A Smartphone-Based Intervention to Improve Colorectal Cancer Screening in African American Men

Protocol Number: R44CA246899

National Clinical Trial (NCT) Identified Number: NCT06052202

Principal Investigator*: Samantha Leaf

Sponsor: ISA Associates, Inc.

Grant Title: Reducing Colorectal Cancer Health Disparities: An mHealth Intervention to Improve Screening among African American Men

Grant Number: R44 CA246899-02A1

Funded by: National Cancer Institute

Version Number: v.1

10/19/2024

CONFIDENTIALITY STATEMENT

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STATEMENT OF COMPLIANCE

(1) [The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.]

INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the *Statement of Compliance* above.

Principal Investigator or Clinical Site Investigator:

Signed:  Date: 10/2/2025

Name*: Samantha Leaf

Title*: Senior Research Scientist

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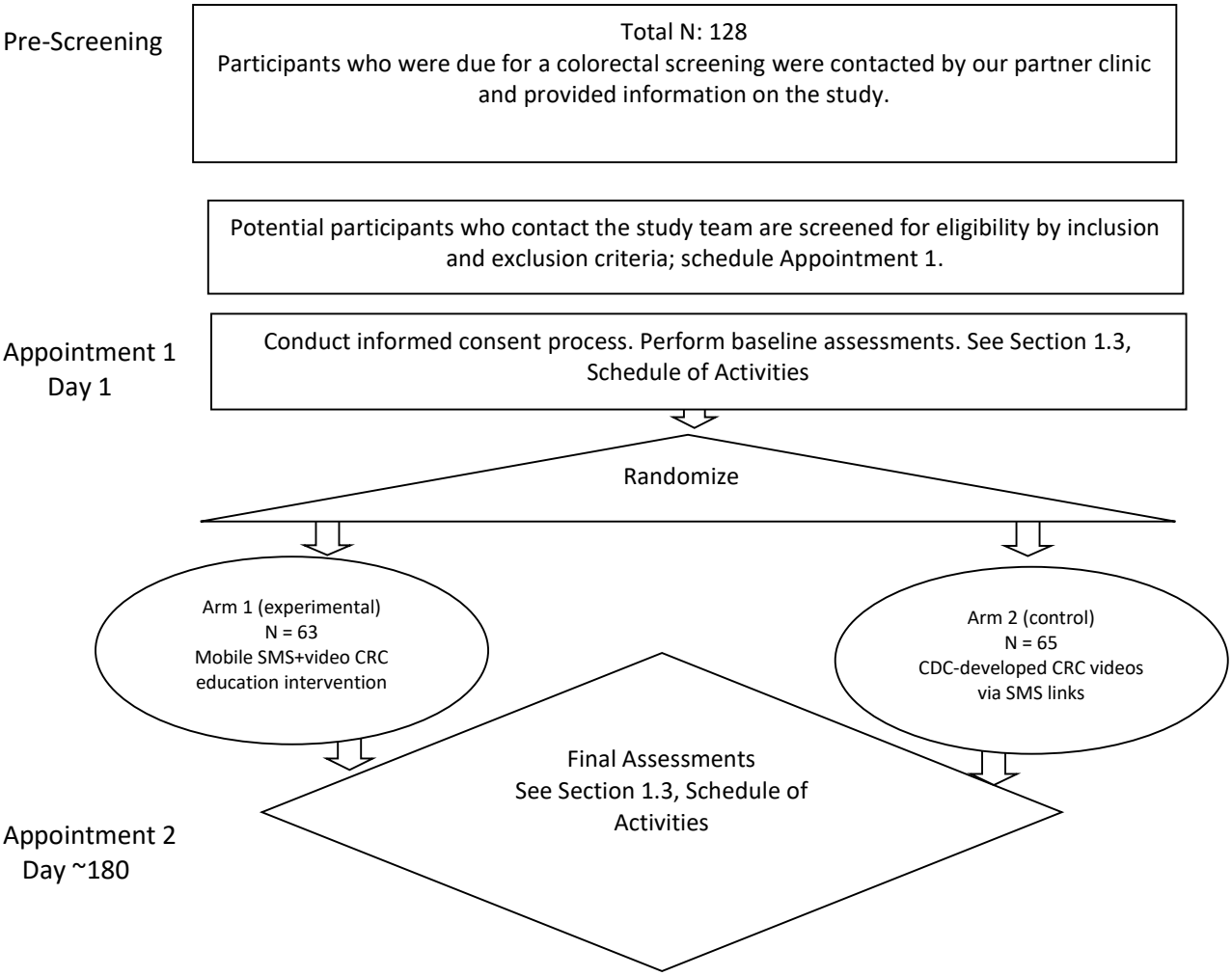
1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title:	Reducing Colorectal Cancer Health Disparities: An mHealth Intervention to Improve Screening among African American Men
Grant Number:	R44CA246899
Study Description:	Two-arm, parallel-group randomized controlled trial comparing a tailored, SMS-delivered mobile education program with attention-control (CDC video links) to improve completion of any guideline-concordant colorectal cancer (CRC) screening by ~6 months among Black/African American men who are non-adherent to CRC screening.
Objectives*:	Objectives: Primary—evaluate effect on completion of any guideline-concordant CRC screening since enrollment. Secondary—evaluate effects on CRC beliefs (severity, susceptibility, benefits/barriers), knowledge, self-efficacy, and medical trust.
Endpoints*:	Endpoints: Primary—binary indicator of any CRC screening since enrollment assessed at follow-up. Secondary—validated scale scores at baseline and follow-up.
Study Population:	Black/African American men who are aged 45–75, non-adherent to CRC screening, and smartphone owners in Washington, DC
Phase* or Stage:	Phase II clinical trial
Description of Sites/Facilities Enrolling Participants:	Single U.S. community health center in Washington, DC
Description of Study Intervention/Experimental Manipulation:	The study intervention includes a structured series of text messages that deliver links to brief, mobile-friendly videos on colorectal cancer risk, guideline-recommended screening options (FIT/FOBT, FIT-DNA, colonoscopy, CT colonography, and flexible sigmoidoscopy), and strategies to overcome common barriers. Messages are automated and paced over approximately 6–9 weeks, resulting in an estimated total exposure of about two hours of content. Comparator: CDC-developed CRC education links delivered by SMS and paced over 6 weeks. Estimated video length is 30–40 minutes total.
Study Duration*:	18 months
Participant Duration:	6 months

1.2 SCHEMA

Flow Diagram



1.3 SCHEDULE OF ACTIVITIES

The schedule below is provided as an example and should be modified or replaced as appropriate.

	Pre-screening (Pre-consent)	Appointment 1 Day 1	Day 2-60	Day 61-180	Appointment 2 Day ~180
EHR Review Eligibility	X				
Study information sent to potential participants	X				
Confirmatory eligibility screening	X				
Informed Consent		X			
Demographics		X			
Outcome Evaluation					
Receipt of guideline-concordant CRC screening		X			X
CRC severity scale		X			X
CRC susceptibility scale		X			X
Colonoscopy benefits/barriers scale		X			X
Stool test benefits/barriers scales		X			X
CRC Knowledge questionnaire		X			X
Self-efficacy scale		X			X
Medical trust scale		X			X
EHR Record Review					X
Randomization		X			
Control Intervention			X	X	
Experimental Intervention			X		
Adverse Events Reporting		X		X	X

2 INTRODUCTION

No text is to be entered in this section; rather it should be included under the relevant subheadings below.

The following subsections should include relevant background information and rationale for the clinical trial. This should be a brief overview (e.g., approximately 3-7 pages). Referring to relevant intervention manuals for more detail is appropriate. Text for Sections 2.1 and 2.2 may come from the Background and Significance section of the grant application.

2.1 STUDY RATIONALE

Colorectal cancer (CRC), the second overall leading cause of cancer death, is particularly burdensome for African American men, who have high incidence of the disease with lower survival rates at all CRC stages.

Screening (e.g., colonoscopy, stool-based tests) can prevent most cases of invasive CRC. However, uptake is inadequate, especially among low SES African American men. Most efforts to increase CRC screening in this group utilize in-person or telephone-based education and navigation. While effective, these approaches are resource intensive, limiting their adoption by organizations that serve low SES Black men, such as Federally Qualified Health Centers (FQHCs).

