test options. This practice is contributing to low screening rates.[7,8] Provider recommendation has been well-documented as the most important predictor of CRC screening. Although colonoscopy is the most appropriate test for people at increased risk for CRC, those at average risk – the majority of the population - can be screened with less invasive tests. Unfortunately, colonoscopy is frequently the only CRC screening test recommended by providers.[7,8]

This common practice of universally recommending colonoscopy may actually reduce CRC screening adherence, especially among racial/ethnic minorities[7] and is considered a missed opportunity for some patients to be screened.[8] Evidence of the negative impact of this practice is that almost half of patients in safety net hospitals do not complete the test. Overall, from 38-50% of persons who are referred for colonoscopy cancel or do not attend their scheduled appointments.[9-13] A review of administrative data from our local public safety net hospital showed that colonoscopy cancellation and no-show rates were 41% among Hispanic patients, 58% in Caucasian patients, and 60% in African American patients in 2014. Because of the high patient volume, this means that 1150 people in one health system who were referred for colonoscopy went unscreened in that year alone.

Significant disparities in CRC incidence and mortality exist for racial/ethnic minorities, people with less education, and those with no insurance. CRC incidence and mortality rates are higher among African Americans than all other racial groups.[14] Although mortality rates have been decreasing for all groups over the last 20 years, declines among African Americans began later and have been slower, resulting in a widening racial disparity. The mortality gap is growing for each stage of diagnosis, with the greatest disparity observed for distant-stage CRC.[15] Differences in access to screening and treatment account for more than half of the racial disparity in CRC mortality rates.[1,16-18] Other contributing factors to disparities include unequal access to and receipt of quality treatment, a higher prevalence of comorbid conditions, and lower rates of participation in CRC screening.[19] Hispanics are slightly less likely than non-Hispanic whites to be diagnosed with localized CRC (38% vs. 40%) and more likely to be diagnosed with distant-stage disease (21% vs. 19%) due to lower screening rates and less access to timely medical care.[20] Hispanics age 50 and older are less likely to have had a recent CRC screening test than non-Hispanic whites - 47% vs. 62%, respectively. There are also differences in CRC screening rates by country of origin; Hispanics from Mexico and Central or South America are least likely to have

had a recent screening test.[21,22] Improving CRC screening rates among racial/ethnic minorities has been identified as the first target to reducing these disparities.[23]

Patient-level barriers to CRC screening include low knowledge levels about CRC and CRC screening tests, perceptions of not being at risk for CRC, mistrust, fear of pain/discomfort, fear of finding cancer, embarrassment, unpleasantness of the bowel preparation.[9,24-26] Difficulty finding time, transportation difficulties, and costs of the tests have been identified as barriers to CRC screening by people with low incomes.[9,24,27] Lack of social support has been identified as a barrier to CRC screening; family and friends who had negative experiences with screening tests can actively discourage participation.[27] In a recent trial, the most common barriers to CRC screening were lack of knowledge about the test, fear, worry about test results and the bowel preparation.[28] Inadequate bowel preparation is a major impediment to effective CRC screening with colonoscopy, and 25-30% of patients presenting for colonoscopy have not adequately cleansed, or emptied, their bowel.[10,29-31] Suboptimal cleansing of the bowel leaves residual fecal matter that obscures polyps, leads to missed diagnoses, extends the time needed for the exam, and results in incomplete or aborted colonoscopies.[10,30-34] This is a significant problem among patients in safety net health systems, where up to 30% of patients who do attend their colonoscopy appointment have not adequately cleansed their bowel.[10,30,33] In addition, poor bowel preparation has been estimated to increase the cost of CRC screening by 22% in public hospitals due to patients needing to repeat colonoscopy or have another test earlier than suggested by current practice guidelines.[33] Finding effective approaches to help patients who are willing to have a colonoscopy prepare for that test will reduce costs for patients and health systems, an especially important goal for those with limited resources.

Gaps in our knowledge: Both computer-tailored and patient navigator interventions have been shown to increase CRC screening rates and improve bowel preparation, but no comparative studies have been conducted and none have evaluated the additive effect of combining these approaches for CRC screening. ***(RQ-1)*** People differ on the types and levels of intensity of interventions needed to move them to complete CRC screening.[35] Upon completion of this study, we will have determined the comparative effectiveness of two readily translatable theory-based interventions to increase CRC screening. Further, we will identify *moderators and mediators* of intervention effects that will help us understand, respectively, who benefits most (and least) from which type of intervention and through what mechanisms the interventions are working. The proposed comparative analyses will inform decisions about interventions that can: 1) increase CRC screening; 2) improve bowel preparation for those having a colonoscopy; and 3) reduce CRC morbidity and mortality for low-income and minority patients, who bear a disproportionate burden from this preventable disease.

B. Significance ***(RQ-1, RQ-6))***

Although an estimated 50,000 people will die from CRC in 2015, adherence to guideline-appropriate screening could significantly reduce this mortality rate.[1] The U.S. Preventive Services Task Force recommends screening for colorectal cancer (CRC) using fecal occult blood testing, sigmoidoscopy, or colonoscopy in adults, beginning at age 50 years and continuing until age 75 years.[2] Increasing CRC screening among low-income, uninsured, and minority patients has potential to reduce the well-established disparities in CRC morbidity and mortality experienced by these groups. Significant disparities exist with lower CRC screening rates observed in populations served by safety net hospitals, that is, those with less education, lower incomes, and no health insurance. Improving patients' knowledge of CRC, their personal risk factors, benefits and harms of CRC screening, and what each test entails along with providing support and tangible assistance to overcome barriers will increase the numbers of CRC screening tests completed, increase the number of people who adequately prepare for colonoscopy, and lower healthcare costs.

The effectiveness of CRC screening is dependent on patient acceptance and completion.[4] Two main issues limit utilization of colon testing. First, providers recommend colonoscopy to patients as the only screening test without offering any alternatives. Second, patients often do not understand the need for colonoscopy, especially when they have no bowel problems. Up to 50% of people who receive a recommendation for screening colonoscopy fail to complete the test, with non-completion rates highest in safety net hospitals.[9,10,12] Reasons for non-completion include low levels of knowledge about the need for colonoscopy in the absence of symptoms, fear of pain, unpleasantness of bowel preparation, and confusion about dietary restrictions and medications.[36] As mentioned, several test options are available and offering patients alternatives to colonoscopy is essential if we are to achieve optimal screening rates among all Americans.

In our local public safety net hospital, one of the largest in the nation, significant proportions of patients who are referred by their primary care provider, and scheduled, for colonoscopy do not attend their appointments. In 2014, colonoscopy no-show/cancellation rates were 41% in Hispanic patients, 58% in Caucasian patients, and 60% in African American patients. These numbers represent approximately 1150 people in one year in one health system who, despite being referred and scheduled for colonoscopy, were never screened for CRC because they did not complete this test. Evidence shows that safety net health systems are particularly impacted by this problem.[9-13] We conducted interviews with 48 patients in our safety net hospital who were scheduled for colonoscopy - 100% of these patients reported that their provider had not offered any other CRC screening test option besides colonoscopy. In addition, when asked why they did not complete the test, many reported that their provider had never explained what a colonoscopy was or why it was needed. In addition, the majority of these patients had been scheduled for, but did not attend, prior colonoscopy appointments. Large numbers of patients are indicating they are unwilling to have a screening colonoscopy.

B.1. Effective interventions that increase risk-based CRC screening for all patients have been developed but not compared nor combined. *(RQ-1)* Providers have limited time to counsel patients about why CRC screening is important, which tests options are available, and what each test entails.[37,38] Both patient navigation and tailored DVD interventions that can be delivered in the privacy of people's homes and are available when they are needed most have great potential to increase CRC screening and improve bowel preparation for those who choose colonoscopy. Such interventions supplement face-to-face clinical encounters, providing support and guidance for patients undergoing this unfamiliar, invasive procedure.

Computer-tailored interventions are effective approaches to increase CRC screening *(RQ-5).*[28,39-41] Computer-tailored interventions are defined as "any combination of information and behavior change strategies intended to reach one specific person, based on characteristics that are unique to that person, related to the outcome of interest, and derived from individual assessment."[42] Tailoring refers to a process of creating individualized interventions that use demographic and psychosocial data collected from each person to generate customized feedback to meet his or her unique needs.[42,43] Computer-tailored health communications can be delivered using a variety of media but computer technology is required for the tailoring process. Tailored interventions have influenced health behavior change in relation to smoking cessation, dietary change, physical activity, mammography and CRC screening.[44-49] Tailored interventions are more effective than non-tailored interventions that do not take into account individual characteristics of intervention recipients.[50,51] Studies have shown that tailored interventions eliminate superfluous information and are: 1) more personally relevant to the recipient; 3) attended to; 4) more likely to lead to thoughtful consideration of behavior change; and 5) more useful than non-tailored information in helping people enact behavior change.[52]

Several reviews of tailored intervention trials have demonstrated their effectiveness.[49,53,54] A meta-analysis of 57 tailored intervention trials showed they changed health behaviors and that the most effective tailored interventions were those that focused on preventive and screening behaviors.[53] In a synthesis of 63 randomized trials that met inclusion criteria, 49 studies reported that tailored interventions were superior to control/comparison conditions for improving diverse outcomes.[54] Among 28 published studies, a significant aggregate effect size (OR=1.42) was observed for tailored interventions to increase mammography rates.[49] A recent review concluded that interactive multimedia computer interventions have become the standard medium for delivering tailored health information.[55] Since interactive computer programs can deliver tailored information via audio and video, they have great potential to reduce heath disparities because they make relevant information accessible to people with poor reading skills, low health literacy, and/or poor vision.[55] As shown in Table 1, several studies have shown that computer-tailored interventions increase CRC screening rates.[56-60] Our research team has extensive experience developing and testing computer-tailored interventions to increase cancer screening. We have conducted randomized trials to test tailored interventions delivered via print, telephone, tablet computers, interactive touch-screen computers, and DVD. [59,61-66] One of our recent studies tested a tablet-based computer intervention to increase CRC screening among low income African American

Table 1. Effects of Computer-Tailored Interventions on CRC screening: Results from Randomized Trials

Author/Year	Outcome	Tailored	Usual Care/ Non-tailored	Difference
Basch/2006	Any test	27.0%	6.1%	21
Myers/ 2007	Any test	43.8%	32.6%	11
Manne/2009	Any test	28.4%	15.4%	13
Rawl/2015	Any test	22.1%	5.2%	17

primary care patients in Eskenazi Health, our safety net hospital and setting for the proposed study (R01 CA115983, PI: Rawl). At 6 months, patients who received the tailored intervention were significantly more likely to have been screened compared to usual care (OR=1.81; CI=1.08, 3.04); 26% of the intervention group were screened compared to 18% of the usual care group (p=.03).[64] In another study we tested a tailored DVD intervention to promote mammography and found that women who received the tailored DVD and had household incomes less than $75K were significantly more likely to have a mammogram (OR=1.51, p=.017) than those receiving usual care (R01 NR008434, PI: Champion).[67] Among the 244 African American women enrolled in this trial, the DVD was significantly more effective than usual care at increasing mammography rates for women whose incomes were less than $30K (OR=5.34, CI=1.12, 25.42).[68] Of the 926 women who received the mailed DVD, 92% reported they viewed it and rated it high on a usability scale.[65] Our research, and that of others, has demonstrated that tailored interventions are an effective approach to increasing cancer screening, especially for low-income and minority populations.

A tailored DVD, delivered via the mail or the internet, may be an effective, inexpensive, and easy to disseminate approach to promoting CRC screening and, for those who choose colonoscopy, improving quality of bowel preparation. Because intervention effects can differ across groups, it is critical to examine moderators of intervention effects, that is, for which groups the intervention is more or less effective. Also, in order to understand how or why an intervention is effective, mediators of intervention effects must be identified. ***(RQ-1, RQ-3, RQ-4)***

B.2. Strong evidence supports patient navigation (PN) as an effective approach to increase CRC screening. *(RQ-5)*[11,39-41] Patient navigation (PN) in the context of cancer has been defined as a "barrier reduction-focused intervention" that: 1) is provided to individual patients for a defined episode of cancer-related care; 2) has a definite endpoint when provision of services is complete; 3) targets a defined set of services to complete an episode of cancer-related care; 4) focuses on reducing patient-level barriers to accessing care; and 5) reduces delays in accessing care with an emphasis on timeliness and reduction in the number of patients lost to follow-up".[69] The effectiveness of patient navigation for increasing cancer screening rates has been well established in selected populations. Dr. Harold Freeman's pioneering work demonstrated the effectiveness of PN to increase mammography at a safety net hospital in Harlem.[70,71] Numerous studies have supported the effectiveness of PN interventions to increase CRC screening.[39,40,72-80]

Table 2. Effects of PN on CRC Screening: Results from Randomized Trials

Author/Year	Outcome	Navigated	Usual Care	Difference
Lasser/2009	Any test	31.0%	9.0%	22
Ma 2009	Any test	77.0%	10.8%	66
Percac-Lima/2009	Any test	27.0%	12.0%	15
Honeycutt/2013	Any test	43.0%	11.0%	32

A comprehensive review conducted by a member of our research team (Dr. Paskett) who led the National Patient Navigation Program, concluded that navigation was an effective approach to increasing cancer screening; four of the studies reviewed focused on CRC screening, three on breast cancer screening and one on cervical cancer screening.[81] Table 2 shows effect sizes obtained in randomized trials testing PN interventions. Health systems recently began implementing PN services, prior to generation of substantial evidence of their effectiveness, and dissemination of these programs has been widespread.

Both computer-tailored and patient navigator interventions have been shown to increase CRC screening rates and improve bowel preparation, but no comparative studies have been conducted and none have evaluated the additive effect of combining these two approaches for CRC screening. *(RQ-1, RQ-4, RQ-5)* People differ on the types and levels of intensity of interventions needed to move them to complete CRC screening.[35] The proposed study will determine the comparative effectiveness of two promising theory-based interventions and examine moderators that will increase understanding of who responds to brief versus more intensive (interpersonal) interventions. The **impact of this study** will be an enhanced understanding of which interventions are most effective for increasing CRC screening among those who are least likely to be screened. The study's **innovation** lies in careful attention to comparing these approaches with each other and with usual care, as well as exploration of moderators and mediators of intervention effects.

This application is being submitted in response to the PCORI funding announcement for applications focused on *Improving Healthcare Systems.* Consistent with the intent of this priority, this proposed study will compare the effects

of two health system-level approaches designed to improve access, support patient self-care, use innovative health information technology, coordinate care, and deploy the workforce effectively.

Upon completion of the proposed study, we will have determined the comparative effectiveness of two readily translatable theory-based interventions to increase CRC screening. Further, we will identify moderators and mediators of intervention effects that will help us understand, respectively, who benefits most (and least) from which type of intervention and through what mechanisms the interventions are working. The proposed comparative analyses will inform decisions about interventions that can increase screening, improve quality of bowel preparation for those having a colonoscopy, and reduce morbidity and mortality from CRC for low-income and minority populations, who disproportionately bear the burden of this preventable disease.

