Sterling Achieve More. IRB

office 770.690.9491 **toll free** 1.888.636.1062 **fax** 770.690.9492
6300 Powers Ferry Road Suite 600-351 Atlanta, Georgia 30339
www.sterlingirb.com **e-mail** info@sterlingirb.com

STUDY APPROVAL – INITIAL

Date Issued:	June 13, 2019
Issued To:	Sponsor and/or CRO
Protocol Title:	Reaching Minority Men Where They Are
IRB ID:	**7292-*MASTER**
	Please include the IRB ID# on all correspondence pertaining to this study.
Sponsor:	Centers for Disease Control and Prevention

Review Type:	Expedited
Review Determination:	Approved
Approval Date:	**June 13, 2019**
Contingency Verification Date (*if applicable*):	
Study Expiration Date:	**June 12, 2020**
Study Status Report Due:	**30 Days Prior to Expiration Date**

Approved Principal Investigators:

7292-KEdwards (Kerstin Edwards)

Please see Section A for approved study items.

Please see Section B for additional study information.

Please see Section C for Sponsor Responsibilities.

The current Sterling IRB Membership List is available on our website, www.sterlingirb.com.

The above referenced study was reviewed and **approved** as indicated above. If applicable, satisfaction of the Board-determined contingencies was verified by the Chairman or his/her designee on the date listed above.

Sterling IRB will conduct continuing review of this study. Approval will expire on the Study Expiration Date listed above, and if the study is to continue the Sponsor must receive Sterling IRB approval for study continuation prior to the expiration date. The Sponsor should submit the **Study Status Report** not less than one month prior to the last Sterling IRB meeting preceding the expiration date (form available in Sterling IRB's web portal, SilverLink). If approval for study continuation is not obtained prior to the expiration date, the study will be considered to be in noncompliance with Federal Regulations and IRB requirements, may be suspended, and may be subject to termination.

Sterling IRB
Achieve More.

office 770.690.9491 **toll free** 1.888.636.1062 **fax** 770.690.9492
6300 Powers Ferry Road Suite 600-351 Atlanta, Georgia 30339
www.sterlingirb.com **e-mail** info@sterlingirb.com

SECTION A: APPROVED STUDY ITEMS

- Protocol (March 1, 2019)
- * Participant Informed Consent Form (Version Date: March 1, 2019)
- * *Reaching Minority Men Where They Are* Survey Questionnaire Consent Form (FINAL 04/02/2019)
- Waiver of Documentation of Informed Consent

Study Materials:

- * *Reaching Minority Men Where They Are* Survey Questionnaire (FINAL 04/02/2019)
- * Minority Men Focus Group Questions – Men with type 2 diabetes (Revised April 26, 2019)
- * Minority Men Focus Group Questions – Men at risk for type 2 diabetes (Revised April 26, 2019)

Recruitment Materials:

- * Telephone Recruitment Screening Script [Screener for focus groups with minority men with/at-risk for type-2 diabetes Revised April 26, 2019]

For approved recruitment/study materials, you may insert or change site-specific information without resubmitting to the IRB. This is not applicable to the Informed Consent Form(s).

***** For any approved items which are labeled with the **asterisk (*)** symbol, copies of these items can be found in SilverLink in the Attachments page for this submission's Event. Items not labeled with the asterisk (*) symbol will be provided by the Sponsor/CRO.

You must use the most current Informed Consent Form(s) approved by Sterling IRB for consenting participants.

End of Section A

Sterling IRB
Achieve More.

office 770.690.9491 **toll free** 1.888.636.1062 **fax** 770.690.9492
6300 Powers Ferry Road Suite 600-351 Atlanta, Georgia 30339
www.sterlingirb.com **e-mail** info@sterlingirb.com

SECTION B: STUDY INFORMATION

Sterling IRB has determined that the research involves minimal risk.

Sterling IRB determined that this study represents the following category(ies) of research eligible for expedited review:

- research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)
- research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies

End of Section B

Sterling Achieve More. IRB

office 770.690.9491 **toll free** 1.888.636.1062 **fax** 770.690.9492
6300 Powers Ferry Road Suite 600-351 Atlanta, Georgia 30339
www.sterlingirb.com **e-mail** info@sterlingirb.com

SECTION C: SPONSOR RESPONSIBILITIES

The Sponsor is responsible for overseeing the initial and continuing review and approval of the proposed study. This includes an expectation that the Sponsor will monitor the conduct of research in accordance with applicable regulations as well as any other requirements established by the IRB at the time of approval. Please refer to Sterling IRB's website, located at www.sterlingirb.com, for a more detailed explanation of the Sponsor's responsibilities.

- Check all information in the Approval Document and Informed Consent Form(s) for accuracy. **Let our office know ASAP if there are any inaccuracies.**
- Please note the due date listed on the Approval Document for the Study Status Report. **This report is required by the Board and by Federal Regulations.**
- Sterling IRB has developed web-based content outlining the responsibilities of the Sponsor. This content can be located on the Sterling website, www.sterlingirb.com.
- Any changes to the research must be submitted in writing to Sterling IRB for review and approval prior to implementation.
- Sterling IRB should be informed immediately of any serious adverse reaction or should any unanticipated problems involving risks to the subject or others occur, or if any other safety information becomes available, irrespective of whether the event occurred at a Sterling IRB approved site.
- Local prejudices or negative attitudes in the community toward the conduct of research projects must be reported immediately.
- State/provincial or local laws (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) pertaining to Patient/Volunteer Bill of Rights and specific state/provincial or local laws (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) laws concerning research which affect the conduct of clinical research must be enforced.
- Non-English speaking subjects enrolled in this study must be provided with an informed consent written in their fluent language, which must be approved by Sterling IRB before use.

If you have any questions please call our office at 888-636-1062.

End of Section C / End of Document