To address the need for an effective, affordable, and scalable strategy to increase CRC screening among African American men, this project developed a mobile colorectal cancer screening intervention (m-CRCSI) for this group. m-CRCSI is based on the health belief model (HBM) and delivered via mobile phone. It includes text messages designed to improve CRC knowledge and health beliefs. Some text messages include links to videos, including educational instruction and unscripted peer narratives. Program content is designed to reduce health literacy barriers and promote CRC screening adherence.

A prototype m-CRCSi was developed in Phase I. This development was informed by formative research with community-based care providers and target end-users. The results of Phase I far exceeded the proposed benchmarks and strongly support the usability, acceptability, and potential effectiveness of the intervention.

During Phase II we completed development of the m-CRCSi. Then, in collaboration with Family and Medical Counseling Service (our partner FQHC), we examined the effectiveness of the m-CRCSi to increase CRC screening in African American men. Participants were randomly assigned to either the intervention condition or to a matched control condition. Secondary measures assessed health beliefs, trust in the medical system, and knowledge.

2.2 BACKGROUND

<u>CRC Screening Saves Lives</u>

Most CRCs develop from precancerous polyps. Because these polyps grow slowly, early detection and removal can prevent the majority of cases from becoming invasive cancer.[2,9,10] For average risk adults, the US Preventive Services Task Force (USPSTF) recommends regular screening between 50 and

75.[33] Several tests are approved to detect CRC or precancerous polyps. The "gold standard" is colonoscopy, a direct visualization of the colon and rectum.[2] This is the only procedure that allows for simultaneous detection and removal of polyps throughout the entire colon and rectum. It also requires retesting only every 10 years.[2,34] Despite these advantages, significant barriers associated with colonoscopy include availability, cost, transportation, and the need to fully cleanse the colon with laxatives prior to testing.[2] As a result, stool-based screening methods, like the guaiac fecal occult blood test (gFOBT) and fecal immunochemical test (FIT), are popular alternatives.[2,35,36] Both detect blood from CRC in stool but require annual rescreening. A newer fecal test, FIT-DNA, can detect either blood or genetic mutations shed by CRC and polyps and is recommended every 1-3 years.[2] Irrespective of which fecal test is performed, any positive result should be followed by colonoscopy.[2] Ultimately, most medical and research professionals agree that "the best test is the one that gets done."[37]

CRC Screening in African American Men

Unfortunately, adherence to any of these CRC screening options is far too low. This is especially true among men, particularly those who are younger and low SES.[38,39] Given this, it is not surprising that screening compliance is particularly poor among low SES African American men.[2,11]

Socioeconomic disadvantage in the United States is associated with lower colorectal cancer screening rates.[12-15] Contributing factors include inconsistent health insurance,[40,41] out-of-pocket costs for CRC screening tests,[40,42] and few interactions with primary care.[43] In clinical settings, some patients report receiving less comprehensive counseling about screening and fewer screening recommendations,[40,41,44] as well as feeling unheard or treated impersonally.[45] Clinicians may also be less aware of practical barriers faced by patients with fewer resources[46,47] and expectations about patient dependence or follow-through can vary by socioeconomic context.[48]

In addition to institutional and provider-level concerns, many individuals with fewer socioeconomic resources face substantial cognitive and emotional challenges to colorectal cancer (CRC) screening. Lack of trust in the medical system, encompassing concerns about fairness in care and discomfort in clinical settings, is commonly reported,[41,46,49-53] particularly among lower-SES populations.[54] In addition, Black men and low income patients typically have lower health literacy (i.e., difficulty understanding health information to make health decisions) [25,55,56] and limited CRC knowledge.[41,55,57] Finally, underestimation of personal CRC risk and confusion about available screening options (e.g., believing that a digital rectal exam screens for CRC) are frequent and can depress screening uptake.[64-67]

Increasing CRC Prevention Efforts Among Low SES African American Men

The Community Preventive Services Task Force (CPSTF) recommends patient education to increase CRC screening rates.[68] Indeed, studies show that educational approaches, especially when culturally-targeted, improve screening rates among low SES African Americans.[58,69-71] Many of these initiatives involve in-person or phone-based education from nurses, health educators, or community health workers (CHWs). For example, Menon and colleagues developed a tailored, telephone-based intervention that focused on improving CRC knowledge and reducing screening barriers. Among a primarily male, unemployed African American sample, receipt of these counseling calls by health educators led to higher rates of CRC screening compared to usual care.[72] Similarly, CHW-delivered group education among a sample of mostly publicly-insured African Americans increased screening at 6-month follow-up relative to controls.[73]

Another common approach to delivering CRC education is through patient navigation (PN). Patient navigators are trained professionals who provide personalized education and assist with scheduling and completing cancer-related medical appointments. Research demonstrates that PN increases CRC screening adherence among low SES African American men.[74-77] Unfortunately, PN and other in-person educational interventions are costly and resource intensive.[69,78-80] Further, PN services are typically not reimbursable by insurance providers, requiring health care organizations to absorb their expense.[69,79,80] Until the return on investment of these services is established, these approaches will continue to have poor uptake.[74,81-84]

In particular, resource- and cost-intensive interventions are unlikely to be practicable for health care organizations that serve low SES African American men, such as Federally Qualified Health Centers (FQHCs). FQHCs are community-based organizations that provide health care services regardless of an ability to pay. There are nearly 1,400 FQHCs operating 12,000 service delivery sites in all 50 states plus the District of Columbia. These health centers serve almost 30 million patients each year.[85] In 2019, only 45% of eligible patients seen in FQHCs were adherent to CRC screening.[85] Researchers have suggested that implementing effective interventions at FQHCs may be particularly impactful on CRC incidence and mortality, given the role these centers play in serving low SES and underinsured populations.[58] Indeed, the CDC's Colorectal Cancer Control Program was created to increase CRC screening rates among these populations by funding cost-effective, evidence-based interventions in FQHCs and similar health care systems.[86]

To address the need for an effective, affordable, and scalable intervention to increase CRC screening among African American men, we developed m-CRCSi: a theory-based, tailored mobile CRC screening intervention for this group. The Health Belief Model (HBM), a widely used theoretical framework for understanding health behavior, guided development.[26,87] The HBM successfully predicts African American men's CRC screening.[72] More importantly, interventions based on this model significantly increased CRC screening rates among low-income African Americans.[88] The HBM posits that a person is more likely to perform a health behavior when he: understands the seriousness of an illness (perceived severity) and feels there is a realistic chance he will develop it (perceived susceptibility), expects the health behavior will reduce risk of illness (perceived benefits) with relatively few costs (perceived barriers), is aware of the health behavior (cues to action), and believes he can perform it (self-efficacy).[26] Theory-based assessments of these health beliefs were used to tailor m-CRCSi. Moreover, the program contextualized HBM constructs consistent with the particular health beliefs and information needs of low SES African American men[30,31] and integrated congruent imagery, language, and values.[31] Interventions targeted in this way are rated more positively, perceived as more credible, and lead to greater adherence to health behavior recommendations than generic interventions.[89-91]

2.3 RISK/BENEFIT ASSESSMENT

The following subsections should include a discussion of known risks and benefits, if any, to human participants. Text from the corresponding sections of the Human Subjects section of the grant application, and/or IRB package may be used here.

2.3.1 KNOWN POTENTIAL RISKS

This behavioral study (surveys plus SMS-linked educational materials) is **minimal risk**. No drugs, devices, or invasive procedures are involved; therefore package inserts or an Investigator's Brochure are not applicable. Risks align with published literature on health communication and mobile health interventions and fall into psychological and privacy domains, with negligible physical, social, legal, or economic risk.

We believe that the potential risks of collecting the survey data are small. It is possible that as a result of completing the research survey questions, a participant may learn that he is at risk for CRC. This realization may be accompanied by distress. If this should occur during the survey administration, participants will be encouraged to discuss their concerns with FMCS staff, who are trained to address these issues and to provide medical and psychological treatment as needed. They will also be provided with a list of resources in the informed consent that can provide information about CRC and recommended screening tests. To minimize this risk, participants will be completing their surveys on the computer. Their names will not be associated with their responses. In addition, the questions will be phrased in ways to minimize any potential discomfort and participants will be free to skip any question they do not wish to answer. Finally, the research team is using survey items that have been successfully used in past research with similar populations.