C. Study Design and Approach. (*RQ-2, RQ-3, RQ-4, RQ-5, RQ-6*)

We will use a three-group randomized trial design to compare the effectiveness of two theory-based interventions to promote completion of CRC screening among individuals at average risk for CRC and, for those who complete colonoscopy, high quality bowel preparation. We will enroll an ethnically diverse group of 450 men and women who canceled, or did not attend, their colonoscopy appointment and randomize them to receive: 1) a tailored DVD intervention; 2) the tailored DVD *plus* a patient navigator intervention; or 3) usual care. The aims of this study are to:

1. **Compare the effectiveness of two interventions designed to promote CRC screening among people at average risk for CRC - a tailored DVD versus the tailored DVD *plus* telephone-based patient navigation - to each other and to usual care.**

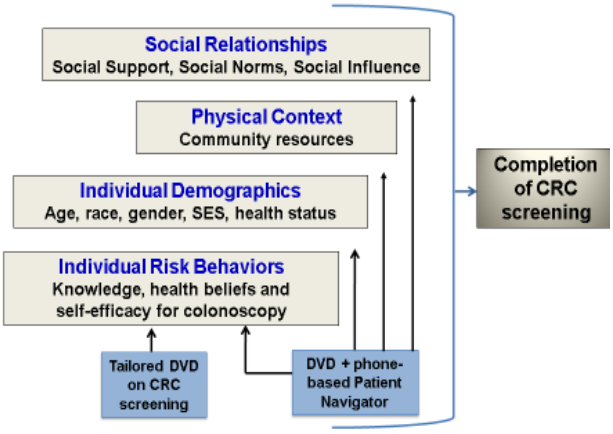
   Hypothesis 1.1: Participants who receive the tailored DVD *plus* telephone-based patient navigation intervention will have higher rates of colorectal cancer screening with fecal immunochemical test (FIT), colonoscopy, or either screening test compared to those who receive the tailored DVD alone.

   Hypothesis 1.2: Participants who receive either intervention will have higher rates of colorectal cancer screening with fecal immunochemical tests (FIT), colonoscopy, or either screening test than those who receive usual care.

   Hypothesis 1.3: Participants who receive either intervention who complete colonoscopy will have: 1) better quality of bowel preparation; 2) less anxiety about the procedure; and 3) greater satisfaction with the colonoscopy experience than those who receive usual care.
2. **Examine age, race/ethnicity, sex, and income as potential moderators of intervention effects. *(RQ-4)***
3. **Examine changes in knowledge and health beliefs (perceived risk, perceived benefits, perceived barriers, and self-efficacy) as potential mediators of intervention effects. *(RQ-6)***

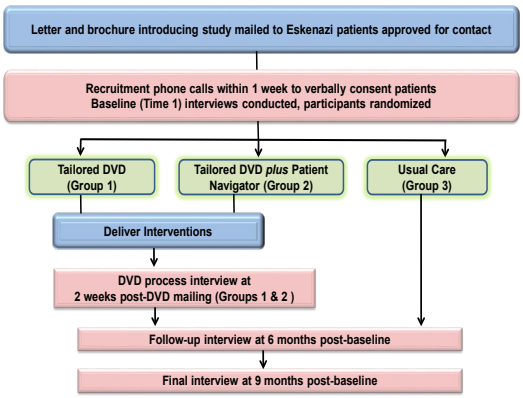
Both interventions can serve as adjuncts in any existing health care system to facilitate completion of CRC screening and improve the quality of bowel preparation. A number of complex factors may contribute to low CRC screening completion rates after provider referral, but more work is needed to understand these factors.[1] We will explore whether the effects of these interventions differ for various subgroups of participants. Heterogeneity of treatment effects will be determined by examining age, sex, and race/ethnicity as potential moderators. ***(HT-1)***

Figure 1. Conceptual Model Adapted from Warnecke, et al. 2008



C.1. Conceptual Model. The model guiding this study was adapted from Warnecke and colleagues (Figure 1).[82] This multilevel model shows the proximal, intermediate, and distal determinants of health that will be targeted by the interventions. Consistent with this model, we will test a telephone-based patient navigation intervention that will provide social support (social relationships) and access to community resources (physical context) for people who have been scheduled for colonoscopy. Specifically, the patient navigators (PNs) will provide individualized support based on assessment of demographics, knowledge, health beliefs, and barriers. By interacting with the health care system and community resources, they will assist patients to overcome their unique logistical and other barriers to CRC screening. A tailored DVD titled *"Time to **ACT**: **A**pproaches to **C**olon **T**esting"* will be designed to increase knowledge, health beliefs, and self-efficacy for CRC screening.

C.2. Design. A three-group randomized controlled trial will be conducted to compare the effectiveness of two interventions to promote CRC screening test completion. Eligible men and women who were scheduled for colonoscopy in the endoscopy unit at Eskenazi Health (our safety net health system) but did not attend their appointment will be invited to participate. After baseline data are collected via structured telephone interviews, participants will be randomized to receive: 1) a mailed DVD titled *Time to **ACT**: **A**pproaches to **C**olon **T**esting*; 2) the mailed DVD *plus* a patient navigator (PN) intervention; or 3) usual care (See Figure 2). ***(RQ-2, RQ-3, RQ-4, RQ-5)***



Study Design and Schema

C.3. Setting and Recruitment. ***(PC-2)*** On a weekly basis, Eskenazi Health IT department will generate lists of age-eligible patients at average risk who did not attend their colonoscopy appointment. The list will include 2 groups of average risk patients who missed their appointment: 1) patients who had a colonoscopy screening ordered; and 2) patients who had a recent fecal immunochemical test (FIT) that was positive with a follow-up order for colonoscopy. Due to differences in physician ordering practices, the follow-up colonoscopy can be ordered as a colonoscopy screening, colonoscopy diagnostic, or colonoscopy high risk. Patients will be approved for contact by Dr. Fatima, Director of the Eskenazi Health Endoscopy Department. Patient information will be released to the study's data manager, the Eskenazi Endoscopy Department's Patient Navigator nurse, and trained research staff at the IU School of Nursing using secure electronic data transfer methods. Information disclosed is limited to that which is necessary to determine eligibility and to contact patients by mail and telephone. As a first step, the Endoscopy Patient Navigator nurse or nurse designee will screen patients by looking back 10 years and excluding any with a history of adenomatous polyps, sessile serrated polyps, or any mass suggestive of neoplasia. Patients with a history of hyperplastic polyps, lymphoid tissue, or no polyps will be

recruited. To be eligible, these patients must: 1) have been referred for a colonoscopy that was not done (i.e, canceled or no show); and 2) be 50 to 75 years old if non-African American or 45-75 years old if African American. Patients meeting these inclusion criteria will be excluded for the following reasons: 1) unable to speak, read, and write English; 2) a personal history of having a colonoscopy at a non-Eskenazi Health location where polyps were found and they were the type that could turn into cancer; 3) FIT negative result in the past 12 months; 4) a personal history of CRC; 5) a personal history of conditions that place them at high risk for CRC such as ulcerative colitis, Crohn's disease, or known hereditary syndromes such as familial adenomatous polyposis or hereditary nonpolyposis colorectal cancer; 6) a family history of CRC which increases their risk; and 7) speech, hearing, cognitive, and/vision impairment. Trained research staff at the IU School of Nursing will recruit patients using procedures consistent with clinic and HIPAA requirements. Recruiters will send introductory letters, signed by the Principal Investigator and a co-investigator who is a member of the Eskenazi Medical Staff , along with a recruitment brochure and Study Information Sheet that explains the study to all approved patients. The letter informs patients that they will receive a phone call about the study within the next week unless they call a toll-free number to say they do not wish to be contacted. One week after letters are mailed, trained recruiters at the IU School of Nursing will call potentially eligible participants who have not opted-out to explain the study requirements, potential risks and compensation, and answer questions. Adequate speech, hearing, and cognition of potential participants will be confirmed by recruiters based upon the phone conversation. They will then proceed to determine eligibility, obtain both verbal informed consent and verbal HIPAA Authorization, and schedule a convenient time to conduct the baseline interview. Each participant who is not reached will be called back up to, but no more than, 10 times. Recruiters will record each call attempt including the date, time, disposition, and callback preference. Participants who decline to participate will be thanked for their time, with their response and reason for refusal recorded.

Re-contact efforts will be attempted for patients who were originally excluded from the study due to reporting a history of colon polyps (histology type unspecified). Amendment 013, approved by the IRB last year on 5/30/2018, allows patients with a history of benign colon polyps to be included in the study. The Endoscopy Patient Navigator nurse or nurse designee will review the records of these previously excluded patients to determine if: (1) the polyp histology type was benign; and (2) a colonoscopy is still needed. Patients with benign polyps who are due for a colonoscopy will be re-contacted following the usual recruitment procedures described above. A slightly modified version of the study introductory letter which notes in the opening paragraph that patients may now be eligible will be used in lieu of the standard introductory letter.

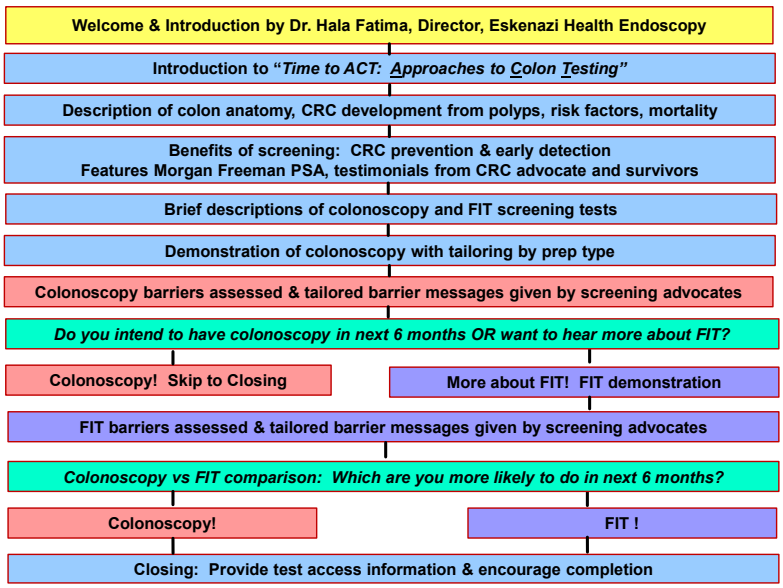
Additionally, re-contact efforts will be attempted for patients who previously gave their verbal consent to participate but failed to return the written informed consent and HIPAA Authorization in order to be officially enrolled. The IRB approved a change to the protocol on 11/27/2018 which discontinued the requirement for informed consent and HIPAA Authorization to be obtained in writing. These patients may now be willing to be enrolled since written forms do not need to be completed and returned to the research office. This cohort of patients will be re-contacted following the usual recruitment procedures described above. A slightly modified version of the study introductory letter which explains in the opening paragraph that written consent forms are no longer required for enrollment will be used in lieu of the standard introductory letter.

C.4. Intervention and Usual Care Descriptions. ***(PC-1, PC-2, PC-3, RQ-2, RQ-5).*** The tailored DVD titled *"Time to **ACT**: **A**pproaches to **C**olon **T**esting"* and patient navigator interventions are described in the following sections. All phases of intervention refinement will be conducted in consultation with our Community Advisory Board, which will be comprised of 8 members of the target population. Our Community Advisory Board (CAB), Ms. Sylvia Strom, our patient stakeholder and Chair of the CAB, and Ms. Rivienne Shedd-Steele, Director of the Indiana University Simon Cancer Center's Office of Health Disparities and Community Engagement, will ensure the relevance of both interventions to a diverse group of users. By interacting with the patient navigator, participants will receive a barrier-reducing intervention that will be individualized based on their knowledge, health beliefs about CRC screening, and identified logistical barriers. The tailored DVD addresses these same theoretical concepts and will incorporate colors, screen designs, and music preferred by our CAB. Usual care in the Eskenazi Health System endoscopy department begins with referrals for screening

colonoscopy that are generated by primary care providers in this integrated health system. Primary care providers enter colonoscopy orders into the electronic health record which are immediately communicated to the endoscopy department. Endoscopy department staff schedule an appointment, typically within 4-5 weeks of the referral, and mail an information packet about the procedure along with written instructions for completing the bowel preparation. The packet includes instructions to call with any questions and if necessary, to reschedule the appointment. Within 1-2 days prior to the scheduled appointment, an endoscopy department nurse telephones each patient to remind him/her of their appointment and answer any questions about the procedure, including completing the bowel preparation.

C.4.a Tailored DVD. The 20 minute tailored DVD will be refined during the first 11 months in collaboration with Eo Studios in Athens, Georgia. The tailored DVD will be an expansion of our prior work in which we developed and tested a computer tablet-based tailored intervention to promote CRC screening in primary care settings (1R01-CA115983; Rawl, PI). For that study, we collaborated with Eo Studios, an experienced production company, to create a computer program with graphics, animations, video clips, and audio clips that were specifically targeted to African Americans. The program incorporated narrative colors, screen designs, and music preferred by our Community Advisory Board who worked with us on that study. Because some members of our target audience had limited health literacy, the program was completely narrated and required minimal reading. Some graphs, animations, videos, still images, and narrated messages from that interactive program will be used to refine/expand the new DVD program. However, we will need to adapt the existing program for a broader audience. Although we have video and audio clips of testimonials from people who overcame common barriers to CRC screening, we will need to develop segments that demonstrate the newer fecal immunochemical test (FIT) and update instructions for completing the bowel preparation. Simple and clear instructions, with illustrations, video clips, audio clips and animations will be developed for split-dosing of GoLYTELY® and Miralax, the two most common bowel preparations prescribed at Eskenazi. We have approximately 200 unique photographs acquired from on-site photography/videography and digital imaging libraries available from our prior studies. We also have a large number of audio clips that will be incorporated along with full-motion video clips demonstrating CRC screening tests, steps for completing them, and key testimonials. Additional graphics, video, and animations will be designed by Eo Studios. Animation will be incorporated in a variety of ways. For example, animation will be used within charts or graphs developed to illustrate CRC risk and animated icons and sound will be incorporated throughout the program to enhance the look, feel, consistency, and usability of the program. Our patient stakeholders (CAB members) will guide refinement of the tailored DVD. ***(PC-1, PC-3)***

Figure 3. DVD CONTENT & FLOW



The DVD content and flow are shown in Figure 3. After a brief introduction to the purpose of the DVD, the narrator will explain the location of the colon, what it does, and how colon cancer develops from polyps. The program will describe the benefits of CRC screening and two commonly used screening tests: colonoscopy and the fecal immunochemical test (FIT) which is a type of stool blood test. Barriers that people may have about screening tests will be assessed and messages delivered to overcome these barriers. Messages will be delivered by men and women who are CRC survivors and CRC screening advocates who vary in race and ethnicity. The DVD will provide demonstrations of each screening test, dietary restrictions, and the steps to complete them. All information will be presented with graphics, video demonstrations, and animations to accompany the narration. The goal will be to make the content easy to find and navigate. Minimal navigation expertise will be necessary. Once the "Play" button is selected by the viewer, the program will automatically advance. Selected sections of the program will be available for re-playing by using the DVD Menu. The overarching intent of the study is to create both English and Spanish versions of the DVD. However, development of the English version will take precedence due to time constraints by Eo Studios, our design firm. We will open the study using the English version only and require that participants be able to speak, read, and write English in order to be eligible for enrollment. Development of the Spanish version will occur in 2018. When the Spanish version is completed, we will submit an Amendment to the IRB, along with the necessary accompanying documents, to offer the study to Spanish speaking patients. (*PC-2, PC-4)*.

C.4.b. Telephone-based Patient Navigation Intervention. The telephone based intervention has been developed and tested in prior research by our Ohio State University team members. Patient navigation (PN) also supplements face-to-face clinical encounters with primary care providers and extends the limited time devoted to preventive care and health counseling. The proposed telephone PN intervention is theory-based and will be designed to: 1) increase knowledge, perceived benefits, and self-efficacy; 2) reduce barriers; 3) enhance access; and 4) provide social support. Theoretical constructs, objectives, and content of the PN interactions (minimum of two) are described elsewhere. Development of the web-based navigator protocol and documentation system (tracking log) will occur in collaboration with our biostatisticians and expert data manager**.** The goal of the protocol will be to guide trained PNs to counsel participants by telephone within a standardized framework. The protocol will serve as a counseling guide but will allow navigators flexibility to individualize contacts based on a participant's expressed needs and concerns. The interface will provide prompts to assist PNs and allow them to document all encounters with, and on behalf of, participants.

PNs will be trained to initiate as many encounters as needed to assist patients to complete CRC screening; however, a minimum of 2 telephone calls will be placed to all participants randomized to this group. The initial call will be placed approximately 2 weeks after mailing of the DVD to allow time for receipt and viewing of the DVD. During the initial call, the PN will use the web-based counseling protocol to first assess whether the participant has viewed the DVD. If the participant has not yet viewed the DVD, the PN will remind him or her to do so, answer any questions about accessing it, and reschedule the call for a later date. If the participant has viewed the DVD, the PN will then counsel to answer any questions and increase the participant's knowledge of CRC screening, risk factors, and the benefits and harms of each screening test. **The PN will then focus on assessing and reducing barriers to CRC screening and enhancing access**. The web-based protocol will generate a checklist of topics and suggested talking points for PNs to use during each call. All encounters between the PN and the patient, as well as activities and contacts with others (GI resource nurse, primary care provider, community resources) that the PN initiates on behalf of the patient will be documented in the web-based documentation system. A sample of the PN tracking and documentation system as well as content covered in PN calls is included elsewhere.

For patients who request a FIT, the PN will mail the test and place a follow-up call to answer questions about the test and encourage completion. Although there may be more intervening phone encounters, the PN will call participants who schedule a colonoscopy 1-2 days prior to their appointment. During this call, PNs will focus on: 1) reviewing the colonoscopy procedure and what the participant will experience; and 2) providing support and guidance for completing the bowel preparation, including managing dietary and medication restrictions. Although the protocol will provide structure for the PN calls, PNs will have complete flexibility to respond to and document participants' specific questions, needs, barriers, and concerns. In addition, PNs will record all actions taken to assist participants in the web-based documentation system.

C.4.c. Training of Patient Navigators. PNs will be IU School of Nursing research RNs who are familiar with the study protocol and knowledgeable about CRC. They will have prior patient engagement experience. Initial training will be a half-day session presentation by our Ohio State University co-investigators, Dr. Mira Katz and Chasity Washington, who are experts in navigation. Training objectives will be to have PNs: 1) understand the principles of patient navigation; 2) understand the scope of their role; 3) deliver barrier reducing messages to promote CRC screening uptake; 4) prepare participants scheduled for a colonoscopy; and 5) assist participants in completing a stool blood test (FIT). The Eskenazi Endoscopy Patient Navigator nurse will attend the training session and provide information on local resources that she currently uses for transportation, financial assistance, etc. This session will also include a presentation on intervention fidelity and quality assurance by an Ohio State co-investigator. A second half-day session will be conducted by the study's Clinical Research Coordinator. The DVD intervention will be viewed so that navigators are refreshed on what colon health information patients will receive prior to their contacting them. In this session, PNs will also practice delivering the phone scripts, making entries into the training version of the REDCap PN database, and role-play common patient scenarios likely to be encountered. PNs will practice and role-play until they have reached 100% compliance with the intervention protocol. After the initial training sessions, monthly conference calls will occur among the PNs, Clinical Research Coordinator, and the Ohio State PN quality assurance monitor. The calls will include additional training, a Grand Rounds case presentation, and the opportunity to discuss any concerns related to patient navigation. From these discussions, future training topics will be identified. Potential monthly training topics include: 1) addressing challenging situations; 2) revisiting patient empowerment approaches; 3) health literacy; 4) self-care: approaches to avoid feeling burned out; 5) time management; and 6) updates on community resources.

C.5. Intervention Pretesting *(RQ-2, PC-1, PC-3).* Usability testing will occur with individual user feedback from members of the target audience. We will recruit 5 patients from our target population for individual user testing. Usability of the tailored DVD will be evaluated by assessing ease of use, content (leveling and appropriateness), aesthetic appeal, and cultural relevance. We will present prototypes of both interventions to our CAB (who represent our target population) as components are designed. The information gathered during individual user testing will be used to revise both interventions.

C.6. Intervention Delivery *(RQ-2)*. The tailored DVD program will be made available to subjects in two formats: DVD and a web version. At the start of subject accrual, the program will be limited to DVD format. During the baseline interview, participants will be asked about access to a DVD player. For patients who have access to a DVD player, we will mail the tailored DVD. Since the numbers of patients who have access to the Internet is growing, and DVD players may be less common in the future, we will also make the tailored interactive program available for viewing online via the Internet for people who have such access. A Gallup poll conducted in 2013 showed that 80% of U.S. homes have a DVD player and 73% have Internet access.[83] For those who have access to both a DVD player and the Internet, the format for delivery of the tailored DVD will be based on participant preference. The DVD, or link to the website, will be mailed directly to participants' homes after the baseline interview is completed. A letter will be included that instructs participants to view the DVD within the next 2 weeks and provides a toll-free number to call for technical assistance if needed. Trained research assistants and the project manager will be available to provide technical assistance to any participant who has difficulty viewing the DVD or accessing the tailored program online. If neither of these technologies is available in the home, through family or friends, or at the public library, we will loan portable DVD players to participants along with enclosed instructions and mailers for returning players to the research office.

Patient navigators will begin contacting participants by phone about 2 weeks after mailing the DVD to set up an initial phone appointment, depending on the participant's preference and availability. PNs will be trained to make as many contacts as needed to assist patients to complete CRC screening; however, a minimum of two calls will be placed to all participants randomized to the tailored DVD plus PN group. If navigators are unable to reach participants by phone, a letter will be mailed requesting that participants contact them.

C.7. Intervention Fidelity. *(RQ-2)* Published recommendations to ensure intervention fidelity address five components that are described below.[84,85] 1) Study design. The three group design ensures blinding of outcome data collectors to

participant group assignment, as feasible. 2) PN training. Training is addressed in Section B.6 above. 3) Intervention delivery. To ensure consistency of intervention delivery, evaluation of intervention processes is essential and several strategies will be used. DVDs or instructions with a link to view the program on the web will be mailed to participants. All PN calls will be recorded for quality assurance purposes, with a subsample randomly selected for evaluation. Audiotaped PN calls will be evaluated using a checklist we developed in prior studies. Project staff will discuss intervention delivery issues, technical support requests, and any unusual events during biweekly research team meetings. Modifications will be made as necessary and recorded to ensure appropriate intervention delivery and maintenance of protocol integrity. Decisions about modifications will be made jointly by the research team and recorded. 4) Intervention receipt. Since all participants in the intervention arms will receive the tailored DVD via mail or a web link, we will call each participant approximately 2 weeks after mailing to conduct a process evaluation of this intervention. Through the process interview, we will assess receipt of the DVD or web link, how much of the DVD was viewed (none, part, or all), as well as satisfaction with and relevance of the content for those assigned to both intervention groups. Participants will receive a $50 gift card for completing this process interview. Specific evaluation questions that assess user experience and satisfaction are included elsewhere. 5) Intervention enactment. All participants who return a completed FIT will have enacted the behaviors recommended in the interventions. Those who attend a colonoscopy appointment are routinely asked about their experience with, and ability to complete the bowel preparation and refrain from eating solid food before the test. This information is documented in the EMR, and colonoscopy procedure notes will provide evidence that participants who choose this test have enacted the behaviors recommended in the interventions. **The PN documentation record will provide additional data to support intervention enactment by participants assigned to this group.**

C.8. Data Collection. (*RQ-6, PC-2, PC-3*) Trained data collectors/interviewers who are employed by the Indiana University Center for Survey Research (CSR) will collect data via structured telephone interviews. Interviews will be conducted at baseline (T1), at 6 months post-baseline (T2), and at 9 months post-baseline (T3). If unable to reach participants when a phone interview is due, we will mail a letter to them requesting that they contact the CSR data collection team so that the interview may be completed. Reminder letters will be mailed to participants about 1 month before the T2 and T3 interviews are due. Process interviews will be conducted with participants assigned to the DVD intervention group approximately two weeks after mailing of the DVD. The baseline interview includes a question to confirm age eligibility and assesses the following: demographics, health literacy, health status, patient activation, CRC knowledge, CRC fear, cancer fatalism, colonoscopy-related procedural anxiety, social support, and media exposure. For both colonoscopy and FIT, the baseline interview asks questions about participants' experience with each test and readiness to screen by each test. Health beliefs for perceived CRC risk and colonoscopy and FIT perceived benefits, perceived barriers, and perceived self-efficacy are also collected. At completion of the baseline interview, participants will be randomized. People assigned to DVD or DVD + PN intervention groups will be told they will receive a DVD or instructions to access the website to view the program (based on their preference). Those in the tailored DVD + PN group will also be told they also will receive a phone call from the nurse navigator in about a week.

The DVD process interview will assess receipt of, viewing of, and satisfaction with the DVD and will be done approximately 2 weeks post-mailing of the DVD. Receipt, experience and satisfaction with the PN intervention, for those randomized to the DVD+PN group, will be assessed as part of the 6 month interview (T2). The 6 month interview will also assess changes in knowledge, patient activation, CRC fear, cancer fatalism, and colonoscopy-related procedural anxiety. Health beliefs for colonoscopy and FIT will be assessed as will self-reported CRC screening intention, uptake and satisfaction with the screening experience (for those who completed screening). At 9 months, we will assess self-reported CRC screening intention, uptake and satisfaction with the screening experience (for those who completed screening since T2). Participants will receive a $50 gift card for the baseline interview, a $50 gift card for the 6 month interview and a $50 gift for completing the 9 month interview; a total of $150 for participants who complete all three interviews. Participants who complete the additional DVD process interview will receive another $50 gift card for a total of $200 in gift cards. By using gift cards with an appealing dollar amount over the 9 month data collection period, we hope to incentivize participants to remain in the study. Additional retention strategies which we will use include mailing

participants a magnetic, refrigerator clip customized with the ACT Study name, phone number, and message “Working Together for Better Health”. The refrigerator clip will serve as a visible reminder of their participation in the study and provide a convenient way for them to know how to contact us. Participants will also be mailed newsletters and a birthday card. Our Research Assistants will make “check-in” calls to thank participants for continuing in the study, ensure that the gift card incentive was received, confirm that they have a working DVD player (if randomized to the DVD only or DVD + Patient Navigator group), remind participants of the next step, answer questions, etc. These brief calls are scheduled to occur at 4 different times over the 9 month time frame in order to keep participants continually engaged. For participants who miss who the DVD process interview, 6 month follow-up interview, or Patient Navigation intervention, we will mail them a letter. This letter lets participants know that we understand that it's not always possible to complete a study procedure when due and reassures them that they can still be in the study. By sending this letter, we hope to counteract any inclination participants may have about dropping out of the study because they missed a step.

Table 3 on the following page describes the measures and data collection timeline.

Table 3: Data Collection Timeline

Measures	Baseline Interview (T1)	Process Interview (2 weeks after mailing DVD)	Follow-up Interview at 6 months post-baseline (T2)	Final Interview at 9 months post-baseline (T3)	12 months post-baseline (Final medical record review)
Demographics, social support, media exposure	X				
Health literacy, health status to include co-morbidities	X				
CRC screening experience and readiness to screen, patient activation, health beliefs (perceived CRC risk, benefits of screening, barriers to screening, self-efficacy for screening), CRC fear, cancer fatalism	X		X		
Colonoscopy-related procedural anxiety	X		X	X	
CRC and screening knowledge	X		X		
Receipt, viewing and satisfaction with the DVD		X			
Receipt, experience & satisfaction with the PN			X		
Self-report of CRC screening intention and completion			X	X	
Satisfaction with the screening experience			X	X	
Trial participation feedback				X	
Medical record review: CRC screening test completion, quality of bowel preparation			X	X	X

C.9. Measures. The primary study outcomes of CRC screening completion with any test (FIT or colonoscopy), and quality of bowel preparation (for those who complete colonoscopy), colonoscopy-related procedural anxiety and satisfaction with the CRC screening experience are described in this section. Secondary outcomes of the interventions include changes in knowledge and health belief variables (perceived risk, benefits, barriers, and self-efficacy). Other measures include patient activation, CRC fear, cancer fatalism, and satisfaction with the interventions. Measures have been extensively tested and refined in preliminary studies, and are described in more detail elsewhere.

PRIMARY OUTCOME MEASURES: *(RQ-6, PC-2, IR-4)*

Completion of any CRC screening test *(fecal immunochemical test (FIT) or colonoscopy)* will be measured by medical record review. FIT and colonoscopy completion dates will be extracted from the electronic medical record. Because self-report of CRC screening has correlated well with medical record data,[86,87] we will also use validated items from our previous research to ask participants if they have had a CRC screening test (FIT or colonoscopy) as well as their plan to have one in the next 6 months (only for those who have not yet completed screening).

Quality of bowel preparation will be assessed two ways for those participants who attend their colonoscopy: 1) by participant self-report of their bowel prep experience and 2) via review of electronic medical records. When patients arrive in the endoscopy department, a nurse assesses their experience with the bowel preparation and adherence to dietary restrictions. Patients who report they were unable to complete the bowel prep or have eaten in the past 24 hours are considered inadequately prepped for the procedure and sent home. These patients must repeat the preparation to cleanse the bowel and reschedule their colonoscopy. For those who report successful completion of the bowel prep and adherence to dietary restrictions, quality of the bowel preparation (i.e. degree of cleanliness/emptiness of the bowel) is evaluated by the endoscopist during the colonoscopy. Standard practice is to evaluate bowel preparation quality using an assessment similar to the Aronchick 5-point scale where 1=*excellent,* 2=*good*, 3=*fair*, 4=*poor*, and 5=*inadequate*. Adequate is a term that may also be used to describe the quality of bowel preparation as a single descriptor or in addition to the Aronchick assessment as excellent (1), good (2), or fair (3). Procedural notes including endoscopists' ratings of the quality of the bowel prep are entered into ProVation, a menu-driven software program. Therefore, participants will be considered inadequately prepped if they are: 1) deemed inadequately prepped from self-report during initial nursing assessment OR 2) if the endoscopist rates the quality of the bowel prep as poor (4)

or inadequate (5). Eskeanzi Health is introducing the Boston Bowel Preparation Scale (BBPS) as another type of bowel preparation quality measure. The BBPS measures quality on a 10 point scale of 0-9. BBPS evaluations will also be entered into ProVation by the endoscopist and compared to the Aronchick findings. A decision will be made at a later time as to whether or not the BBPS ratings will be included in reporting this study outcome.

SECONDARY OUTCOMES AND OTHER MEASURES *(RQ-6, PC-3, IR-4)*

Demographics, health literacy, health status, social support, and media exposure will be assessed with items we have used in prior studies. Items will assess age, gender, marital/partnered status, number of persons living in the household, ethnicity, race, ethnic origin, education, employment, income, and insurance status. Additional items will assess health literacy, health status, comorbid conditions, and social support for having a colonoscopy. These items have been used for descriptive reporting in our previous research without interpretation or scoring difficulties. In the proposed study, questions about media exposure will assess previous exposure to information about CRC and colon testing.

Colonoscopy-related procedural anxiety will be measured using the 6-item short form of the State Anxiety Scale of the State-Trait Anxiety Inventory developed by Spielberger.[88] This scale measures how an individual is feeling right now when thinking about having a colonoscopy. Validity and reliability have been widely reported and this scale has been commonly used in studies of colonoscopy-related anxiety.

Perceived risk *for CRC* will be assessed using two measures that consist of 5 items: a 4-item scale and a single item that assesses comparative age-adjusted risk. The summated risk scale was originally developed for breast cancer[89,90] and adapted to CRC[91]. Validity and reliability have been extensively tested with diverse population groups. Internal consistency reliability analyses from previous studies yielded Cronbach's alphas ranging from 0.75 to 0.79.[59,92]

CRC screening experience and readiness to screen will be measured separately using 5 categorical items for colonoscopy and 6 categorical items for FIT. These items have been used in our prior studies to stage participants in terms of their readiness to uptake screening behaviors.