While the m-CRCSi includes sensitive information about CRC and one's risk for developing it, it is only accessible on a participant's personal mobile phone. Before engaging with the intervention, all participants will be educated in mobile phone security best practices, including password-protecting one's phone, erasing sensitive text messages, and turning off message preview functionality (i.e., so that text message content is not previewed on the phone's lock screen). In addition, all participants must opt-in to receiving intervention messages by sending a text message to a study-provided number. Participants will be told that they may choose to opt-out of the intervention and messages at any time. Further, our strict security strategy will include transmitting data to participants from a secure server, which reads telephone numbers and then transmits data to a personal phone through a secure communication protocol HTTPS to a SMS text messaging gateway. HTTPS will provide authentication of the third-party SMS text messaging service that the program will use to transmit the text messages, ensuring that no data (e.g., phone numbers) are intercepted by a third party. In addition, all assessment items completed by experimental group participants will be encrypted in the program database, the program database will be hosted on a separate server from the web application, and the hosting servers will be behind a web application firewall. Access to content on the mobile webpages will require authentication and the text-based active links to web content will be set to expire after a set time or number of access attempts.

We believe that the potential risks of going through either the experimental or control conditions is small. It is possible that, as a result of reviewing either the m-CRCSi or control materials, a participant may learn that he may have put himself at risk of developing CRC by not being screened. These realizations may be accompanied by distress. If this should occur, participants will be encouraged to discuss their concerns with FMCS staff, who are trained to address these issues and to provide medical and psychological treatment as needed. The informed consent will also provide information on alternative methods for receiving the type of information available in the m-CRCSi and control materials.

2.3.2 KNOWN POTENTIAL BENEFITS

Include a discussion of known potential benefits from either clinical or nonclinical studies. For behavioral or social intervention studies, relevant published literature should provide relevant benefits information. For studies including a licensed or approved product, a package insert or device labeling should be used as a primary source of benefits information. If the study includes an investigational product, the Investigator's Brochure (IB) should be a primary source of the benefits information.

Describe any physical, psychological, social, legal, or any other potential benefits to individual participants or society in general, as a result of participating in the study, addressing each of the following:

- *Immediate potential benefits*
- *Long-term potential benefits*

Note that payment to participants, whether as a non-coercive inducement to participate or as compensation for time and inconvenience, is not considered a "benefit." Provision of incidental care is also not to be considered a benefit. For details of compensation see ***Section 5.5, Strategies for Recruitment and Retention****.*

There are several benefits to participating in the proposed research to both the research participants and others. The first is the development of a state-of-the-art mobile intervention that can provide participants with valuable tailored information about CRC, the CRC screening tests that are available, the benefits of screening, and how to overcome barriers to screening. m-CRCSi is designed to improve CRC knowledge and health beliefs, with the ultimate goal of increasing CRC screening and reducing health disparities. Because the intervention is mobile, the information can be accessed at a time and place of the user's choosing. This information should not only be of interest to participants but also help them understand the CRC screening tests that are available to them and the value of being screened. This research also has the potential to benefit many other African American men, as ISA will use participant input to make changes in the design of the m-CRCSi to better meet the needs of the larger community of African American men. Given that the potential risks are very small, the risk to participants seems quite reasonable in relation to the benefits.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

Include an assessment of known potential risks and benefits, addressing each of the following:

- *Rationale for the necessity of exposing participants to risks*
- *A summary of the ways that risks to participants were minimized in the study design*
- *Justification as to why the value of the information to be gained outweighs the risks of participation in the study*

As indicated above, the risks to study participants are small. ISA will protect against any potential risk and ensure the confidentiality of the data using multiple methods. First, to protect against psychological risk or discomfort in completing the survey, participants will be informed of the confidentiality of the surveys (i.e., they will contain no personally identifying information) and the secure nature of the computer-based survey tool. In addition, questions will be phrased in a way to minimize discomfort and participants will be free to skip questions they do not wish to answer. No one outside the study team will have access to

the data. Moreover, participants will be told specifically that if, because of reviewing their assigned materials or completing the research surveys, they are feeling distressed about their physical health, they should discuss their concerns with an FMCS staff member. They will also be provided with a list of resources in the informed consent that can provide information about CRC and screening.

To maintain confidentiality of all data collected, no names or other identifying information will be included with the recorded MRR screening data, on the survey, or as part of m-CRCSi or the control materials. As noted earlier, the file that will link the participant name to the user ID and study phone number will be maintained on a password protected computer that will not house the survey data. The only people that will have access to the linking file will be the Principal Investigator and her staff. Finally, we will utilize strict security protocols – described previously – to protect the confidentiality of all information transmitted via SMS and stored on our secure server as part of the m-CRCSi intervention.

To protect against any breaches of confidentiality, all project staff proposed to conduct the data collection have received or will receive training on the protection of research participants and are or will be well versed in the Code of Federal Regulations (including 45 CFR 46 and 42 CFR) and the Belmont Report. ISA continually obtains information from the Office for Human Research Protections (OHRP) at NIH on new regulations regarding the protection of human subjects, which is disseminated to all staff. Further, participants will have the MRR procedure explained to them and will be asked to complete a medical release form before any medical records are extracted. In addition, any ISA staff proposed to work on the MRR and EHR extraction are or will be trained in all applicable HIPAA regulations.

After all participants have completed follow-up surveys, the linking file housed on the ISA computer – the only file that contains participant's personal information (e.g., name, phone number) – will be deleted. In addition, the Windows Eraser program will be used to completely remove (i.e., "wipe") the linking file from the computer by overwriting it several times using government-sanctioned deletion algorithms. Deidentified participant research data from the baseline and follow-up surveys will be retained for 3 years from the submission of the final financial report to NIH, in keeping with guidelines described in the NIH Grants Policy Statement.

The Phase II evaluation will provide very important information about the efficacy of the m-CRCSi to improve health beliefs and increase completion of recommended CRC screening tests among low SES African American men. This data is critical to developing a successful program that can help men prevent CRC or find it early when treatment is most successful. Knowledge gained from this field test will be integrated into the final program prior to marketing to FQHCs and other health care organizations. We believe that the risks associated with this Phase II effort are reasonable in relation to the valuable information we will receive.

3 OBJECTIVES AND ENDPOINTS

Provide a description of the study objectives and endpoints, as well as a justification for selecting the particular endpoints, in the table format included below. This will provide clear articulation of how the selected primary and secondary endpoint(s) are linked to achieving the primary and secondary objectives and an explanation of why endpoint(s) were chosen. Data points collected in the study should support an objective or have a regulatory purpose. Therefore, careful consideration should be given prospectively to the amount of data needed to support the study's objectives.

*An **objective** is the purpose for performing the study in terms of the scientific question to be answered. Express each objective as a statement of purpose (e.g., to assess, to determine, to compare, to evaluate) and include the general purpose (e.g., feasibility, acceptability, engagement of the intervention target, identifying mechanisms of action, mediation, moderation, efficacy, effectiveness, dissemination, implementation).*

*A study **endpoint** is a specific measurement or observation to assess the effect of the study intervention. Study endpoints should be prioritized and should correspond to the study objectives and hypotheses being tested. Give succinct and precise definitions of the study endpoints used to address the study's primary objective and secondary objectives (e.g., specific diagnostic tests that define safety or efficacy, clinical assessments of disease status, assessments of psychosocial characteristics, patient reported outcomes, behaviors or health outcomes). A full description of study endpoints, including administration, scoring, psychometrics, adjudication of endpoints, etc., belongs in **Section 8**, **Study Assessments and Procedures**.*

A putative mechanism of action is the theorized explanation for how the intervention functions.

*Consider whether primary and secondary endpoints should be adjusted for multiple comparisons, family-wise error rates, alpha inflation, etc. Details of any such adjustments should be included in **Section 9.4.2, Analysis of the Primary Endpoint(s)** and **Section 9.4.3, Analysis of the Secondary Endpoint(s)**.*

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
To evaluate whether the intervention increases CRC screening in noncompliant African American men.	• Medical Records Review verification of colorectal cancer screening since study entry • Self-report of CRC screening since study entry	Tests causal mechanism
Secondary		
To evaluate whether the intervention improves health beliefs and knowledge in noncompliant African American men.	• Perceived severity of CRC • Perceived susceptibility to CRC • Perceived barriers to colonoscopy and stool tests • Perceived benefits of colonoscopy and stool tests • Trust in the medical system	Tests causal mechanism or potential moderating effects

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
	• CRC knowledge	

4 STUDY DESIGN

No text is to be entered in this section; rather it should be included under the relevant subheadings below.