Perceived Benefits of FIT and colonoscopy will be respectively measured separately using the 3-item and 4-item summated scales used in our prior studies.[89,90,92,93] Cronbach alpha coefficients obtained in preliminary studies were 0.72 for our 3-item benefits of stool testing scale and 0.69 for our 4-item colonoscopy benefits scale.[92]

Perceived Barriers to FIT and colonoscopy will be measured by separate summated Likert scales developed and validated by our team and used in previous studies.[90,93,94] Barriers to FIT are measured using a 10-item scale; barriers to colonoscopy are measured using a 16-item scale with the same 4-point Likert response options. Cronbach alphas for the FIT barriers scales was 0.82 and for the colonoscopy barriers scale, 0.89.[59,92]

Self-efficacy for FIT and colonoscopy will be measured separately on a 7 item scale for FIT and an 11-item scale for colonoscopy using 4-point Likert response options where 1="not at all sure" to 4="very sure" that I am able to do each of the steps involved in CRC screening. Self-efficacy scales for FIT and colonoscopy had Cronbach alphas of 0.87 and 0.88, respectively, in our previous studies.[59,92]

CRC Fear will be measured using an 8-item scale that assesses participants' emotional reactions to thinking about CRC. This scale was originally developed to assess breast cancer fear and had an internal consistency reliability of .91 in our prior mammography studies. Construct validity has been shown through factor analysis and testing of theoretical relationships.[95] We will adapt the cancer fear scale for CRC by substituting colon cancer for breast cancer.

Cancer Fatalism will be measured using Mayo's modification of the Powe Fatalism Inventory, which assesses the degree to which a person equates cancer with death.[96-98] This scale uses 4-point Likert response options for 11 statements that assess cancer fear, pessimism, predetermination, and inevitability of death. The Cronbach alpha for this scale was 0.86.[92]

Knowledge of CRC and Screening will be measured using an 9-item multidimensional scale that has been tested in preliminary studies and found to have content and construct validity. Several aspects of knowledge about CRC and CRC screening tests will be assessed, including risk factors.

Patient Activation will be measured using the 13-item short form Patient Activation Measure (PAM) scale developed by Hibbard. It assesses patient knowledge, skill, and confidence for self-management. This scale uses 4-point Likert response options.

User Experience with the DVD will be measured using a 15-item scale developed to assess participant's experience with the tailored DVD. The scale will include items to assess cognitive engagement, personal relevance of information, and

esthetic/emotional appeal of the program. Items will be scaled so that higher scores reflect a more positive user experience on all dimensions. Items selected will be based on relevant literature and effective use in our prior studies. We will also include 6 quantitative items to assess the DVD in terms of being helpful, providing new information, and whether or not it would be recommended to others.

Satisfaction with the Patient Navigator will be measured using 19 items tailored for study relevancy from the 26-item satisfaction scale used in the national Patient Navigation Research Program. This scale assesses participants' degree of satisfaction with the help received from the navigator using a 3-point response scale where 1=not satisfied and 3=very satisfied. An additional 20 items assess participants' satisfaction with the interpersonal relationship with the navigator using 4-point Likert response options where 1=strongly disagree and 4=strongly agree.

Trial Participation feedback will be collected using 4 independent items. Participants will be asked to tell us what they enjoyed, if anything, about being in the study. They will also be asked to tell us what was the hardest part about being in the study. Additionally, participants will be asked if they would recommend the study to others who need a colon test (yes or no response options). Lastly, participants will be asked if they are willing to be contacted in the future about participating in other research studies (yes or no response options).

C.10. Training of Recruiters and Data Collectors. (PC-2) Recruiters will be trained by the PI and project manager whereas data collectors will be trained, supervised, and monitored by the Center for Survey Research (CSR) staff in collaboration with the PI. Detailed training manuals for recruiters and data collectors that were developed for our preliminary studies will be modified for the proposed study. Initial training sessions for recruiters and data collectors will include: 1) overview of study objectives and rationale; 2) description of interventions; 3) description of data collection instruments; 4) protection of human subjects, HIPAA and confidentiality issues; 5) cultural sensitivity; 6) roles and responsibilities of project staff members; 7) schedules; 8) documentation and reporting requirements; and 9) quality assurance procedures. Time will be allocated for multiple discussion and question/answer periods.

Recruiters will be trained on effective recruitment procedures, including: 1) study recruitment letters, procedures, and telephone scripts; 2) handling problems or questions during telephone recruitment; 3) use of the REDCap tracking database to log recruitment and other study procedures; and 4) recruitment monitoring and quality assurance procedures. Training will include demonstrations of effective recruitment calls. Following demonstrations and practice sessions, recruiters will role-play and receive feedback until they have reached 100% compliance with guidelines for recruitment integrity.

Data collectors selected from CSR for this study will be experienced interviewers. Prior to the study-specific training described below, CSR data collectors will have completed a rigorous 9-hour telephone interviewing training course, with four hours spent in hands-on practical experience in which the trainee-to-supervisor ratio is 5:1. This training course covers: 1) the interviewer's role in survey research; 2) standardized interviewing techniques; 3) administration of survey introductions and refusal aversion techniques; 4) use of computerized sample management and data collection systems; 5) protection of human subjects and sensitive information; and 6) daily case management. Comprehension of concepts and techniques and skill in their execution are assessed through a battery of tests at appropriate intervals in the training course; trainees do not matriculate to the next phase until all prior phases are mastered. Additionally, CSR data collectors will be trained on: 1) specific interviews to be conducted for each wave of data collection; 2) handling problems or questions during data collection; and 3) data monitoring and quality assurance procedures. Training will include demonstrations of effective data collection interviews using the computer-assisted telephone interview software (CATI). Following demonstrations and practice sessions, data collectors will role-play and receive feedback until they have reached 100% compliance with guidelines for data collection integrity.

C.11. Quality Assurance of Recruitment and Data Collection. ***(PC-2)*** Job performance of data collectors will be closely monitored by the project manager and the IU Center for Survey Research (CSR) supervisors to ensure their adherence to the study protocol. Telephone interviewing stations at the CSR allow supervisors to listen to interviews and view data collectors' computer screens remotely in real-time without the knowledge of the interviewers. All data collectors will be monitored regularly, with a goal of once during every shift. One monitoring session will include listening to at least 20 interview questions. The project manager will routinely listen to randomly recorded recruitment calls to ensure

adherence to the recruitment script and handling of refusals. Ten percent of all interviews and recruitment calls will be monitored for quality assurance purposes. Feedback will be provided after monitoring sessions to correct any performance weaknesses.

C.12. Sample Size, Power Analyses *(RQ-2, RQ-4, IR-3)*. The revised sample size estimate of 115 per group for analyses is based on ensuring adequate power for Aim 1 (see Table 4). The main objective is to compare the 12-month CRC screening rates with any test among the three groups, so the binary outcome of any CRC screening test completion at 12 months as documented in the electronic medical record has driven calculation of our sample size. For Aim 1, we will first test whether there is any overall group difference in CRC screening completion rates using a chi-square test at 5% significance level. If a significant difference is observed, pairwise comparisons will be conducted at α=1.7% (5%/3 pairwise tests) to account for multiple testing. Expected CRC screening rates, based on prior studies demonstrating the effects of computer-tailored and PN interventions, are shown in Tables 1 and 2, respectively. We have revised our DVD only effect calculations from the original estimate of 15.5% to 20% for this group. We originally proposed a DVD only effect size of 15.5% based upon the average effect size of studies listed in Table 1. This 15.5% estimate assumed that the lowest rate observed in the DVD only group might be near 20% (Rawl, 2015) and lowered that rate even further to 15.5% to be more conservative, as statisticians typically assume very conservative effects when doing power calculations. However, by assuming a value closer to, but still less than the lowest rate observed in the literature for a comparable population (which was 22% seen in Rawl, 2015 per Table 1), the samples sizes can be reduced to 115 per group for Aim 1. This sample size will afford at least 80% power for all three comparisons per Table 4 below. To allow for an approximate 25% attrition which the project is experiencing as of May 31, 2019 and still have 115 per group for analyses, a total sample size of 450 enrolled subjects is required.

Table 4. Revising the expected rate in the DVD group to 20% (still smaller than the smallest rate for a tailored intervention in Table 1)

Comparison	Rates	Sample Size for Groups	Power
PN+DVD vs DVD only	44% vs 20%	115 vs 115	92%
PN+DVD vs Usual Care	44% vs 5%	115 vs 115	99%
DVD only vs Usual Care	20% vs 5%	115 vs 115	80%

Several studies have shown that patient navigation is an effective method to increase CRC screening rates especially in minority groups with effect sizes shown in Table 2 (average of 33.7). We conservatively estimated a 44% (less than 33.7 + 20 = 54%) effect size for the PN + DVD since we will enroll patients who have previously canceled a screening colonoscopy appointment. For usual care, we used the estimate from Rawl, 2015 in Table 1 as it is most similar to the proposed study. See Table 5 below for summary. At 12 months, 115 in each group will yield at least 80% power for detecting the pair-wise differences (44% v. 20% v. 5%) in completion rates among the three groups using pair-wise chi-square tests or bivariate logistic regression models and a two-sided α=.017 level. Back-calculation, assuming an attrition rate that is approximately 25% from the sample size needed at 12 months, it requires that we approach 600 eligible subjects to enroll 450 (75% participation rate) and randomly assign them to the three intervention groups (150 per group). By 12 months, the 150 in each intervention group will decrease to 115 through an approximate 25% attrition. The multivariable logistic regression models for the intervention effect on the CRC screening completion outcome while accounting for covariates will very likely have greater than 80% power, more than for the bivariate models because a smaller sample size is required when covariates are added to the model.[99] In addition, this sample size will most likely ensure greater than 80% power for other outcomes of Aim 1 (quality of bowel preparation, anxiety, and satisfaction) because they are continuous or ordinal variables. Specifically, the analysis of continuous outcomes using a general linear model will have 99% power to detect a

Table 5. Power Analyses

Time/Test	PN plus DVD (n=115 at 9 mos)	DVD only (n=115 at 9 mos)	Usual Care (n=115 at 9 mos)	Power
9 month/ Any Test	44%	20%	5%	.80-.99

small effect size of .50 standard deviation units between outcome means, and the ordinal logistic regression models will have more information than the binary models.

For Aim 2, our main interest is in whether the intervention effects differ by age, race, gender, and income. We consider this aim to be exploratory as we do not have preliminary data to estimate the effect sizes; however, we feel it is important to explore interactions in this study as they may identify subgroups of patients who may not need the more intensive support of a PN. For Aim 3, the revised sample size of 115 per group will allow for the detection of mediation effects with 80% power assuming the effect sizes from the intervention to mediator and from the mediator to outcome are moderate or higher (which is what is typically assumed in a power calculation). For Aim 3, to test mediation effects, we will use the percentile bootstrap method to estimate the indirect/mediated effect.[100] Simulations of the two-path mediation model in Mplus[101] (Table 2) show that 115 subjects per group are needed to have 80% power to test the total indirect effect using the Sobel approach when the effect of the independent variable (the intervention variable here) on the mediator is small (.2) and independent variable on outcome is medium (.39). Using the percentile bootstrap method instead of Sobel should afford the same or greater power.

C.13. Data Analyses. ***(IR-3, IR-5, MD-3, MD-5, HT-1, HT-2, HT-3, HT-4)*** Preliminary analyses will compare baseline demographic information across groups using means and standard deviations for continuous variables and frequency distributions for categorical variables. We will adjust for those characteristics in subsequent analyses if significant differences emerge at a conservative level for inclusion of a covariate (p<.20). Characteristics of participants who drop out by 9 months will be compared with those who remain to determine what biases may exist. ***(MD-4)*** The above analyses will be conducted using ANOVA, chi-square tests, or exact or non-parametric equivalents. If there appear to be biases in dropout, we will conduct pattern mixture models analyses to see how the results could change based on the MAR assumption ***(IR-5, MD-2, MD-3, MD-5).*** Primary analysis of outcomes will employ an intent-to-treat analysis; all participants will be included regardless of compliance with interventions. The main outcome, CRC screening completion with any test (FIT or colonoscopy) will be extracted from medical records for all participants, including those who drop out or are lost to follow-up. Intervention exposure will be measured and its effects will be accounted for in the intent-to-treat analysis. First, we will know whether participants viewed none, part, or all of the DVD. Second, we will document how many contacts PNs make to or on behalf of participants assigned to that group. These variables (viewed none/part/ or all of the DVD and number of navigator contacts) will be added as covariates in analyses. For all aims, sensitivity analysis will be conducted as needed for each outcome to assess the effects of the model assumptions on the results ***(IR-5).*** Assumptions, such as normality of residuals, will be checked and appropriate modifications to the analysis plan applied if needed, such as transformations or use of non-parametric methods. From our prior studies, we expect missing data to be minimal (less than 2%) for subjects during participation. For missing data on scales, we will use mean imputation as long as two-thirds of the questions have been answered (or per validated instrument instructions, if otherwise). ***(MD-2, MD-3)***

For Aim 1, we will test the primary hypothesis related to comparing intervention effects among the three randomized groups (H1.1: PN+DVD vs. DVD only and H1.2: PN+DVD vs. usual care and DVD only vs. usual care) using the outcome of completion of CRC screening using *any test* at 12 months post-baseline. In addition, quality of bowel preparation, procedural anxiety, and satisfaction with the screening experience will be examined as outcomes. As an initial assessment of CRC screening completion at 12 months, we will use a chi-square test for a 3 x 2 (group by screening completion) contingency table to test whether completion rates differ across groups. If the p-value for the overall test is significant at the .05 level, pair-wise 2 x 2 tests will be conducted at the .05/3=.017 level. However, the primary analyses for Aim 1 will involve fitting multivariable logistic regression models of the primary outcome of 12-month CRC screening test completion (yes/no). Independent variables will be group assignment and continuous and categorical individual characteristics. These models will also allow us to investigate intervention effects on CRC screening test completion while adjusting for potential confounders. Group assignment will be coded using dummy variables with usual care as the reference category. For H1.3, quality of bowel preparation will be analyzed for those participants who complete colonoscopy with proportional-odds ordinal logistic regression using an ordinal dependent variable *(1=excellent, 2=good, 3=fair, 4=poor, 5=inadequate*). If some outcome categories are sparse, the outcome will be dichotomized into adequate

(*excellent or good*) versus inadequate (*fair, poor, or inadequate*). The outcomes of anxiety and satisfaction are continuous outcomes and will be modeled with linear regression.

Aim 2. Examine age, race/ethnicity, sex and income as potential moderators of intervention effects. *(RQ-4, HT-1, HT-2, HT-3, HT-4)* We will fit multivariable models as in Aim 1, except now including interaction terms for age (< 65, age 65+), race/ethnicity (Non-hispanic Black, Non-hispanic White), sex (male, female), and annual income (<$15,000, ≥$15,000), respectively. Moderators will be identified by significant interaction terms in regression models. The key moderation effects of interest will be between PN+DVD vs. DVD only. Moderation of PN+DVD vs. usual care, and DVD only vs. usual care also will be examined. Hispanics will be excluded from race/ethnicity interaction tests due to small sample sizes.

Aim 3. Examine changes in knowledge and health beliefs (knowledge, perceived risk, perceived benefits, barriers, and self-efficacy) as potential mediators of intervention effects. *(RQ-6)* Mediation analysis will be conducted to identify potential mediators. Specifically, for each of the variables (changes in knowledge, perceived risk, perceived benefits, perceived barriers, and self-efficacy) mediation effects will be estimated in an logistic regression setting, fitting the appropriate mediation models using MPlus[100] and then testing indirect effects using the percentile bootstrap approach to estimate the indirect effect.[101] We will fit models that estimate the effects of PN plus DVD vs usual care and DVD only vs usual care, and also models that compare the strength of the indirect effects between the PN plus DVD and DVD only arms. We expect to see a difference in mediation effects mainly on barriers, with the PN plus DVD having a greater mediation effect on barriers than DVD only.