4.1 OVERALL DESIGN

This is a Phase II single-site randomized, 2-arm between-subjects study examining differences in CRC screening and related beliefs between participants randomized to the experimental intervention and those randomized to the attention control condition (text messages providing CRC information and links to CDC-developed videos). Outcomes were assessed at baseline and again at 6-months post-baseline. We hypothesized that experimental participants would be more likely to get screened for CRC and report more positive beliefs about screening than control participants. Participants were assigned to conditions by an algorithm programmed into the study computer using a permuted blocks randomization scheme. Blocks of size 4 and 6 were used. Assignments within blocks was be random but balanced among the two conditions and the order of the blocks (4 vs 6) also was random. This procedure will ensure that the number of participants randomized to each condition was equal, that any imbalance among the conditions at any point during the recruitment and randomization was modest, and that it would be very difficult to guess the assignment of the next participant. Randomization was administered via computer-based admin system and triggered by the study coordinator.

The intervention – m-CRCSi – combines text messages with brief educational and motivational videos to provide CRC education, reduce screening barriers, and promote timely screening.

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

Participants in the control condition received a text explaining that over the next several weeks they would be receiving information about CRC developed by the CDC. Over the next 8 weeks, users receive 16 text messages with either information about CRC or links to CDC-developed videos about CRC. These texts and videos include information about CRC, CRC screening tests, barriers and benefits to CRC screening, and other health-related beliefs about CRC. This control condition was chosen to provide a close match to the content, format, and delivery schedule of the experimental intervention. This study design was chosen to allow for a comparison between the m-CRCSi intervention and widely available video-based content developed by the leading public health agency protecting the health of Americans.

4.3 JUSTIFICATION FOR INTERVENTION

m-CRCSi is an effective, affordable, and scalable intervention to increase CRC screening among African American men. The intervention is based on the Health Belief Model (HBM). The HBM posits that a person is more likely to perform a health behavior when he: understands the seriousness of an illness (perceived severity) and feels there is a realistic chance he will develop it (perceived susceptibility), expects that the health behavior will reduce risks from the illness (perceived benefits) with relatively few costs (perceived barriers), is aware of the health behavior (cues to action), and believes he can perform it (self-efficacy). The intervention integrates text messages and videos because the majority of African American men own and use smartphones. Delivered across 5 "chapters," the videos are designed to address potential health literacy concerns by providing brief and clear information about CRC and screening options. It is expected that men will engage with all intervention content.

4.4 END-OF-STUDY DEFINITION

A participant is considered to have completed the study if he or she has completed the baseline assessment and the 6-month follow-up assessment.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Provision of signed and dated informed consent form
2. Stated willingness to comply with all study procedures and lifestyle considerations and availability for the duration of the study
3. Males; ages 45-75
4. Self-identify as Black or African American
5. Noncompliant with CRC screening recommendations via medical records review
6. Access to a smartphone

5.2 EXCLUSION CRITERIA

An individual who meets any of the following criteria will be excluded from participation in this study:

1. Lack of limited English literacy skills
2. Presence of colorectal cancer or a previous colorectal cancer diagnosis

5.3 LIFESTYLE CONSIDERATIONS

N/A

5.4 SCREEN FAILURES

Screen failures are defined as participants who consent to participate in this study but are not subsequently assigned to the study intervention or entered in the study. Re-screening is permitted if circumstances change.

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

Participants will be recruited by 2-3 community health workers employed by our partner medical clinic. The partner clinic serves Washington, DC communities east of the Anacostia River and are an integral part of the community with extensive outreach efforts including a needle exchange mobile van program and oral rapid HIV testing at DMV sites. Based on the clinic's wide range of services, it is likely that participants' health status will range from those who are healthy to those who are managing one or more chronic diseases or infections (e.g., Hepatitis C, diabetes, hypertension). Recruitment will occur at the partner clinic and in the surrounding community where outreach activities are conducted. Specifically, 2-3 community health workers will hand out palm cards to African American men in the primary care waiting rooms and at community outreach events (e.g., health fairs). The recruiters, as well as the text on the palm card, will instruct interested participants to contact the onsite field test coordinator for more information about the project and will provide the room number, a telephone number, and the hours during which the field test coordinator is available. We successfully used this strategy to recruit African American men from the same clinic for a recent randomized trial of a computer-based HIV behavioral intervention.

To maximize retention, this study will employ several techniques that have proven successful in previous research projects conducted at the clinic with similar populations. First, the onsite field test coordinator will collect as much contact information as the participant feels comfortable providing (e.g., additional phone numbers, email address, preference for calls v. text messages). This will include asking about secondary contacts – these are alternate phone numbers where the participant can be reached, such as the number of a parent, spouse, or friend. To protect participant's privacy, the field test coordinator will record how the project should be identified when calling each secondary contact (e.g., "the colorectal cancer project" v. "the phone study"). We have successfully retained participants whose personal phones were temporarily unavailable (e.g., the phone was broken or disconnected, the participant got a new number) using this strategy. Second, we will offer reminder texts or calls the day before a scheduled appointment. Third, if a participant misses a scheduled appointment, the field test coordinator will implement the retention protocol with the goal of rescheduling the missed appointment. Specifically, the field test coordinator will contact the participant via his preferred contact method the day of the missed appointment and – if he is not reached – every two business days thereafter for one week. If the participant is not reached within a week, the ISA field test coordinator will begin calling the alternate contacts' phone numbers. If the participant is not reached after calling each alternate contact once, the field test coordinator will continue contacting the primary number every two days for an additional week. If the participant is not reached after two weeks, the field test coordinator and the Principal Investigator will meet to determine whether additional contacts are warranted or if the participant should be categorized as "lost to follow up."

In general, retention rates for projects conducted at the clinic have been high. The clinic is well regarded in the community and many participants visit regularly for medical care or other services. We believe the proposed study will have similarly favorable retention rates.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

No text is to be entered in this section; rather it should be included under the relevant subheadings below.

6.1 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S) ADMINISTRATION

No text is to be entered in this section; rather it should be included under the relevant subheadings below.

6.1.1 STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION

m-CRCSi is an effective, affordable, and scalable intervention to increase CRC screening among African American men. The Health Belief Model (HBM) will guide intervention development. The HBM posits that a person is more likely to perform a health behavior when he: understands the seriousness of an illness (perceived severity) and feels there is a realistic chance he will develop it (perceived susceptibility), expects that the health behavior will reduce risks from the illness (perceived benefits) with relatively few costs (perceived barriers), is aware of the health behavior (cues to action), and believes he can perform it (self-efficacy). Theory-based assessments of these health beliefs will be used to tailor the intervention. It will also be targeted by contextualizing HBM constructs with the health beliefs and information needs of African American men and by integrating congruent imagery, language, and values.

Participants meet “William,” a Black health educator, who hosts five short video chapters: CRC basics; personalized screening guidance; colonoscopy deep-dive; stool-test options; and real-world roadblocks (cost, access, distrust, logistics) with practical workarounds. Content mixes host segments, expert Q&A (Dr. Malcolm), and men’s roundtables to normalize screening, name fears, and model solutions. After Chapter 1, a brief health history routes men to tailored messages: average-risk vs high-risk; unscreened vs up-to-date; under-45 paths; symptom prompts. Chapter 2 scripts change accordingly, then branch into colonoscopy vs stool-test education with concrete prep tips, tradeoffs, and “which test fits you” framing. A participant learns the basics, receives a personalized plan, selects a test that fits, uses reminders and resources to overcome barriers, and confirms screening via “SCREEN”—all with minimal clinic lift and high resonance.

Attention-control materials consist of a series of text messages including information and links to CDC-produced videos covering CRC risk, screening options, and general prevention. Over 8 weeks, users receive 16 text messages with either information about CRC or links to CDC-developed videos about CRC. These texts and videos include information about CRC, CRC screening tests, barriers and benefits to CRC screening, and other health-related beliefs about CRC.

6.1.2 ADMINISTRATION AND/OR DOSING

Participants in the intervention arm receive a fully automated, mobile program that blends short, pre-recorded video chapters with behaviorally informed SMS prompts. Delivery is remote and device-based (links arrive by text; videos open on the participant's phone), so all exposure occurs in participants' everyday settings rather than in clinic (video host "William," a health educator, introduces and guides the experience). The curriculum phase consists of a sequenced video pathway with five content areas: (0) Orientation/how-to; (1) CRC basics and screening rationale; (2) a tailored "Your Screening Plan"; (3) colonoscopy skills/support; and (4) stool-test skills/support, followed by (5) "Roadblocks" with practical workarounds. This structure (multiple brief videos per chapter) is scripted and enumerated in the master outline. A complete ("full-dose") curriculum exposure is defined as viewing the core chapter set (0–5) with the tailored branch in Chapter 2 (average- vs high-risk; screened vs unscreened) and the colonoscopy and/or stool-test micro-modules appropriate to that branch. Immediately after education, participants enter a Post-Education Screening Assistance (PESA) phase driven by SMS logic. This phase checks status, offers tips/resources, and schedules periodic reminders keyed to whether a colonoscopy or stool test is planned, scheduled, completed, or not planned. Example schedules include check-ins and supports at 2, 3, 5, 6, 8, 10, 12, 14 days and beyond, with the system extending supportive messaging out to roughly 16 weeks (e.g., 88, 94, 100, 108, and 116 days since the initial PESA trigger).

Curriculum frequency/intensity. Videos are brief (micro-learning format) and delivered via SMS links in sequence; the program advances if a user stalls, with nudges to keep momentum. The curriculum comprises multiple short videos across Chapters 0–5; for dose accounting, we treat each chapter as a "session," yielding ~5 sessions for a full curriculum dose (with additional sub-sessions in the tailored Chapter 2 branch and the chosen test-skills modules).
PESA frequency/intensity. After education, SMS prompts occur on a fixed timer and/or when users report milestones (e.g., "scheduled in 2–4 weeks," "don't know date yet," "planning to schedule"). Messages cluster early (2–10 days), then taper while extending for up to ~116 days if screening has not yet occurred.
Engagement prompts and escalations. If the post-education questionnaire is not completed within 5 days, targeted nudges are sent to re-engage and route the appropriate support stream.

There are **no live interventionists** and **no participant-to-participant interaction** after randomization. All contact is one-to-one, automated, and virtual: a pre-recorded health educator hosts the videos; the SMS engine personalizes cadence and content based on responses (e.g., keywords such as SCREEN) and branching logic. No face-to-face or group sessions are conducted.

Control arm receives 1–2 SMS per week for 8 weeks providing information about CRC and linking to CDC materials.

6.2 FIDELITY

*No text is to be entered in this section; rather it should be included under the relevant subheadings below. This section refers to efforts made to confirm that the intervention is appropriately conducted by the interventionist(s). It is distinct from the content of **Section 6.4, Study Intervention Adherence**, which is intended to capture a study participant's adherence to an intervention.*

6.2.1 INTERVENTIONIST TRAINING AND TRACKING

Timed text messages – called nudges – are sent to experimental participants at pre-specified intervals if they have not engaged with or completed a video chapter. After 7 days, an autodrop of the next chapter is triggered even if participants have not completed the previous chapter. Although no one "administers" the intervention content, study staff may assist with enrollment logistics and basic tech support. Staff will not advise on screening choices or alter message timing/content. If a participant becomes "stalled" (i.e., they have not engaged with intervention content in over 7 days and have not completed the intervention), an email message is sent to the study coordinator. The study coordinator then contacts the participant to inquire about any issues or questions and reinforce the importance of engaging with the intervention.

To ensure consistent delivery across arms, we will perform routine quality control (QC) checks using the SMS platform's audit logs and dashboards. QC procedures include: (a) automated monitoring of send failures (hard/soft bounces) with daily review and same-day re-send or number verification; (b) timing-drift checks comparing scheduled vs. actual send times (tolerance ±5 minutes for fixed-time sends; ±24 hours for week-based sequences) with corrective action logged; (c) weekly link-uptime validation (HTTP status and redirect integrity) for all URLs in both arms, with broken links replaced from a preapproved list; and (d) parity audits to confirm equivalent contact frequency and timing windows across study arms. All QC activities are documented in an audit trail (issue, detection date, corrective action, verification). Responsibility: Study Technologist (daily automated checks) and Project Manager (weekly parity audit); oversight by the PI.

Control fidelity is tracked via delivery logs, weekly link checks, and audit reports confirming scheduled sends and link availability.

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

Participants will be assigned to conditions by an algorithm programmed into the computer-based research portal. Randomization will utilize a permuted-blocks randomization scheme. Blocks of size 4 and 6 will be used. Assignments within blocks will be random but balanced among the two conditions and the order of the blocks (4 vs 6) also will be random. This procedure will ensure that the number of participants randomized to each condition will be equal, that any imbalance among the conditions at any point during the recruitment and randomization will be modest, and that it will be very difficult to guess the assignment of the next participant. Because the intervention and control materials are inherently different, participants and research staff cannot be blinded to assignment. To limit bias, primary outcome ascertainment (MRR-verified receipt of CRC screening within 6 months) will be conducted by clinic staff who abstract electronic health records without reference to group assignment; two abstractors will review each record and reconcile discrepancies, providing an additional safeguard against bias.

6.4 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION ADHERENCE

Participants' adherence is tracked entirely through platform telemetry. During the curriculum phase, the SMS system records each linked video open and completion at the chapter/video level, issues time-based nudges when progress stalls (e.g., Day 2/4/6/7 rules for Chapter 1), and—if needed—auto-advances to the next assessment to preserve momentum. In the post-education phase, completion of the brief status questionnaire is monitored; automated reminders are sent at 2, 4, and 5 days if incomplete. Thereafter,

scheduled check-ins and resources continue on a fixed cadence (extending to ~116 days for noncompleters), and participant replies (including the keyword SCREEN) are logged as adherence signals and to close out the program when screening is reported.

Mandatory activities to remain an active participant are: consent, baseline questionnaire completion, randomization, and provision of a working mobile number (to enable delivery). All subsequent educational exposures (video views) and assessments are encouraged and tracked but not required for continued participation; the system's escalation (nudges/auto-drops) is designed to maximize exposure without removing participants for nonresponse.

Source records for adherence include the SMS platform logs (timestamps, message types, opens/completions, replies) and assessment completion flags. Optional activities available to participants (and tracked when used) include engaging the built-in reminder system and revisiting resources/videos; use is captured by link launches and elapsed time triggers.

No in-person visits are required for adherence. For transparency in reporting dose/exposure, we will summarize: number of curriculum videos delivered/opened, assessment completion and days-to-completion, number of SMS messages delivered and proportion eliciting a reply, days retained in the assistance stream, and whether/when screening was confirmed via SMS.

Control-arm adherence (e.g., link click-throughs or time on page) is not collected. To minimize participant burden and maintain parity with standard informational outreach, we verify delivery only, using SMS send logs. Primary analyses are intention-to-treat and do not rely on control exposure metrics.

6.5 CONCOMITANT THERAPY

N/A

6.5.1 RESCUE THERAPY

N/A

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

No text is to be entered in this section; rather it should be included under the relevant subheadings below.

7.1 DISCONTINUATION OF STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

When a subject discontinues from the intervention but not from the study, remaining study procedures will be completed as indicated by the study protocol. If a clinically significant finding is identified (including, but not limited to changes from baseline) after enrollment, the investigator or qualified designee will determine if any change in participant management is needed. Any new clinically relevant

finding will be reported as an adverse event (AE). The data to be collected at the time of study intervention discontinuation will include the following: the reason(s) for discontinuing the participant from the intervention, and methods for determining the need to discontinue

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request.
An investigator may discontinue a participant from the study for the following reasons:

- Lost-to-follow up; unable to contact subject
- Participant withdraws consent for further participation and/or data use.
- Participant texts "STOP" to the experimental intervention phone number.
- Safety concerns: any SAE or AE judged related to participation that warrants removal, per the Data and Safety Monitoring Plan and IRB reporting rules.
- Ineligibility discovered post-enrollment, duplicate enrollment, or other protocol violations that compromise data integrity.
- Investigator decision that continued participation poses undue burden or risk (e.g., credible threats of harm), consistent with IRB policies.