C.14. Potential problems, strategies and benchmarks for success. Potential problems are described below along with plans to minimize them. ***(IR-6, MD-1, MD-2, MD-4***)

- *Loss to follow-up:* It is anticipated that there will be some loss to follow-up because of participant dropout, death, or relocation. Based attrition data through May 31,2019 , we estimate the loss to be approximately 25% over the 9-month study period, which has been accounted for in the revised power analysis and sample size determination.
- *Limited internal validity:* Randomization will minimize the influence of extraneous variables on outcomes.
- *Missing data*: Missing data will be minimized through the use of telephone data collection methods and through interviewer training. All characteristics at baseline will be examined to determine potential bias that would require subsequent caution regarding interpretation of results.
- *Limited generalizability*: We will recruit participants from one safety net system who will be predominantly low-income, which limits generalizability. However, we will compare outcomes for a racially diverse group of low-income patients and explore whether age, sex, or race/ethnicity moderate the effects of the two interventions. ***(RQ-4, IR-6)***
- *Sample bias*: Based on our preliminary studies, we estimate that approximately 55% of eligible people who are contacted will be willing to participate. It is possible that those who are motivated to complete CRC screening will self-select into the study. To examine the representativeness of our sample, we will compare demographic characteristics of those who agree to participate with those who do not. ***(PC-2, IR-6)***

C.15. Impact: At the completion of this study, we will have developed two theory-based and highly translatable and easy to disseminate interventions to promote CRC screening and improve quality of bowel preparation for those who undergo colonoscopy. These interventions will be designed to be flexible and modifiable as science advances and as the needs of individual patients and health care systems change. Interventions that are easily modified to meet the needs of diverse populations and settings that counsel patients about the need for CRC screening, support them to complete screening in a timely manner, and assist those who undergo colonoscopy to properly prepare (cleanse their bowel) for the procedure are urgently needed. Knowledge of the comparative effectiveness of these interventions will inform the next steps required for translation of interventions into clinical practice.

D. Project Timeline and Milestones

Activity by Quarter: Beginning with July 2016	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2 (NCE: 6 Mo)
Finalize protocol/ IRB approval	X																	
Registration of trial on clinical trials.gov	X																	
Advertise/hire research staff	X																	
Training research staff	X	X																
Intervention refinement	X	X	X															
Stakeholder/Comm. Advisory Board meetings	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Intervention pre-testing			X															
Development/testing of databases		X	X															
Participant enrollment (n=450)					X	X	X	X	X	X	X	X	X					
Completion of 25% of enrollment (n=113)								X										
Completion of 50% of enrollment (n225)									X									
Completion of 75% of enrollment (n=338)											X							
Completion of 100% of enrollment (n=450)													X					
Baseline interviews, intervention delivery					X	X	X	X	X	X	X	X	X	X	X			
Process evaluation interviews					X	X	X	X	X	X	X	X	X	X	X			
6 month interviews							X	X	X	X	X	X	X	X	X			
9 month interviews								X	X	X	X	X	X	X	X	X		
Medical record audits									X	X	X	X	X	X	X	X	X	
Data cleaning and preliminary analyses											X	X	X	X	X	X		
Analysis, write-up, dissemination														X	X	X	X	X
Datasets and codebooks prepared for sharing																	X	X
PCORI Reports		X		X		X		X		X		X		X		X		X

Meetings of investigators and stakeholders will be on-going throughout the study period. All investigators will attend monthly research team meetings. Clinical and patient stakeholders will meet with investigators every other month during the first 9 months of the study. Stakeholder meetings will be held quarterly throughout the remainder of the funding period. Other milestones are reflected in the timeline and include:

- **Start-up** will occur during the first 2-3 months of the proposed project and will involve finalizing the study protocol, obtaining IRB approval, and hiring and training research staff. In addition, the patient navigation and tailored DVD interventions will be refined, with patient navigators hired and trained, during the first 9 months.
- **Participant enrollment and baseline data collection** will begin in Month 13 and continue for 24 months, accruing approximately 20 participants per month or 5 each week.
- **Intervention delivery** will begin in month 14 and continue for 28 months
- **Follow-up data collection** will occur at 6 months after the baseline interview (T2) and at 9 months post-baseline (T3). Process interviews also will be conducted to assess receipt, viewing (of the DVD), and satisfaction with the interventions.
- **Data analysis,** reports, abstracts, and publications will be prepared during the final 15 months of the study.
- **A 6 month no cost extension period** will allow us to complete the 12 month EMR review, conduct data cleaning and analyses, and prepare the Final Progress Report.

E. Patient Population (*RQ-2, RQ-3, RQ-4, PC-1, PC-2)*

E.1. Sample and eligibility criteria. 450 people who canceled or did not attend their colonoscopy appointment will be enrolled in this study. Participants will be eligible if they are 50-75 years old if non-African American or 45-75 years old if African American and were referred to Eskenazi's endoscopy unit for a colonoscopy. Stratified block random assignment to each of three groups will be performed within 12 strata formed by crossing sex, three race/ethnicity groups, and two age levels (male/female, Black/White/Hispanic, age<65/age 65+) to ensure that the three randomized groups are comparable in distribution of sex, race/ethnicity, and age. At the completion of the baseline interview, patients will be randomly assigned to the tailored DVD-only group, the tailored DVD plus patient navigator group, or usual care. Based on the 65% participation rate we achieved in our recent R01 conducted in this same health system, we conservatively estimated our participation rate at 55%. However, our actual, cumulative participation rate for eligible subjects was 75% through May 31, 2019. Therefore, we will need to contact approximately 600 eligible people to enroll 450. Data from 2014

indicate the availability of 1150 potentially eligible patients during that 12 month period (See Table 6). An estimated 2200 would be available over the 24 month enrollment period. Based on our preliminary studies, no more than 20% attrition was anticipated at 9 months. Actual data from Year 3 of this project as of May 31, 2019 shows an attrition rate closer to 25% at the 6 month follow-up timepoint. This approximate 25% rate is being used in re-calculating the sample size required.

Table 6. Colonoscopy orders, completion rates and non-completion rates by race/ethnicity and gender

Race/ethnicity	Colonoscopies ordered N	Colonoscopies ordered %	Colonoscopies completed N	Colonoscopies completed %	Colonoscopies NOT completed N	Colonoscopies NOT completed %
Black/African American	1254	64%	505	40.3%	749	59.7%
White/Caucasian	664	34%	280	42.2%	384	57.8%
Hispanic	44	2%	26	59.1%	18	40.9%
Sex: Male	806	41%	324	40.2%	482	59.8%
Female	1156	59%	487	42.1%	669	57.9%
Total	**1962**	**100%**	**811**	**41.3%**	**1151**	**58.7%**

E.2. Study Site, Colonoscopy Referral, and Scheduling Process. Patients who have been scheduled for, but not completed, colonoscopy at the endoscopy department in our local safety net health system will be recruited. The Eskenazi Endoscopy Department has 4 procedure rooms and is staffed each day by 2-3 gastroenterologists. In a recent 12-month period, 5,702 procedures were performed, with an average of 20-35 scheduled daily. Colonoscopy referrals come from nine clinics/community health centers that comprise the Eskenazi Primary Care Network/ Community Health Centers. Eskenazi Community Health Centers see approximately 205,000 patient visits/ year, with 50% of visits financed by Medicare or Medicaid and 40% financed by the county indigent care health insurance program or self-pay. The indigent care program provides financial assistance to patients at or below 200% of the federal poverty level who have inadequate or no healthcare coverage. The Eskenazi clinics and endoscopy department use an integrated electronic medical record (EMR) system as their clinical data repository for patient care. Primary care providers enter referrals (orders) for colonoscopy into the EMR and patients are automatically scheduled using an open access system (i.e., no appointment with a gastroenterologist required). The referral is sent electronically via the EMR from the primary care clinic to the endoscopy unit. Within one week, patients receive a letter with their colonoscopy appointment date/time along with written instructions for preparing for the test and for rescheduling if they cannot attend. Reminder calls are placed by an endoscopy nurse 1-2 days prior to the appointment. Most of the cost for colonoscopy is covered by the indigent care program. Patients with commercial or governmental coverage pay the amount specified by their insurer; those without insurance who have household incomes below 200% of poverty are eligible for the indigent care program and pay $40 for colonoscopy. Patients without insurance who do not qualify for the indigent care program pay 50% of the cost at the time of scheduling and 25% after the test is complete.

E.3 Recruitment. Trained study staff will recruit participants using procedures consistent with clinic and HIPAA requirements. On a weekly basis, Eskenazi Health IT department will generate lists of age-eligible patients at average risk who did not attend their colonoscopy appointment. The list will include 2 groups of average risk patients who missed their appointment: 1) patients who had a colonoscopy screening ordered; and 2) patients who had a recent fecal immunochemical test (FIT) that was positive with a follow-up order for colonoscopy. Due to differences in physician ordering practices, the follow-up colonoscopy can be ordered as a colonoscopy screening, colonoscopy diagnostic, or colonoscopy high risk. Patients will be approved for contact by Dr. Fatima, Director of the Eskenazi Health Endoscopy Department. Patient information will be released to the study's data manager, the Eskenazi Endoscopy Department's Patient Navigator nurse, and trained research staff at the IU School of Nursing using secure electronic data transfer methods. Information disclosed is limited to that which is necessary to determine eligibility and to contact patients by mail and telephone. As a first step, the Endoscopy Patient Navigator nurse will screen patients by looking back 10 years and excluding any with a history of adenomatous polyps, sessile serrated polyps, or any mass suggestive of neoplasia. Patients with a history of hyperplastic polyps, lymphoid tissue, or no polyps will be recruited. Research staff at the IU

School of Nursing will send introductory letters, signed by the Principal Investigator and a co-investigator who is a member of the Eskenazi Medical Staff, along with a recruitment brochure and Study Information Sheet that explains the study to all approved patients. The letter informs patients that they will receive a phone call about the study within the next week unless they call a toll-free number to indicate they do not wish to be contacted. One week after letters are mailed, trained recruiters at the School of Nursing will contact potentially eligible participants who have not called the toll-free number. Recruiters will explain the study and answer questions about study requirements, potential risks, and compensation. Adequate speech, hearing, and cognition of potential participants will be confirmed by recruiters based upon the phone conversation. They will then proceed to determine eligibility, obtain both verbal informed consent and verbal HIPAA Authorization, and schedule a convenient time to conduct the baseline interview. Each participant who is not reached will be called back up to, but no more than, 10 times. Recruiters will document each call attempt including the date, time, disposition, and callback preference. Participants who decline to participate will be thanked for their time, with their response and reason for refusal recorded. Proposed recruitment procedures have been previously tested and found to be successful in our prior studies. Any unanticipated challenges to recruitment will be discussed with the research team, our CAB and clinical stakeholders.

F. Research Team and Environment

Research Team Experience. This proposal builds upon extensive preliminary work conducted by these investigators at Indiana and the Ohio State Universities. Dr. Rawl's program of research began with development of valid and reliable instruments to measure health beliefs about CRC screening. We then developed and tested theory-based interventions to promote discussions about risk-appropriate CRC testing between patients and providers. Drs. Rawl, Champion, Imperiale, and Perkins recently completed a randomized trial of a tablet-based, computer-tailored intervention to increase CRC screening among 672 African American patients in primary care settings. Drs. Rawl, Schwartz and Imperiale are collaborating on a PCORI-funded study to examine the impact of including detailed quantitative information into a decision aid for CRC screening (Schwartz, PI). Ms. Rivienne Shedd-Steele, Director of the Indiana University Simon Cancer Center's Office of Health Disparities and Community Outreach, has been a long-term collaborator with this team. She has been instrumental in assisting with identification of patients and community leaders who have served as Community Advisory Board members on numerous studies. During the past year, Drs. Rawl and Fatima and two Eskenazi endoscopy nurses collaborated on a mixed methods pilot study to examine barriers and facilitators of colonoscopy completion among Eskenazi patients. Through in-depth telephone interviews, we heard directly from patients about the challenges they face regarding colonoscopy. Drs. Paskett and Katz are lead investigators at The Ohio State University, one of nine sites that comprise the National Patient Navigation Research Program. This program has tested the effects of patient navigation for people with abnormal screening results. Their expertise in designing and testing navigation as an intervention is essential to this project. Eo Studios President and CEO, Mark Magnarella, has extensive experience developing award-winning health media including tailored DVD and web-based programs such as our tailored tablet-based intervention and our web-based intervention to promote mammography. His company's collaboration on refinement of the DVD and producing both web-based and DVD-based delivery formats is also essential to the success of this project.

Data collection methods, instruments, recruitment procedures, training protocols, and theory-based interventions tested in our preliminary studies provide strong evidence that the proposed methods are both feasible and effective. This study represents the logical next step in our active program of research to test innovative approaches to increase CRC screening. This highly qualified team of investigators has a strong history of collaboration and extensive experience conducting behavioral, intervention, and health services research.

Please see the *People and Places* section for biosketches of all key personnel and detailed site descriptions.

Study Site: Eskenazi Hospital and Health System is the local safety net health system serving residents of Marion County, Indiana, and the metropolitan Indianapolis area. The Eskenazi Endoscopy Department has 4 procedure rooms and is staffed each day by 2-3 gastroenterologists. In a recent 12-month period, 5,702 procedures were performed, with an average of 20-35 scheduled daily. Colonoscopy referrals come from nine clinics/community health centers that comprise the Eskenazi Primary Care Network/ Community Health Centers. These centers see approximately 205,000 patient visits/ year, with 50% of visits financed by Medicare or Medicaid and 40% financed by the county indigent care health insurance program or self-

pay. The indigent care program provides financial assistance to patients at or below 200% of the federal poverty level who have inadequate or no healthcare coverage. The Eskenazi clinics and endoscopy department use an integrated electronic medical record (EMR) system as their clinical data repository for patient care. Primary care providers enter referrals (orders) for colonoscopy into the EMR and patients are automatically scheduled using an open access system (i.e., no appointment with a gastroenterologist required). The referral is sent electronically via the EMR from the primary care clinic to the endoscopy unit. Within one week, patients receive a letter with their colonoscopy appointment date/time along with written instructions for preparing for the test and for rescheduling if they cannot attend. Reminder calls are placed by a clinic secretary 1-2 days prior to the scheduled appointment. The non-completion rate was 59% in 2014 meaning that approximately 1150 people went unscreened for CRC in that one-year period.

G. Engagement Plan (*PC-1, PC-3, PC-4, RQ-2, RQ-5, RQ-6*)

G1. PLANNING THE STUDY:

A diverse 6-member Community Advisory Board (CAB) was actively engaged in the planning of this study, providing valuable input and critique of the proposed plan. The following individuals participated in a 2-hour dinner meeting during which the PI provided background information about CRC, past studies completed, and the proposed study aims, design, and interventions. All members expressed great enthusiasm about the study, believed it was an important topic that is highly relevant to their communities, and provided helpful feedback regarding what should be included. All six agreed to continue to work on this project as members of the CAB and are described below.