The reason for participant discontinuation or withdrawal from the study will be recorded on a dedicated Case Report Form (CRF). Participants who withdraw or are discontinued after randomization will not be replaced; enrollment continues until the target sample size is reached.

7.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if he or she fails to respond for the 6-month follow-up call and study staff are unable to contact the participant after at least 3 attempts.

The following actions must be taken if a participant fails to respond for a required study appointment:

- The site will attempt to contact the participant, reschedule the missed baseline or follow-up appointment, counsel the participant on the importance of maintaining the assigned visit schedule and ascertain if the participant wishes to and/or should continue in the study
- Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant (where possible, 3 telephone calls including to a secondary contact number). These contact attempts will be documented in the participant's study file.
- Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

8 STUDY ASSESSMENTS AND PROCEDURES

No text is to be entered in this section; rather it should be included under the relevant subheadings below.

8.1 ENDPOINT AND OTHER NON-SAFETY ASSESSMENTS

This individually randomized, remote trial evaluates a mobile, video+SMS colorectal cancer (CRC) screening education program versus a standard-materials control. All study activities are conducted virtually; no study-specific physical exams, imaging, or biospecimen collection occur. Outcome verification uses medical record review (MRR) and self-report.

Screening, eligibility, and enrollment

- **Eligibility confirmation window.** Up to 30 days prior to enrollment. Site staff confirm basic eligibility from clinic records (e.g., age, overdue for CRC screening per guidelines, active phone number).
- **Consent & MRR authorization.** Participants complete electronic informed consent and provide HIPAA authorization for MRR.
- **Baseline survey.** Immediately post-consent, participants complete a baseline questionnaire.
- **Randomization.** After baseline completion, participants are assigned to intervention or control.

Interventions begin (initial administration conditions)

- **Intervention arm.** Participants receive an SMS link to the curriculum hub and proceed through brief, pre-recorded videos with tailored branches, followed by a post-education screening assistance (PESA) text sequence.
- **Control arm.** Participants receive text messages, some with links to standard educational materials via SMS. A working mobile number and ability to receive texts are required for delivery; there are no in-person or group sessions.

Measures and assessments (non-safety)

Baseline (pre-randomization)

- Demographics and contact details (mobile number required for delivery).
- CRC screening history (ever screened; modality and timing if applicable).
- Psychosocial measures (e.g., CRC knowledge; perceived risk/severity; perceived benefits/barriers for stool tests and colonoscopy; medical trust; self-efficacy).

During intervention (process/dose)

- Platform telemetry: timestamps for each SMS, link launches, chapter/video opens (percent viewed), assessment completions, participant replies (including keyword confirmations), and time in the assistance stream. These are used for exposure/dose summaries and adherence monitoring (not safety).

Follow-up (primary outcome window)

- **Primary outcome ascertainment:** Receipt of any guideline-concordant CRC screening within 6 months post-randomization, verified by MRR (test type, date, and result if available) and self-report.
- **Follow-up questionnaire:** repeat of key psychosocial measures to explore mechanisms and acceptability.

Outcome definitions (non-safety)

- **CRC screening completion:** Documentation in the medical record or self-report of colonoscopy, FIT, FIT-DNA, CT colonography, or flexible sigmoidoscopy performed within the 6-month window (plus any pre-specified grace period).

- **Exposure/dose metrics:** Number of SMS delivered; proportion eliciting a response; number/proportion of videos opened by chapter; completion of the immediate post-education questionnaire; and elapsed days in PESA until closeout.

Administration, scoring, and data quality

- **Administration.** All questionnaires are administered via telephone.
- **Scoring.** Multi-item scales are scored per codebook (sum or mean of valid items; higher scores reflect greater endorsement or knowledge, as defined). Missing-data rules (e.g., minimum items required) are pre-specified.
- **Data capture.** Survey responses and SMS telemetry are time-stamped and stored on the study platform; MRR uses standardized abstraction forms with dual review and reconciliation.

Qualified personnel

- **MRR:** Conducted by trained study staff (e.g., clinic research coordinators) using a standardized abstraction guide; complex clinical ambiguities are adjudicated by a qualified clinician (e.g., physician or advanced practice provider).
- **Telephone-based assessment:** Conducted by trained study staff.

Use of existing clinical data and HIPAA

The study uses existing medical charts to verify CRC screening. HIPAA, applicable federal/state laws, and local institutional requirements are followed. MRR variables include test type and date (and result if available). No central lab is used; no CLIA-covered testing is performed by the study.

Standard of care procedures

All screening tests are ordered and performed as part of routine clinical care, independent of the research team. The study does not alter clinical pathways, rescue therapy, or provider decision-making.

Results returned to participants

Participants receive general educational messages and resource links through the intervention or control SMS sequences. The study does not generate new clinical test results; any clinical results (e.g., from a colonoscopy) are communicated by the healthcare system per usual care.

8.2 SAFETY ASSESSMENTS

No physical examinations, performance tests, imaging, biospecimen collection, special assays, sensors, or EMA are performed by the study. Safety procedures consist of: (1) AE/SAE identification and follow-up; (2) monitoring for distress potentially triggered by educational content; and (3) privacy/technology safeguards (e.g., wrong-number texting, shared phones). AEs are any unfavorable or unintended psychological or practical effect temporally associated with participation in the study's activities (videos, SMS, surveys), whether or not considered related. Examples include: heightened anxiety/distress about CRC risk, dissatisfaction with messaging frequency, perceived breach of privacy (e.g., texts seen by others on a shared device), or escalation of medical mistrust that prompts clinical concern. SAEs would be rare in this context and are defined per IRB policy (e.g., death, life-threatening event, hospitalization) regardless of attribution.

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

No text is to be entered in this section; rather it should be included under the relevant subheadings below.

8.3.1 DEFINITION OF ADVERSE EVENTS

An AE is defined as an event that is unexpected, related or possibly related to research participation, and suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.

8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS

An SAE is defined as an event that results in death, is life-threatening, results in inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, results in a congenital anomaly/birth defect, or may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed.

8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

No text is to be entered in this section; rather it should be included under the relevant subheadings below.

8.3.3.1 SEVERITY OF EVENT

For adverse events (AEs) not included in the protocol defined grading system, the following guidelines will be used to describe severity.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious".

8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION/EXPERIMENTAL MANIPULATION

All adverse events (AEs) will have their relationship to study procedures, including the intervention, assessed based on temporal relationship. The degree of certainty about causality will be graded using the categories below.

- **Related** – The AE is known to occur with the study procedures, there is a reasonable possibility that the study procedures caused the AE, or there is a temporal relationship between the study procedures and the event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study procedures and the AE.

- **Not Related** – There is not a reasonable possibility that the study procedures caused the event, there is no temporal relationship between the study procedures and event onset, or an alternate etiology has been established.

8.3.3.3 EXPECTEDNESS

A member of the research team with appropriate expertise will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study procedures.

8.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study appointments.

All AEs, not otherwise precluded per the protocol, will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, assessment of severity, relationship to study procedures (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study will be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical or psychiatric condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition deteriorates at any time during the study, it will be recorded as an AE.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. Documentation of onset and duration of each episode will be maintained for AEs characterized as intermittent.

The study coordinator will record events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

8.3.5 ADVERSE EVENT REPORTING

Any AE or SAE, whether or not related to study intervention, will be reported to the IRB, NCI, and the Office for Human Research Protections (OHRP). SAE's will be reported to the IRB within 24 hours and AEs will be reported to the IRB within 72 hours. All SAE's and AE's will be reported to NCI and OHRP within two weeks. The initial report will be followed by submission of a completed report to all institutions.

8.3.6 SERIOUS ADVERSE EVENT REPORTING

Any AE or SAE, whether or not related to study intervention, will be reported to the IRB, NCI, and the Office for Human Research Protections (OHRP). SAE's will be reported to the IRB within 24 hours and AEs will be reported to the IRB within 72 hours. All SAE's and AE's will be reported to NCI and OHRP within two weeks. The initial report will be followed by submission of a completed report to all institutions.