Ms. Sandra Bailey is a 56-year-old African American woman who receives health care at Eskenazi Health. Ms. Bailey is a resident of, and a community leader in, the Indianapolis Housing Authority (IHA). She regularly arranges educational opportunities, including health education for IHA residents, most of whom are low-income minorities.
Mr. Robert Breskow is a 55-year-old Caucasian man who resides in Indianapolis and receives his health care through Eskenazi Health Hospital and its clinics. He is a strong advocate for colon cancer screening.
Ms. Beatrice Cork is a 62-year-old African American woman whose mother and father died from colon cancer. Ms. Cork was a member of our Community Advisory Board for our recent study to increase CRC screening for African Americans.
Mr. Thomas Griffin is a 61-year-old African American who is the President of the Indianapolis Chapter of Indiana Black Expo, an annual 5-day event that includes the largest minority health fair in the U.S. and draws African Americans from across the country to Indianapolis every July. Mr. Griffin receives his health care at Eskenazi Health.
Mr. Juan Lagunes is a 51-year-old Latino who also receives health care at Eskenazi Health. Mr. Lagunes is actively involved as a leader of the Hispanic/Latino Ministry at Christ Church Cathedral in Indianapolis.
Dr. Ruth Lambert, PhD, is a retired 72-year-old African American colon cancer survivor who is passionate about community partnerships and engaging as many people in CRC screening as possible.
Mr. Jack Quick is a 70-year-old Caucasian man who also resides in Indianapolis and receives his health care through Eskenazi Health Hospital and its clinics. He is a strong advocate for colonoscopy.
Ms. Sylvia Strom is a 60-year-old Latina who works as the Bilingual Family Advocate and Latino Services Coordinator at the Julian Center, a women's shelter in Indianapolis. She has extensive experience working with the populations served at Eskenazi Health and has assisted many women to access care at Eskenazi. As a Latina fluent in English and Spanish, Ms. Strom will bring an important cultural perspective and language skills to this study.

Clinical stakeholders from the Eskenazi Health Endoscopy Department (Drs. Hala Fatima, who is the Medical Director of the Endoscopy Unit, and Ms. Kimberly Mitchell, Nurse Manager) have been intimately involved in various aspects of this study from identifying the problem, to designing the study, and selecting the comparators (tailored DVD alone vs. DVD + navigation vs. usual care). These clinical stakeholders were actively engaged in discussions to interpret results from an RCT we completed in 2013 (1R01-CA115983; Rawl, PI). Though we had a significant intervention effect in that trial with 27% of African American primary care patients obtaining CRC screening at 6 months post-baseline, 73% of our participants remained unscreened. Further, our data showed that most of these unscreened participants had received a referral for screening colonoscopy from their provider but had not completed that test. Our clinical stakeholders reported that almost

50% of their patients who were scheduled for colonoscopy in their unit either canceled (and did not reschedule) or simply did not show up for their appointments. In addition, at least 6-7 of the patients who come to the endoscopy unit each day (of approximately 30 scheduled) return home without completing the test because they had not been able to complete the bowel preparation process. These patients are often upset about the test being canceled and many do not return or reschedule. Our clinical stakeholders specifically requested assistance to conduct this study to test approaches to better assist patients to prepare for colonoscopy, to improve the colonoscopy experience for patients, and to increase colonoscopy completion rates.

As our next step to prepare this application, Dr. Fatima and two gastroenterology nurses were active collaborators on a preliminary mixed-methods study in which we collected quantitative and qualitative data via telephone interviews. In this study, we heard directly from patients who had and had not completed colonoscopy after receiving a recommendation from their provider. Our quantitative data clearly showed that *knowledge of colorectal cancer and screening* was significantly higher among the completers. In qualitative interviews, 100% of patients reported that their primary care provider had recommended colonoscopy as the only CRC screening test and no alternative tests were offered. Almost a quarter (23%) of patients who did not complete colonoscopy reported that the main reason they did not get a colonoscopy was that their provider never explained what a colonoscopy was and why it was needed – this was the most common reason given. Other barriers to completion were life events (family crises/illness/death) and logistical problems with transportation and finances. **We have designed this study to compare two interventions that will increase knowledge about CRC, screening test options, and personal risk for the disease; increase perceptions of benefits of and self-efficacy for screening, and assist patients to overcome common barriers to CRC screening**.

G2. CONDUCTING THE STUDY:

Patient Partners: The **Community Advisory Board** is described above and consists of 8 people; 4 men and 4 women from, and/or familiar with, the target population. The CAB will be involved in the refinement, dissemination, and implementation of the tailored DVD and the PN interventions. They will also remain engaged throughout the study period and will consult on study implementation (recruitment, intervention delivery) and methods to ensure widespread dissemination of results. Ms. Rivienne Shedd-Steele, Director of the Indiana University Simon Cancer Center's Office of Health Disparities and Community Outreach, works closely with several community groups that will be consulted about this study. These include the Indiana Minority Health Coalition (an active, longstanding statewide coalition), the Indiana Cancer Consortium (a statewide consortium of 60 organizations committed to reducing the burden from cancer), and the Indiana University Simon Cancer Center's Health Disparities Advisory Committee. Ms. Steele has assisted by engaging these groups to recruit Community Advisory Board members and disseminate results.

Ms. Sylvia Strom will serve as the Chair of our CAB and attend monthly research team meetings. As a Latina fluent in English and Spanish, Ms. Strom will bring an important cultural perspective and familiarity with numerous Latino groups to this study. We have reviewed the 4-year timeline for this project and Ms. Strom commits to chairing 6 Board meetings in the first year and quarterly meetings in subsequent years. She agreed to be compensated for working closely with our research team and understands that her responsibilities will be to attend research team meetings, to assist with intervention refinement in the first year, and with implementing the study in Years 2 and 3. In Year 4, she will participate in discussions about analyzing data, understanding the meaning of results, and sharing the findings with important audiences.

Clinical Stakeholders: **Dr. Hala Fatima**, Medical Director of Endoscopy at Eskenazi, and **Ms. Rita Reynolds**, Eskenazi Endoscopy Patient Navigator nurse, will be actively engaged in several aspects of implementing the study. They will assist with development of procedures to identify eligible patients and with refinement of recruitment materials that are consistent with clinic, IRB, and HIPAA requirements. Drs. Fatima and Imperiale will assist with measurement of quality of bowel preparation as well as collection and interpretation of these data from medical records. All clinical stakeholders will participate in regular team meetings and in data analyses, interpretation, and dissemination of study results. Ms. Reynolds will assist with refinement of the tailored DVD and patient navigation interventions as well as navigator training.

See letters of support from our patient partners and clinical stakeholders.

G3. DISSEMINATING THE STUDY RESULTS: *(PC-4)*

The investigators bring a diverse, interdisciplinary perspective to the proposed research and commit to disseminating results of this study through a variety of mechanisms including publications in professional journals and presentations at professional and research meetings. For example, Drs. Rawl, Carter-Harris and Champion will present findings at national/international research meetings including the Society of Behavioral Medicine, the American Society of Preventive Oncology, and the Oncology Nursing Society. Drs. Imperiale and Fatima are gastroenterologists and clinical researchers who will present findings at Digestive Diseases Week and other meetings attended by clinical gastroenterologists. Dr. Schwartz is a clinical scientist and primary care physician who will share findings at the Society for Medical Decision-Making annual conference. Ms. Reynolds, our clinical stakeholder will assist in disseminating results to endoscopy nurses attending regional and national meetings.

In addition to sharing results with professional groups, we will disseminate our findings through numerous local, regional and statewide mechanisms. Ms. Strom, Ms. Shedd-Steele, and Community Advisory Board members will assist with preparation of lay summaries of the study findings and identification of venues for distributing results. CAB members represent influential community organizations through which widespread dissemination can occur including the Indiana Black Expo, The Indiana Minority Health Coalition, The Hispanic/Latino Ministry of Christ Church Cathedral, and the Indianapolis Housing Authority. The Indiana Cancer Consortium publishes quarterly newsletters and holds an annual meeting where study results can be disseminated. This meeting is attended by a diverse group of members representing more than 60 organizations committed to reducing the burden of cancer in Indiana. The Indiana Minority Coalition has an annual meeting where results can be shared with members of that statewide coalition. Results will be disseminated to lay audiences by publishing summaries in The Indianapolis Recorder and the Indiana Herald, two weekly publications that are widely read by members of the African American Community. Results also will be published in lay publications read by Spanish-speaking residents of the metropolitan Indianapolis area.

G4. PRINCIPLES FOR ENGAGEMENT *(PC-1)*

Reciprocal Relationships: Members of the research team will meet monthly as a group to monitor study progress and will make decisions in conjunction with patient partners and stakeholders. Minutes will be kept at each meeting and all investigators will attend the first meeting of the Community Advisory Board. Progress reports and issues discussed at both investigator team meetings and Community Advisory Board meetings will be shared.

Co-learning: The next meeting of the Community Advisory Board will include all members of the research team, with introductions and explanations of each person's role and contribution to the project. At that meeting, we will focus on an overview of the study and the research process. At subsequent meetings during the first 9 months, we will focus on refinement of the intervention, obtaining patient advisor perspectives on all aspects of the tailored DVD and navigator interventions to maximize effectiveness. Meetings in the remaining years of this study will focus on the challenges faced in implementing the study, solutions to these challenges, analyses of data, interpretation of findings, and creative approaches to disseminating results to participants, professional and lay audiences, health systems and others.

Partnership: Patient partners include Ms. Sylvia Strom and the other 5 members of our Community Advisory Board. Meetings of this group will be scheduled by the PI and project manager at times that are convenient for these partners. Ms. Strom has agreed to co-chair the Community Advisory Board meetings which will occur every two months during the first 9 months of the project to assist with intervention refinement and then quarterly thereafter. Ms. Strom will be compensated for her time, energy, and expertise with a consulting fee of $2400 for the first year and $2000 in each remaining year of the project. CAB members will receive $150 for each 2-hour meeting they attend.

Trust, Transparency, Honesty: At each Community Advisory Board meeting, a progress report will be provided to update partners on the status of the study. At these meetings we will present challenges faced in implementing the study and obtain partner input on how to improve study processes and outcomes. Navigators will be invited to discuss (anonymously) the types of support and assistance needed by participants and resources used; partners will be invited to make comments or suggestions. At the end of each meeting, members of the Community Advisory Board will be given the opportunity to meet privately with the PI to share any concerns or make any additional suggestions.

DISSEMINATION AND IMPLEMENTATION POTENTIAL

For detailed instructions, refer to the Application Guidelines for your PFA. Do not exceed two pages.

A. **Describe the potential for disseminating and implementing the results of this research in other settings.**

Dissemination of Results to Clinical Stakeholders and Researchers

The investigators bring a diverse, interdisciplinary perspective to the proposed research and commit to disseminating results of this study through a variety of mechanisms including publications in professional journals and presentations at professional and research meetings. For example, Drs. Rawl, Carter-Harris, and Champion will present findings at national/international research meetings including the Society of Behavioral Medicine, the American Society of Preventive Oncology, and the Oncology Nursing Society. Dr. Schwartz is a clinical scientist and primary care physician who will share findings at the Society for Medical Decision-Making annual conference. Drs. Imperiale and Fatima are gastroenterologists and clinical researchers who will present findings at Digestive Diseases Week and other meetings attended by gastroenterologists. Ms. Reynolds, another clinical stakeholder, will assist in disseminating results to endoscopy nurses attending regional and national meetings.

Dissemination of Results to Patients and Communities

In addition to sharing results with relevant professional groups, we will disseminate our findings through numerous local, regional and statewide mechanisms. Ms. Strom, Ms. Shedd-Steele, and our Community Advisory Board members will assist with preparation of lay summaries of the study findings and identification of other venues for distributing study results. The Indiana Cancer Consortium publishes quarterly newsletters and holds an annual meeting where study results can be disseminated. This meeting is attended by a diverse group of members representing more than 60 organizations committed to reducing the burden of cancer in Indiana. The Indiana Minority Coalition has an annual meeting where results can be shared with members of that statewide coalition. Results will be disseminated to lay audiences by publishing summaries in The Indianapolis Recorder and the Indiana Herald, two weekly publications that are widely read by members of the African American Community. Results also will be published in lay publications read by Spanish-speaking residents of the metropolitan Indianapolis area.

B. Describe possible barriers to disseminating and implementing the results of this research in other settings.

Because we cannot predict with certainty what the results of this trial will show, it is difficult to predict the barriers to dissemination and implementation. If both interventions are found to be effective, then health systems could choose to make one or both types of interventions available to patients, depending on available resources. Regardless of whether overall effects are weak or strong, analyses to examine whether interventions are more or less effective for different age groups, men, women and/or participants of different races/ethnicities will be useful. If no overall effects are observed and no moderators identified, the challenge will be to explain such null findings.

Translation to clinical practice rarely occurs based on results from one trial. Although this study will make an important contribution and generate new knowledge about comparative effectiveness, additional research to confirm these results or examine whether effects can be replicated with other populations will be needed. Another barrier to dissemination and implementation may be related to concerns about the generalizability of our findings. Since this study is specifically focused on one safety net health system, it will be necessary to compare the effects of these interventions in other settings including, but not limited to, similar safety net systems that serve predominantly low-income, ethnically-diverse populations.

C. Describe how you will make study results available to study participants after you complete your analyses.

In collaboration with our Community Advisory Board, we will develop a newsletter that will be mailed to study participants to share study results. If the IRB approves the use of a Spanish version of the DVD, use of study documents in Spanish, and Spanish-speaking subjects are enrolled, then both English and Spanish versions of the newsletter will be developed.

REPLICATION AND REPRODUCIBILITY OF RESEARCH AND DATA SHARING

For detailed instructions, refer to the Application Guidelines for your PFA. Do not exceed two pages.

A. Describe the ability to reproduce potentially important findings from this research in other data sets and populations.

It is expected that results of any clinical trial must be disseminated within a short time after the end of the trial. If these two health system-based interventions prove to be as successful as we anticipate, our goal will be to disseminate our study outcomes so that others can adapt these interventions to fit their own clinical settings and populations as needed and adopt them. In addition, since one study is seldom sufficient for proving the comparative effectiveness of any interventions, we will share our methods with investigators who may want to replicate our study in other settings. We will clearly describe our methods in publications and share our research protocols and interventions with interested parties who request them.

As part of our progress report at the end of Year 1, we will deliver the complete study protocol as it has been implemented for the study. Included in this protocol will be the study sample, hypotheses being tested, all measures used for the project, and the plan for analyzing data. It is anticipated that this protocol will be altered very little (if at all) from the original proposal submitted for funding. Within three months after the project end date, our variable codebook with data definitions will be available along with detailed explanations of the quantitative data analysis procedures used. All of this information will be provided electronically to interested parties who request it.

In addition, this clinical trial will be registered at **www.clinicaltrials.gov**

The patient navigator intervention, including all support and services provided by navigators, will be carefully documented and captured in an electronic database. Training manuals for recruiters and data collectors that are developed to ensure all data are collected accurately and consistently will be made available to other investigators. We will make the tailored DVD readily available to other health care providers and organizations to download electronically for use in their own settings. This will ensure that the intervention and all elements of the study can be replicated as closely as possible. Samples of the content of both interventions are included elsewhere.

B. Describe how you will make a complete, cleaned, de-identified copy of the final data set used in conducting the final analyses available within nine months of the end of the final year of funding, or your data-sharing plan, including the method by which you will make this data set available, if requested.

We will make SAS and SPSS copies of the complete, cleaned, de-identified final data set used to conduct the final analyses available within nine months of the end of the final year of funding. Data will be available to interested parties per request to the Principal Investigator.

C. Propose a budget to cover costs of your data-sharing plan, if requested.

No additional funds are requested.

PROTECTION OF HUMAN SUBJECTS

For additional guidance, refer to Section 5.0, "Human Subjects Research Policy," of the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports, from the U.S. Department of Health and Human Services. For detailed instructions, refer to the Application Guidelines for your PFA. Do not exceed five pages.

A. Risks to Participants

Human Subjects Involvement and Characteristics: Participants in this study will be non-Hispanic Black, non-Hispanic White, and Hispanic men and women who have been scheduled for colonoscopy at the Eskenazi Health Endoscopy Unit. To protect patient privacy and confidentiality, study recruitment procedures have been developed that are consistent with Indiana University and HIPAA policies governing the use of protected health information for research purposes. These policies require provider consent prior to contacting patients. Permission to contact individual patients will be obtained from the Director of the Endoscopy Department, and introductory letters will be generated by trained recruiters. In addition, the letter introducing the study will include a toll-free number for participants to call if they do not wish to be contacted about the study.

Data/Material Sources: Data will be obtained from self-report via telephone interviews conducted at baseline, at 6 months and at 9 months. CRC screening test completion and quality of bowel preparation will be evaluated through electronic medical records. Data on patient navigator encounters and services provided will be obtained from an electronic database created for navigators to document all contacts they make with, and on behalf of, participants.

Potential Risks: Involvement in the proposed investigation does not present any additional physical risks to participants. The proposed research does involve slight emotional or psychological risk. Possible fear or anxiety may be generated via exposure to messages regarding colorectal cancer, family history, or screening. There is also a potential risk for loss of confidentiality since research team members will know participants' identities. These risks will be described in the Study Information Sheet.

B. Adequacy of Protection Against Risks

Recruitment and Informed Consent: Recruitment of subjects follows a plan approved by the Institutional Review Board at Indiana University Purdue University at Indianapolis. On a weekly basis, Eskenazi Health IT department will generate lists of age-eligible patients at average risk who did not attend their colonoscopy appointment. The list will include 2 groups of average risk patients who missed their appointment: 1) patients who had a colonoscopy screening ordered; and 2) patients who had a recent fecal immunochemical test (FIT) that was positive with a follow-up order for colonoscopy. Due to differences in physician ordering practices, the follow-up colonoscopy can be ordered as a colonoscopy screening, colonoscopy diagnostic, or colonoscopy high risk. Patients will be approved for contact by Dr. Fatima, Director of the Eskenazi Health Endoscopy Department. Patient information will be released to the study's data manager, the Eskenazi Endoscopy Department's Patient Navigator nurse, and trained research staff at the IU School of Nursing using secure electronic data transfer methods. Information disclosed is limited to that which is necessary to determine eligibility and to contact patients by mail and telephone. As a first step, the Endoscopy Patient Navigator nurse or nurse designee will screen patients by looking back 10 years and excluding any with a history of adenomatous polyps, sessile serrated polyps, or any mass suggestive of neoplasia. Patients with a history of hyperplastic polyps, lymphoid tissue, or no polyps will be recruited.

To be eligible, these patients must: 1) have been referred for a colonoscopy that was not done (i.e, canceled or no show); and 2) be 50 to 75 years old if non-African American or 45-75 years old if African American. Patients meeting these inclusion criteria will be excluded for the following reasons: 1) unable to speak, read, and write English; 2) a personal history of having a colonoscopy at a non-Eskenazi Health location where polyps were found and they were the

type that could turn into cancer; 3) FIT negative result in the past 12 months; 4) a personal history of CRC; 5) a personal history of conditions that place them at high risk for CRC such as ulcerative colitis, Crohn's disease, or known hereditary syndromes such as familial adenomatous polyposis or hereditary nonpolyposis colorectal cancer; 6) a family history of CRC which increases their risk; and 7) speech, hearing, cognitive, and/or vision impairment. Trained research staff at the IU School of Nursing will recruit patients using procedures consistent with clinic and HIPAA requirements. Recruiters will send introductory letters, signed by the Principal Investigator and a co-investigator who is a member of the Eskenazi Medical Staff , along with a recruitment brochure and Study Information Sheet that explains the study to all approved patients. The letter informs patients that they will receive a phone call about the study within the next week unless they call a toll-free number to say they do not wish to be contacted. One week after letters are mailed, trained recruiters at the IU School of Nursing will call potentially eligible participants who have not opted-out to explain the study requirements, potential risks and compensation, and answer questions. Adequate speech, hearing, and cognition of potential participants will be confirmed by recruiters based upon the phone conversation. They will then proceed to determine eligibility, obtain both verbal informed consent and verbal HIPAA Authorization, and schedule a convenient time to conduct the baseline interview. Each participant who is not reached will be called back up to, but no more than, 10 times. Recruiters will record each call attempt including the date, time, disposition, and callback preference. Participants who decline to participate will be thanked for their time, with their response and reason for refusal recorded.

Re-contact efforts will be attempted for patients who were originally excluded from the study due to reporting a history of colon polyps (histology type unspecified). Amendment 013, approved by the IRB last year on 5/30/2018, allows patients with a history of benign colon polyps to be included in the study. The Endoscopy Patient Navigator nurse or nurse designee will review the records of these previously excluded patients to determine if: (1) the polyp histology type was benign; and (2) a colonoscopy is still needed. Patients with benign polyps who are due for a colonoscopy will be re-contacted following the usual recruitment procedures described above. A slightly modified version of the study introductory letter which notes in the opening paragraph that patients may now be eligible will be used in lieu of the standard introductory letter.

Additionally, re-contact efforts will be attempted for patients who previously gave their verbal consent to participate but failed to return the written informed consent and HIPAA Authorization in order to be officially enrolled. The IRB approved a change to the protocol on 11/27/2018 which discontinued the requirement for informed consent and HIPAA Authorization to be obtained in writing. These patients may now be willing to be enrolled since written forms do not need to be completed and returned to the research office. This cohort of patients will be re-contacted following the usual recruitment procedures described above. A slightly modified version of the study introductory letter which explains in the opening paragraph that written consent forms are no longer required for enrollment will be used in lieu of the standard introductory letter.

Protection Against Risk: Recruiters and data collectors will be experienced and trained to detect anxiety or fear. Precautions will be taken to minimize anxiety, fear, and embarrassment. Participants will be informed about the study prior to entry and will understand that they may terminate participation in this study at any time. Participants will understand the general nature of the research before agreeing to participate and will be given the opportunity to decline to answer questions that are objectionable.

The proposed research may present a possible risk to confidentiality because access to medical records will be required to verify screening participation and because recruitment and follow-up procedures require access to and tracking of participants' addresses and telephone numbers. Participants will be given an identification code to separate identifying information from outcome data. All identifying information will be kept in secure file cabinets and password-protected computer files. Analyses will include only summaries of data and personal identifiers will not be included. All project personnel will be educated about the importance of confidentiality and be certified as required by university guidelines.

The proposed research does involve slight emotional or psychological risk. Precautions will be taken to minimize these risks by: 1) thoroughly explaining the study initially; 2) emphasizing that participation is voluntary; 3) allowing the participant to stop the interview at any time; 4) using well-trained interviewers and patient navigators; and 5) coding data for confidentiality. During the PI's 17 years of research experience, few participants in our studies have become distressed or wished to stop the interviews.

C. Required Education in the Protection of Human Research Subjects: Indiana University has a procedure in place to fulfill the NIH requirement for education in the Protection of Human Research Subjects. All grant personnel who are involved in the design or conduct of research involving human subjects on this project already have or will complete this required education prior to the initiation of this project.

D. Potential Benefits of the Proposed Research to Subjects and Others. Participants in intervention groups may benefit from the information and tangible assistance received to encourage them to complete a CRC screening test. Both groups will receive information about colorectal cancer, the benefits of CRC screening, and detailed instructions on completing the bowel preparation for those who undergo colonoscopy. If found to be effective, these interventions will directly benefit patients who, despite having received a recommendation for CRC screening from their provider, did not complete that test. These interventions have great potential to decrease both CRC incidence and mortality in a group that bears disproportionate burden from this disease. This study may also indirectly benefit all people by comparing two effective interventions that can be easily translated into practice in other clinical settings. Information gained from this study may be useful to researchers and health professionals who are interested in developing new interventions to increase CRC screening rates.

E. Importance of the Knowledge to be Gained. This study will contribute to knowledge by answering several important questions. CRC screening has the ability to not only detect cancer in early stages while it is most treatable, but also to prevent CRC through removal of precancerous polyps. However, these benefits are not realized if patients do not adhere to provider recommendations to be screened. This study will aid our understanding of interventions that can increase screening, thereby decreasing risk for development of - and death from - CRC. This comparative effectiveness study will contribute to knowledge about the impact of two promising health system interventions that have potential for translation into clinical practice. Importantly, enhancing our understanding of which subgroups of the study population are more likely to respond to the DVD intervention alone and which members may require more intensive, interpersonal interventions, such as PN, will allow us to intervene more appropriately and efficiently.

F. Inclusion of Women and Minorities. Both men and women will be included in the proposed study. The proposed study will enroll non-Hispanic Black, non-Hispanic White, and Hispanic patients to test two theory-based interventions, alone and combined, against usual care.

G. Inclusion of Children. Children will not be included in the proposed study because CRC screening is relevant to older adults and this cancer primarily affects adults.

H. Data Safety and Monitoring Plan. Two groups of research staff will be extensively trained and monitored throughout the project. The project manager and PI will train and monitor recruiters who will conduct telephone recruitment calls. The IU Center for Survey Research supervisory staff will train their data collectors who will collect data at Time 1 (baseline), approximately 2 weeks post-mailing of the DVD to assigned participants, Time 2 (6 months post-baseline), and T3 (9 months post-baseline) using computer-assisted telephone interviews (CATI). Patient navigators who deliver the navigator intervention will be extensively trained and monitored by the principal investigators. Quality assurance plans are described or referred to in the following sections.

I. Quality Assurance for Recruitment and Data Collection. Performance of recruiters will be closely monitored by the project manager and PI. Recruitment phone calls will be randomly audio recorded to monitor quality and consistency.

Since we are only evaluating recruiters' delivery and not subjects' responses, these recruitment audio recordings will only record the recruiters' voice. Subjects will not be identifiable in recruitment audio recordings. Data collectors will be closely monitored throughout the project by the IU Center for Survey Research supervisors. Telephone interviewing stations at this Center allow supervisors to listen to interviews and view interviewers' computer screens remotely. All data collectors, including the most experienced, will be monitored regularly, with a goal of twice during every shift. One of these monitoring sessions will include listening to at least 20 interview questions. The other monitoring session will be used to listen to recruitment calls to ensure adherence to the recruitment script and handling of refusals. Overall, 10% of all interviews and recruitment calls will be monitored for quality assurance purposes. Feedback will be provided to recruiters and interviewers after each monitoring session to correct any performance weaknesses.

J. Intervention Fidelity. Published recommendations to ensure intervention fidelity address five components that are described in this section.[84,85] 1) Study design. The three group design ensures blinding of outcome data collectors to participant group assignment. 2) PN training. Training is addressed in section B.7 above. 3) Intervention delivery. To ensure consistency of intervention delivery, evaluation of intervention processes is essential and several strategies will be used. DVDs or instructions with link to view the tailored DVD on the web will be delivered via an express mailing courier with delivery confirmation. All PN calls will be recorded for quality assurance purposes, with a subsample randomly selected for evaluation. Audiotaped PN calls will be evaluated using a checklist we developed in prior studies. Project staff will discuss intervention delivery issues, technical support requests, and any unusual events during biweekly research team meetings. Modifications will be made as necessary and recorded to ensure appropriate intervention delivery and maintenance of protocol integrity. Decisions about modifications will be made jointly by the research team and recorded. 4) Intervention receipt. Since all participants in the intervention arms will receive the tailored DVD via mail or a web link, we will call each participant approximately 2 weeks after mailing to conduct a process evaluation of this intervention. Through the process interview, we will assess receipt of the DVD or web link, how much of the DVD was viewed (all, part or none), as well as satisfaction with and relevance of the content. Participants will receive a $50 gift card for completing this process interview. 5) Intervention enactment. All participants who return a completed FIT will have enacted the behavior recommended in the interventions. Those who attend a colonoscopy appointment are routinely asked about their experience with, and ability to complete, the bowel preparation and refrain from eating solid food before the test. This information is documented in the EMR and colonoscopy procedure notes and will provide evidence that participants enacted the behaviors recommended in the DVD. The PN documentation record also will provide data to support intervention enactment by participants assigned to this group.

K. Quality Assurance for Intervention Delivery. Evaluation of intervention processes is necessary to ensure consistency of intervention delivery. Several strategies will be used. First, project staff will discuss intervention delivery issues, technical support requests, and any unusual events during biweekly research team meetings. Modifications will be made as necessary and recorded to ensure appropriate intervention delivery and maintenance of protocol integrity. Decisions about modifications will be made jointly by the research team and recorded. Second, all telephone counseling calls will be recorded for quality assurance purposes, with a subsample randomly selected for evaluation. Audiotaped counseling calls will be evaluated using a checklist we developed in prior studies. Third, participants in each intervention group will be queried about recall and satisfaction with the navigator and/or DVD, as appropriate. Problems with intervention delivery identified through follow-up interviews will be discussed at team meetings and corrected. Specific questions about the users' experience with the interventions are included elsewhere.

L. Quality Assurance for Data Management. Data management will be handled by expert data managers from the Department of Biostatistics. A centralized data entry system will be developed and housed on the secure Web server managed by members of our biostatistics team, led by Dr. Susan Perkins. Data monitoring will occur weekly as data from each interviewer are reviewed for accuracy and completeness. Backup data files will be kept on a secure server managed by the Indiana University Department of Biostatistics and in the project manager's office. All computers that will be used to collect and send data during implementation of the study or to store data at the central location will be password-protected. All tracking and data files also will be password-protected and backed up nightly.

M. Data Integrity and Security. IRB approvals, patient lists, consent and authorization forms when required, and all tracking information will be kept in a locked location. Baseline and outcome data as well as intervention data will be coded to maintain confidentiality. All computers will be password-protected. Only trained grant personnel will have access to data. Once all data have been linked to individuals, all identifiers will be deleted.

N. Identification of Adverse Effects. An IRB-approved Data Safety Monitoring Plan (DSMP) will be used to identify participant adverse effects. The Data and Safety Monitoring Plan (DSMP) for this project begins with extensive training of research staff followed by comprehensive monitoring to ensure the safety of participants and the validity and integrity of the data throughout the project period.

A. Research Staff Training

Three groups of research staff will be trained and monitored throughout the project.

1) Research Assistants (RAs) working on-site at the Indiana University School of Nursing will be trained to effectively recruit participants by mail and phone. These RAs will be specially trained in the recruitment of minority and low-income patients. Training will focus on: 1) HIPAA and IRB regulations designed to protect research participants; 2) mailing of recruitment materials and follow-up recruitment by phone using standardized scripts to explain the study and answer questions; 3) eligibility assessment; 4) obtaining both verbal informed consent and verbal HIPAA Authorization to participate; 5) scheduling the T1 (baseline) interview; 6) handling problems or questions that arise during phone recruitment; 7) use of the REDCap tracking database to log recruitment procedures; and 8) study procedures for on-going recruitment monitoring and quality assurance. Recruiters will practice and role-play phone recruitment until they have reached 100% compliance with guidelines for recruitment.

2) The second group of research staff includes experienced interviewers/data collectors employed by the Center for Survey Research (CSR) at Indiana University. Prior to the study-specific training described below, CSR interviewers/data collectors will have completed a rigorous 9-hour telephone interviewing training course, with four hours spent in hands-on practical experience in which the trainee-to-supervisor ratio is 5:1. This training course covers: 1) the interviewer's role in survey research; 2) standardized interviewing techniques; 3) administration of survey introductions and refusal aversion techniques; 4) use of computerized sample management and data collection systems; 5) protection of human subjects and sensitive information; and 6) daily case management. Comprehension of concepts and techniques and skill in their execution are assessed through a battery of tests at appropriate intervals in the training course; trainees do not matriculate to the next phase until all prior phases are mastered. CSR interviewers/data collectors will then be trained on: 1) administering the study's four phone interviews: T1 (baseline), DVD Process, T2 (6 month) and T3 (9 month); 2) handling problems or questions that arise during data collection; 3) recognizing and reporting potential adverse events; and 4) data monitoring and quality assurance procedures. Training will include demonstrations of effective data collection interviews using the computer-assisted telephone interview software (CATI). Following demonstrations and practice sessions, interviewers/data collectors will role-play and receive feedback until they have reached 100% compliance with guidelines for interviewer data collection integrity.