8.3.7 REPORTING EVENTS TO PARTICIPANTS

N/A

8.3.8 EVENTS OF SPECIAL INTEREST

N/A

8.3.9 REPORTING OF PREGNANCY

N/A

8.4 UNANTICIPATED PROBLEMS

No text is to be entered in this section; rather it should be included under the relevant subheadings below.

8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS

This protocol uses the definition of Unanticipated Problems as defined by the Office for Human Research Protections (OHRP). OHRP considers unanticipated problems involving risks to participants or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.4.2 UNANTICIPATED PROBLEMS REPORTING

The investigator will report unanticipated problems (UPs) to the reviewing Institutional Review Board (IRB). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number
- A detailed description of the event, incident, experience, or outcome
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are serious adverse events (SAEs) will be reported to the IRB within 24 hours and to the funding agency within two weeks of the investigator becoming aware of the event
- Any other UP will be reported to the IRB within 72 hours and to the funding agency within two weeks of the investigator becoming aware of the problem
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and the Office for Human Research Protections (OHRP) within two weeks of the IRB's receipt of the report of the problem from the investigator.

8.4.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

N/A

9 STATISTICAL CONSIDERATIONS

No text is to be entered in this section; rather it should be included under the relevant subheadings below.

9.1 STATISTICAL HYPOTHESES

- Primary Endpoint(s):

We hypothesize that, compared to participants who receive standard educational materials via SMS (control), participants who receive the tailored mobile video+SMS intervention (m-CRCSi) will have a higher proportion completing any guideline-concordant colorectal cancer (CRC) screening within 6 months post-randomization. Alternatively, our null hypothesis is that there will be no difference between arms in screening completion at 6 months.

- Secondary Endpoint(s):

Self-reported proxy screening composite (6 months):
We hypothesize that the intervention arm will report a higher rate of any guideline-concordant CRC screening by 6 months than the control arm; the null hypothesis is that there will be no difference between arms.

CRC knowledge (baseline→6 months):
We hypothesize that intervention participants will show greater improvement in CRC knowledge from baseline to 6 months than control participants; the null hypothesis is that there will be no difference in change between arms.

Perceived susceptibility and severity (baseline→6 months):
We hypothesize that intervention participants will report greater increases in perceived susceptibility and severity from baseline to 6 months than control participants; the null hypothesis is that there will be no difference in change between arms.

Perceived benefits and barriers for colonoscopy and stool testing (baseline→6 months):
We hypothesize that intervention participants will report greater increases in perceived benefits and greater decreases in perceived barriers from baseline to 6 months than control participants; the null hypothesis is that there will be no difference in change between arms.

Medical trust (baseline→6 months):
We hypothesize that intervention participants will report greater increases in trust in the medical profession from baseline to 6 months than control participants; the null hypothesis is that there will be no difference in change between arms.

Self-efficacy (overall; colonoscopy; stool test) and advocacy (baseline→6 months):
We hypothesize that intervention participants will demonstrate greater improvements from baseline to 6 months than control participants; the null hypothesis is that there will be no difference in change between arms.

9.2 SAMPLE SIZE DETERMINATION

To determine the adequate sample size for our study, we examined achieved power and treatment effects for a study examining the efficacy of a conceptually similar intervention with an equivalent data analysis plan. Specifically, Miller et al. developed a digital decision aid to help patients select a CRC screening test before a primary care appointment. Compared to controls, participants assigned to the decision aid were twice as likely to get screened at 6-month followup (30% [67/223] vs. 15% [34/227], difference=15%, 95% CI 7% to 23%; OR = 2.5). Follow-up analyses with only nonwhite participants continued to show a significant positive effect on screening (34% [33/98] vs. 19% [18/94], difference = 15%, 95% CI 6% to 25%; OR=1.79). Based on the similarity of this research to our own, we anticipate similar screening proportions in our study. To estimate power for the binomial logistic regression analysis on the primary outcome measure (MRR-verified CRC screening), we relied on the sub-analysis from Miller et al.'s data. Importantly, the OR in this analysis (1.79) is consistent with the average effect size of SMS-based interventions on health behaviors (OR=1.81). The G*Power 3.1 program was used to

determine that an odds ratio of 1.79, a two-tailed α error probability of 0.05, and 80% power requires a final sample size of 154 to detect an expected difference in screening rates of 15% at the 6-month follow-up. While unlikely, we will anticipate a conservative 20% attrition rate and set our sample size at 193 (n= 154 post-attrition).

As screening-related health beliefs are important secondary outcomes, we also examined power using treatment effects for screening self-efficacy from the Miller et al. decision aid study. Researchers found that participants in the intervention group reported significantly higher screening self-efficacy (n=223, M=3.89, SD=.84) than control participants (n=227, M=3.64, SD=1.00), p=.004. This difference is associated with a Cohen's d = .27. To detect a difference of this size in screening self-efficacy, our study will require a final sample size of 110 participants (α = 0.05 two-tailed; power = .80). The 154 participants remaining in the analyses post-attrition will be sufficient to detect differences health beliefs across the two survey time points.

9.3 POPULATIONS FOR ANALYSES

Because randomization carries the expectation of creating treatment groups equivalent with respect to known and unknown prognostic factors, removing randomized participants from the analysis runs the risk of tampering with this balance and introducing bias into the treatment comparisons. As a result, an intention-to-treat analytic approach will be followed such that all participants randomized into the study will be included in all analyses irrespective of protocol violations post randomization. Even with our best efforts, we can expect some missing data. For the primary outcome, missing data will be limited to cases where we are unable to complete an MRR review. Because we will have medical releases for all participants on our primary outcome, very little missing data is anticipated. For secondary measures, missing data will consist of those who fail to complete the 6-month follow-up survey. We will conduct an initial evaluation of missingness by performing a series of logistic regression analyses where the indicator of missing data is the outcome and potential explanatory variables (e.g., condition, screening status, demographic characteristics) serve as predictors. We will then use imputation to manage missing data.

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

Binomial logistic regression will be the main analytic technique for the primary outcome (MRR-verified completion of a recommended CRC screening test). Logistic regression analyses will also examine treatment differences in type of screening received. For secondary outcomes, linear regression will be used. All analyses will control for any confounding variables not managed through randomization (i.e., group difference p <.10).

9.4.2 ANALYSIS OF THE PRIMARY ENDPOINT(S)

For the primary outcome, if any missing data is identified, both negative and multiple imputation methods

will be used to estimate CRC screening completion. This approach to missing data was successfully used by Vernon and colleagues (Kinney et al, 2014; Steffen et al, 2015). Negative outcome imputation will assume that if there was no MRR-verified CRC screening, the procedure did not occur. Multiple imputation will be based on experimental condition, age at baseline, income, health insurance coverage, and any other covariates predictive of missingness in the imputation model. Twenty imputed datasets will be used to provide a combined estimate for missing values. We will employ SAS PROC MI and SAS PROC MIANALYZE, Version 9.4, to implement these imputation procedures. We will also conduct a complete case analysis including only those participants with a known primary outcome.

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

Linear regression will be used to assess secondary outcomes. All analyses will control for any confounding variables not managed through randomization (i.e., group difference p <.10). For the secondary outcomes, we will conduct multiple imputation for any missing data using the procedures described for the primary outcome.

9.4.4 SAFETY ANALYSES

N/A

9.4.5 BASELINE DESCRIPTIVE STATISTICS

All analyses will control for any confounding variables not managed through randomization (i.e., group difference p <.10).

9.4.6 PLANNED INTERIM ANALYSES

N/A

9.4.7 SUB-GROUP ANALYSES

Study intervention is only for men.

9.4.8 TABULATION OF INDIVIDUAL PARTICIPANT DATA

Individual participant data will not be listed by measure and time point.

9.4.9 EXPLORATORY ANALYSES

N/A

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

No text is to be entered in this section; rather it should be included under the relevant subheadings below.

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

No text is to be entered in this section; rather it should be included under the relevant subheadings below.

10.1.1 INFORMED CONSENT PROCESS

No text is to be entered in this section; rather it should be included under the relevant subheadings below.

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consent forms describing in detail the study intervention, study procedures, and risks will be given to the participant and written documentation of informed consent will be completed prior to starting the study intervention.