3) The third group of research staff includes our School of Nursing research nurse employees who will serve as patient navigators to deliver the navigation intervention by phone. Initial training will be conducted during two separate sessions with the first being a full, one-day session. This first day of training will consist of a series of presentations by our Ohio State University co-investigators, Dr. Mira Katz and Chasity Washington, who are experts in navigation. Training objectives will be to have navigators understand the scope of their role, provide them with support, as well as guide them to resources to assist participants with financial and transportation issues. The REDCap database for documenting navigation encounters will also be introduced. A second half-day

session will be scheduled when the REDCap navigation database is finished so that a live demonstration can be provided to the nurses. This second session will also include a presentation on intervention fidelity and quality assurance by an Ohio State quality assessor. The DVD intervention will be presented so that navigators know exactly what colon health information participants will receive prior to their contacting them. Navigators will be refreshed on their responsibilities and will practice and role-play until they have reached 100% compliance with the navigation intervention protocol. Prior to navigating their first participant, the study's Project Manager will meet with each navigator. The purpose of this final, pre-navigation session is to confirm that: 1) there are no issues with accessing and utilizing the REDCap navigation database; 2) the audio recorder works properly with the phone set-up, and 3) the navigator is able to deliver the intervention content effectively in a simulated call.

B. Project Monitoring

All aspects of the project will be comprehensively monitored by the Principal Investigator and Project Manager on a continuous basis. We will monitor both the progress and quality of: 1) recruitment, enrollment, and attrition; 2) data collection; 3) randomization and stratification; and 4) intervention delivery. All adverse events and protocol non-compliances/deviations will be evaluated by the Principal Investigator and reported to the IRB at the time of Continuing Review (unless earlier reporting is required). Quality assurance procedures will include evaluating audio recordings of calls made by recruiters, interviewers, and navigators. Results of monitoring activities will be reported during monthly research team meetings. The Principal Investigator and research team will also evaluate external, relevant information such as developments in the literature or results of related studies that might impact the safety of participants or direction of the study, as it becomes available.

1) Data Integrity and Security

Patient demographic and tracking information will be maintained in the Indiana University REDCap database. REDCap is a web-based application that is secure (user authentication: log-on/password) with customizable user rights restrictions and full audit trail capability. REDCap was developed specifically around HIPAA security guidelines and is an IUPUI IRB approved method for collecting, storing, and analyzing data. Only approved project staff will have access to the study's REDCap database. Participants will be assigned a unique study identification number within REDCap. This number will be used to code participants' baseline, intervention, and outcome data to maintain confidentiality. Once all data has been linked to individuals, all personal identifiers will be deleted. Hardcopies of letters, along with completed written informed consents and HIPAA Authorizations that were required prior to the protocol being changed, will be stored in locked file cabinets located within the Project Manager's locked office. Access to the office will be limited to the research project staff. All audio recordings will be coded using a unique study identification number. Audio recordings of the structured telephone interviews will not include any personal identifiers. Audio recordings of navigation calls may include the participant's last name since these calls with the Patient Navigator nurse are more conversational and the nurse may refer to the participant by last name while talking. Audio recordings of calls made to participants will be uploaded to the study's secure Indiana University [Box Health] folder. [Box Health] is a web-based, password-protected platform residing on a secure network server. After uploading, audio files will be erased from the recording devices. Audio recordings will be deleted from the secure [Box Health] folder after the study is completed.

2) Recruitment

Indiana University School of Nursing research staff will recruit participants using procedures consistent with HIPAA requirements. During the recruitment phase, recruiters will audio record calls placed on one day of each week. The Project Manager will listen to randomly selected calls by each recruiter to evaluate adherence to the recruitment script, correct eligibility assessment, and proper handling of refusals. Feedback will be provided after monitoring sessions to correct any performance weaknesses.

3) Data Collection

Outcome data collection will be handled by expert interviewers/data collectors at the CSR. A centralized data entry system will be developed and housed on the secure server managed by the CSR. All computers that will be used to collect and send data during implementation of the study or to store data at the central location will be password-protected and backed up nightly. Job performance of the interviewers/data collectors will be closely monitored by the Project Manager and the CSR supervisors to ensure their adherence to the study protocol. Telephone interviewing stations at the CSR allow supervisors to listen to interviews and view computer screens remotely in real-time without the knowledge of the interviewers/data collectors. All interviewers/data collectors will be monitored regularly, with a goal of once during every shift. One monitoring session will include listening to at least 20 interview questions. Ten percent of all interview calls will be monitored for quality assurance purposes. Feedback will be provided after monitoring sessions to correct any performance weaknesses.

4) Intervention Delivery

Receipt of the mailed DVD intervention will be monitored by the CSR supervisors and the Project Manager. Participants who report to CSR interviewers/data collectors that they did not receive the DVD by regular mail (or e-mail with link to the web version) will have their contact information verified and a second mailing will occur. The Project Manager will monitor the number of re-mails. The CSR will monitor the number of DVD process interviews not completed due to participants reporting non-receipt.

All patient navigator calls will be recorded for quality assurance purposes. A subsample will be randomly selected for evaluation by our Ohio State University Quality Assurance team member to ensure intervention fidelity and identify problems. Ten percent of each navigator's calls will be monitored for quality assurance. Navigators and project staff will discuss intervention delivery issues, technical support requests, and any unusual events during monthly conference calls. Modifications to the REDCap navigation database will be made, as necessary, to improve intervention delivery and maintenance of the protocol integrity.

5) Adverse Events

The Project Manager and Principal Investigator will monitor the study for adverse events. Since there are no physical risks to taking part in this study, reports of any emotional distress or similar unfavorable reactions will be carefully evaluated. Additionally, any loss of confidentiality will be considered an adverse event and thoroughly investigated. Adverse events will be identified and reported by recruiters, CSR interviewers/data collectors, and research nurses who deliver navigation interventions. Participants will have several study phone numbers available to call should they have a complaint or research-related injury. This includes phone numbers for the Principal Investigator, Project Manager, and IU Human Subjects Office. If a participant calls to register a complaint or report an adverse event, the Principal Investigator will be immediately notified. Adverse events will be discussed at the monthly team meetings and reported to the IRB at the time of Continuing Review.

CONSORTIUM CONTRACTUAL ARRANGEMENTS

For detailed instructions, refer to the Application Guidelines for your PFA. Do not exceed five pages.

The Ohio State University (OSU) provides a rich environment for achieving the objectives outlined in this application. OSU was founded in 1870 as the major land grant institution in the state of Ohio. During the past 128 years, the university has grown to be among the country's leading research universities. Its mission is the attainment of international distinction in education, scholarship, and public service. It is the state's leading comprehensive teaching and research university. OSU is also the state's largest public university composed of 19 colleges and 100 departments, with approximately 42,000 undergraduates, 2,720 professional graduate students and 10,000 graduate students, making it one of the largest single-campus universities in the country. The Health Sciences at OSU include the Colleges of Dentistry, Medicine, Nursing, Optometry, Pharmacy, Public Health and Veterinary Medicine. The Health Sciences colleges are geographically connected within a one-mile radius in a cluster of buildings surrounding the Health Sciences Library and adjacent to the OSU Medical Center, the Ross Heart Hospital and the James Cancer Hospital. In addition to this environment with its wealth of resources, the OSU investigative team has the experience and expertise to carry out the objectives of this proposed study, including experience with interdisciplinary research studies with the goal of developing and testing patient navigator interventions such as this one.

Drs. Electra Paskett and Mira Katz will advise on all aspects of the project, including the development, implementation, and evaluation of the navigator intervention. Dr. Paskett has established working relationships with faculty and staff at The Ohio State University (OSU) and community leaders to conduct important studies including studies among underserved populations in an area that is in need of interventions to improve cancer incidence and mortality rates. Dr. Mira Katz will advise on all aspects of the project, including the development, implementation, and evaluation of the patient navigation intervention program and other study-related matters, as needed. In addition, Dr. Katz has experience in the development, implementation, and evaluation of colorectal cancer screening interventions and she will collaborate with Dr. Rawl on the refinement of the DVD and the surveys. Ms. Chasity Washington, the Program Director for the Diversity Enhancement Program at the Arthur G. James Cancer Hospital and Richard J. Solove Research Institute, will develop and implement the initial in-person training for the PN staff as well as subsequent monthly training conference calls. The trainings will help PN staff understand the scope of their job, provide them with support, and empower and guide them to find resources in their community. The trainings will help direct the PN staff in development of their own resource manuals. The Ohio program will guide the PN staff to identify resources in their community that may be able to assist patients. The PN staff will also learn techniques to guide patients to community resources that may help patients overcome barriers related to timely and complete healthcare.

For the initial one day in-person PN training, Dr. Katz and Ms. Washington will travel to Indianapolis. The Eskenazi Endoscopy Nurse Navigator will be consulted in the development of the clinical aspects of the training and availability of local resources. Below is a sample of what the initial training agenda might look like.

A. Overview of Health Disparities/Cancer Disparities

- The inception of PN and patient assistance programs
- Types of PN programs (community based, telephone based, hospital based)
- The need for research to test PN models
- Health disparities by incidence, prevalence, and mortality data

B. Patient Navigation: Roles and Responsibilities

- Describe roles, responsibilities, and core competencies
- Common barriers and approaches to addressing them
- Care management and patient interviewing

C. Overview of Colon Cancer, Colon Cancer Screening, and Cancer Treatment

- Review the colon
- Colon cancer in the United States
- Causes of colon cancer
- Symptoms of colon cancer
- Screening for colon cancer
- Risk factors and prevention for colon cancer
- Treatments and survival for colon cancer
- Myths and misconceptions about cancer
- Cancer control (primary, secondary, and tertiary prevention strategies)

D. Culture and Communication

- Cultural awareness and sensitivity
- Understanding the role of communication in the assessment of patient needs
- Communication techniques to facilitate identification and reduction of barriers
- Patient empowerment and self-efficacy

E. Resource Management

- Types of resources
- Heath system and community assessment
- Asset mapping
- Developing your resource manual

A second half-day session will be scheduled when the REDCap PN database is finished so that a live demonstration can be provided to the nurses. This second session will also include a presentation on intervention fidelity and quality assurance by an Ohio State co-investigator. The DVD intervention will be presented so that navigators know exactly what colon health information patients will receive prior to their contacting them. Navigators will be refreshed on their responsibilities and will practice and role-play until they have reached 100% compliance with the intervention protocol.

Subsequent training will occur through monthly conference calls between the PN staff, Ms. Washington, and the Ohio State PN quality assurance monitor. The calls will include a training piece, a grand round case presentation from each PN and the opportunity to discuss any concerns related to navigation. From this discussion future training topics will be identified. Potential monthly training topics may include:

- Addressing challenging situations
- Revisit patient empowerment approaches
- Health literacy
- Self care: Approaches to avoid feeling burnt out
- Time management
- Review of CRC screening and any changes in screening guidelines

OSU staff and investigators will also work on project-related publications with the University of Indiana team.

The Indiana University Center for Survey Research (CSR) is a research unit housed within the Office of the Vice Provost for Research at Indiana University Bloomington. For more than three decades, the CSR has earned a reputation for research and methodological consultation services to government, academic, nonprofit, and private sector clients, with a focus on the social sciences, medicine, and education. The CSR provides the management, staff, and facilities required

to conduct all phases of telephone, mail, Internet, and multi-modal projects. CSR staff are trained in all aspects of survey research, including questionnaire design, sampling, telephone and in-person interviewing, cognitive testing, coding, data entry, and data analysis, employing both quantitative and qualitative/mixed methods approaches. CSR staff adhere to the highest academic and government research and ethical standards. The CSR also uses the most current technology to continuously improve the quality and efficiency, as well as ensure the security, of data collection. In addition, as part of the mission of the University, the CSR provides educational and experiential opportunities for students, staff, and researchers, through graduate- and undergraduate-level courses, graduate student practicums, workshops in survey methodology, and individual consultations both internal and external to the University.

CSR Collaborations in Medical, Health, and Public Health Research

Each year, the CSR conducts 25-40 projects. Current or recent major projects in the area of health and medicine include the following:

- **Colorectal and Breast Cancer Screening in Women**, which compares the efficacy of four strategies in promoting colorectal cancer and breast cancer screening among women aged 51 to 75. (IU School of Nursing; *Rawl, Co-I)*
- **Promoting Colon Cancer Screening among African-Americans**, which studied the effects of various interventions developed to improve colorectal screening rates. (IU School of Nursing; *Rawl, PI*)
- **Hospital-Acquired Infection Surveillance Study**, which examined strategies used in hospitals nationwide to control the spread of hospital-acquired infections. (IUB, Sociology)
- **2011 Study of Indiana Registered Nurses**, which surveyed Indiana nurses about their career, educational history, and professional practices. (IUB, Sociology)

Data Collection Services

The CSR provides the full range of data collection services, including focus groups, cognitive interviewing, standardized interviewing, and surveys administered by telephone, mail/paper, Internet, and multiple other modes. The following describes the telephone data collection capabilities of the CSR, as applicable for the IU School of Nursing PCORI Project. The CSR will be an invaluable resource for this project to ensure that efficient training and recruitment are conducted and that high-quality data are obtained for this study. The CSR will provide the following support for this project:

- General management (coordination, hiring, training, server management)
- Development (develop database structures, survey instruments, calling protocols, and samples)
- Production (interviewing, quality control, sample management)
- Post-production (prepare datasets, address updates, methods summary and archiving)

Eskenazi Hospital and Health System is the only local safety net hospital that serves mostly low income residents of all cultures and ethnicities from the greater Indianapolis Metropolitan area, which makes it an ideal clinical setting of this study. Eskenazi provides care to nearly 1 million outpatients per year, with a special emphasis on vulnerable populations of Marion County, Indiana. Eskenazi facilities include a 315-bed hospital and inpatient facilities as well as 11 community health centers located throughout the Indianapolis area. In the Endoscopy unit, approximately 450-500 GI procedures are performed a month, with 75% of those being colonoscopy screenings. For the PCORI study, we will recruit from this pool of already established and scheduled patients.

Eskenazi Health Endoscopy Unit is a brand new teaching facility that was established in December of 2014 (formerly known as Wishard Health Services) and has four fully equipped Endoscopy suites. Each suite is staffed with a physician, registered nurse and an endoscopy scope technician. The majority of patients are referred from one of the eight clinics that comprise the Eskenazi Health Primary Care Network, although consults are received from many area hospitals and clinics as well.

The medical director, nurse manager, and nurses in the Endoscopy Department at Eskenazi Health, our local safety net health system, have been collaborating with the investigator for the past three years. The proposed project came from

conversations with these stakeholders who requested assistance in addressing the costly clinical problem of low attendance and poor bowel preparation at scheduled colonoscopies. This team conducted a preliminary study and had several meetings to design the proposed study. Interviews with 48 patients, provided invaluable data on these patients' perspectives on the barriers and facilitators of colonoscopy completion.

Dr. Fatima is the Medical Director of Endoscopy at Eskenazi Health. Her research has focused on improving endoscopic techniques, minimizing complications of colonoscopy, and understanding factors that influence quality of bowel preparation for colonoscopy. She is well qualified to collaborate on this clinically relevant comparative trial to test two methods increase CRC screening rates and the quality of bowel preparation for patients who complete colonoscopy. In addition to the expertise and guidance of Dr. Hala Fatima, Eskenazi staff will play an integral role in this study. Rita Reynolds is an experienced gastroenterology nurse who is employed in the Eskenazi Endoscopy Department. Ms. Reynolds will assist with identification of eligible patients and serve as the gastroenterology resource nurse for the patient navigators. In Year 1, she will participate in refinement of recruitment materials and processes, development of the patient navigation intervention, and training of navigators. In Years 2-4, she will consult with patient navigators to address medical issues, health care system barriers, and questions that patients and navigators have about the bowel preparation process and test results. Ms. Reynolds will also participate in quality assurance and monitoring of the navigator intervention through monthly conference calls. With a vested interest in and commitment to decreasing the burden this proposal addresses, along with their expertise and the ideal patient population, the Eskenazi team will be an invaluable partner in the conduct of this study.

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