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

The field test coordinator will provide eligible men with a detailed overview of the main points of the study. First, participants will be reminded that, although health information of a sensitive nature will be included in the intervention or control materials and the survey, their names will not be associated with their survey responses or their assigned materials. The field test coordinator will also explain the flow of the study procedures and what will be asked of participants. Participants will be told that the two surveys – the baseline survey and a follow-up survey six months later – will take approximately one hour to complete. They will also be informed that their medical records will be checked again at the end of the study to verify whether they received CRC screening since the study began. Further, men will be told that half of the participants will be asked to go through the m-CRCSi after the first survey while the other half will review CRC materials developed by the CDC via a link texted to their study phone number. Those who do not go through the m-CRCSi will be given access to it after the second survey. All participants will be informed that they will complete the research surveys via telephone with the study coordinator reading the questions and recording participant responses. They will also be told that their assigned materials can all be reviewed remotely on their smartphones. Procedures for mobile phone safety will be reviewed. Finally, the field test coordinator will also explain that participants will receive $75 for completing the baseline survey and $100 for completing the 6-month follow-up survey. Once any participant questions are answered, eligible men will be sent a text message linking to the informed consent form. Next, the potential participant will review the informed consent document. The ISA staff member will remain on the phone while potential participants review the informed consent and will encourage them to ask any questions they may have about the study.

Men who agree to participate will acknowledge their consent by tapping a button labeled "I have read the above and AGREE to participate." Men who choose not to participate will click a button labeled "I DO NOT AGREE and do not want to participate." Those who choose not to participate after reading the informed consent will be thanked for their time and released. All participants will receive a copy of the text message via their preferred channel (e.g., mailed paper copy, texted PDF) for their personal records. The copy will be identical to the digital version. In addition, the consent form will have the name and toll-free telephone number of the Principal Investigator and the IRB Chairperson if participants have any additional questions.

10.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants, the Institutional Review Board (IRB), and sponsor/funding agency and will provide the reason(s) for the termination or suspension. Study participants will be contacted, as applicable, and be informed of changes to study appointment schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Insufficient compliance of study staff to the protocol (ie, significant protocol violations)
- Determination that the primary endpoint has been met
- Determination of futility

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the funding agency, sponsor, IRB, , or other relevant regulatory or oversight bodies (OHRP).

10.1.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, the safety and oversight monitor(s), and the sponsor(s) and funding agency. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally-identifiable information from the study will be released to any unauthorized third party without prior written approval of the sponsor/funding agency.

All research activities will be conducted in as private a setting as possible.

To maintain confidentiality of all data collected, no names or other identifying information will be included with the recorded MRR screening data, on the survey, or as part of m-CRCSi or the control materials. As noted earlier, the file that will link the participant name to the user ID and study phone number will be maintained on a password protected computer that will not house the survey data. The only people that will have access to the linking file will be the Principal Investigator and her staff. Finally,

we will utilize strict security protocols – described previously – to protect the confidentiality of all information transmitted via SMS and stored on our secure server as part of the m-CRCSi intervention.

To protect against any breaches of confidentiality, all project staff proposed to conduct the data collection have received or will receive training on the protection of research participants and are or will be well versed in the Code of Federal Regulations (including 45 CFR 46 and 42 CFR) and the Belmont Report. ISA continually obtains information from the Office for Human Research Protections (OHRP) at NIH on new regulations regarding the protection of human subjects, which is disseminated to all staff. Further, participants will have the MRR procedure explained to them and will be asked to complete a medical release form before any medical records are extracted. In addition, any ISA staff proposed to work on the MRR and EHR extraction are or will be trained in all applicable HIPAA regulations.

After all participants have completed follow-up surveys, the linking file housed on the ISA computer – the only file that contains participant's personal information (e.g., name, phone number) – will be deleted. In addition, the Windows Eraser program will be used to completely remove (i.e., "wipe") the linking file from the computer by overwriting it several times using government-sanctioned deletion algorithms.

It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see *https://grants.nih.gov/policy/sharing.htm*). The PI will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and security for data dissemination and reuse (e.g., all data will be thoroughly de-identified and will not be traceable to a specific study participant). Plans for archiving and long-term preservation of the data will be implemented, as appropriate.

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

Deidentified participant research data from the baseline and follow-up surveys will be retained for 3 years from the submission of the final financial report to NIH, in keeping with guidelines described in the NIH Grants Policy Statement.

10.1.5 KEY ROLES AND STUDY GOVERNANCE

Provide the name and contact information of the Principal Investigator and the Medical Monitor or Independent Safety Monitor. Update table heading to remove non-relevant role.

Principal Investigator
Samantha Leaf, Ph.D.
ISA Associates, Inc.
4501 Fairfax Dr, Ste 601 Arlington, VA 22203
703-739-0880
sleaf@isagroup.com

10.1.6 SAFETY OVERSIGHT

Samantha Leaf, Ph.D., the PI, has the responsibility for assessing adverse events (AEs) and serious adverse events (SAEs) and the ultimate responsibility for all data and safety monitoring. She will conduct weekly reviews of any problems related to quality of data collection, transmission, or analyses and of any AEs and SAEs that occurred in the past week. Further, she will conduct annual reviews of SAEs associated with renewal of IRB approval.

10.1.7 CLINICAL MONITORING

N/A

10.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

We will perform internal quality management of study conduct, data collection, documentation and completion.

Quality control (QC) procedures will be implemented as follows:

Informed consent --- Study staff will review both the documentation of the consenting process as well as a percentage of the completed consent documents. This review will evaluate compliance, accuracy, and completeness. Feedback will be provided to the study team to ensure proper consenting procedures are followed.

Source documents and the electronic data --- Baseline and follow-up survey data will be captured directly in the study database. MRR data will be initially captured via a secure file and transcribed into the study database. All MRR entries will be checked for accuracy by a second study team member.

Intervention Fidelity — Intervention is delivered electronically. Periodic monitoring will check for errors.

Protocol Deviations – The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

10.1.9 DATA HANDLING AND RECORD KEEPING

No text is to be entered in this section; rather it should be included under the relevant subheadings below.

10.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection will be the responsibility of the study staff under the supervision of the site investigator. The investigator will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source data will be completed electronically to ensure legibility.

10.1.9.2 STUDY RECORDS RETENTION

Deidentified participant research data from the baseline and follow-up surveys will be retained for 3 years from the submission of the final financial report to NIH, in keeping with guidelines described in the NIH Grants Policy Statement. No records will be destroyed without the written consent of the sponsor/funding agency, if applicable. It is the responsibility of the sponsor/funding agency to inform the investigator when these documents no longer need to be retained.

10.1.10 PROTOCOL DEVIATIONS

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol, International Council on Harmonisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.

These practices are consistent with ICH GCP:

- Section 4.5 Compliance with Protocol, subsections 4.5.1, 4.5.2, and 4.5.3
- Section 5.1 Quality Assurance and Quality Control, subsection 5.1.1
- Section 5.20 Noncompliance, subsections 5.20.1, and 5.20.2.

It will be the responsibility of the site investigator to use continuous vigilance to identify and report deviations within 5 working days of identification of the protocol deviation. All deviations will be addressed in study source documents. Protocol deviations will be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator will be responsible for knowing and adhering to the reviewing IRB requirements.

10.1.11 PUBLICATION AND DATA SHARING POLICY

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal

manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers 10 years after the completion of the primary endpoint by contacting ISA.

10.1.12 CONFLICT OF INTEREST POLICY

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

10.2 ADDITIONAL CONSIDERATIONS

N/A

10.3 ABBREVIATIONS AND SPECIAL TERMS

AE	Adverse Event
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
CRC	Colorectal Cancer
CRF	Case Report Form
DHHS	Department of Health and Human Services
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Council on Harmonisation
IRB	Institutional Review Board
ITT	Intention-To-Treat
MOP	Manual of Procedures
NCT	National Clinical Trial
NIH	National Institutes of Health
NIH IC	NIH Institute or Center

OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
RCT	Randomized Controlled Trial
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States

10.4 PROTOCOL AMENDMENT HISTORY

*The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale. A **Summary of Changes** table for the current amendment is located in the **Protocol Title Page**.*

Version	Date	Description of Change	Brief Rationale
n/a	n/a	n/a	n/a

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