CLINICAL RESEARCH PROJECT **Protocol # 13-H-0183**
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NHLBI Protocol: Cardiovascular Health and Needs Assessment in Washington D.C. - Development of a Community-Based Behavioral Weight Loss Intervention

Short Title: CV Health and Needs Assessment

Keywords: community-based participatory research, obesity, cardiovascular disease risk, social determinants of health

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	150	M/F	19 years or older

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Ionizing Radiation for Research:	No
Off-Site Project:	Yes
DSMB Involvement:	No
Tech Transfer:	No
IND/IDE:	No
IND Sponsor:	N/A

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1. Précis

Obesity leads to an increased risk of cardiovascular risk factors and death from cardiovascular disease. Therefore, interventions that slow or reverse the obesity epidemic are essential. Community-based interventions can reach those most at risk for obesity and obesity-related cardiovascular risk factors. Interventions based on community-based participatory research (CBPR) principles develop in collaboration with community partners, allowing an intervention's components to be tailored to the unique needs of the community members. To remain consistent with CBPR principles, a community assessment is necessary to understand the needs of the target population. Therefore, we propose a cardiovascular health screening and needs assessment of a sample population from predominantly African-American churches in Wards 5, 7, and 8. These are wards in Washington D.C. where obesity prevalence is highest and resources for physical activity and healthy nutrition are most limited. The screening will involve measuring cardiovascular health factors such as body mass index (BMI), physical activity, dietary intake, total cholesterol, blood pressure, fasting plasma glucose, and cigarette smoking. Based on American Heart Association-established goals, cardiovascular health factors can be defined as ideal, intermediate, or poor, depending on control of risk factors and

lifestyle behaviors. In this protocol, we will determine the prevalence of ideal, intermediate, and poor cardiovascular health factors within the church-based population. We hypothesize that the percentage of the church-based population that meets ideal criteria for each of the cardiovascular health factors will be lower than the percentage meeting intermediate and poor criteria for the cardiovascular health factors. In addition, we will evaluate the use of handheld technology for objectively measuring physical activity and the use of web-based technology for monitoring cardiovascular health factors within the population. We will also evaluate social determinants of health, particularly psychosocial and environmental factors that might hinder weight loss. Finally, we will establish a community advisory board to consult on the planning and implementation of the assessment, and the interpretation and dissemination of study findings. The results of this community-based, cardiovascular health and needs assessment will inform the design and implementation of a future community-based behavioral weight loss intervention.

2. Background

Obesity As A Cardiovascular Health Factor

The obesity epidemic contributes directly to the cardiovascular health of the U.S. population. Obesity promotes an increased prevalence of diabetes, hypertension, and dyslipidemia, but also leads directly to excess cardiovascular morbidity and mortality.[1-3] If obesity trends continue unabated, recent reductions in the incidence of coronary heart disease attributed largely to decreased smoking rates and improved cholesterol and blood pressure levels in the population are expected to reverse in the United States. [4, 5] Additionally, based on projected obesity rates,[6] costs of cardiovascular disease (CVD) are estimated to rise by over $250 billion by 2035.

Obesity can serve as an important target to improve individual- and population-level cardiovascular health. The American Heart Association (AHA) has established goals for improving the cardiovascular health of the U.S. population by the year 2020, based on cardiovascular health factors, including body mass index (BMI), physical activity, dietary intake, total cholesterol, blood pressure, fasting plasma glucose, and cigarette smoking.[7] Of the modifiable cardiovascular health factors, excess weight is associated with inadequate physical activity and poor dietary habits and promotes worsening of blood pressure, glucose, and lipids.[8, 9] Thus, interventions to decrease excess weight through increased physical activity and greater adherence to dietary guidelines would likely improve all other cardiovascular health factors except cigarette smoking.

Ideal, Intermediate, and Poor Cardiovascular Health Factors

For each of the cardiovascular health factors, ideal cardiovascular health for adults is defined as: BMI < 25 kg/m^2, ≥ 150 min/week of moderate physical activity, a healthy dietary pattern including adequate intake of fruits and vegetables, optimal blood pressure, fasting glucose, and total cholesterol levels, and never smoking or quit smoking for greater than 12 months.[7, 10] Cardiovascular health factors can be defined as ideal, intermediate, or poor, depending on control of risk factors and lifestyle behaviors.(**Table 1**) Evidence suggests a stepwise increase

in CVD events, including coronary heart disease death, non-fatal MI, stroke and heart failure, as the number of ideal cardiovascular health factors declines.[11-13]

Cardiovascular Health Factors	Ideal	Intermediate	Poor
Body Mass Index (BMI)	18.5-24.9 kg/m^2	25-29.9 kg/m^2	≥30 kg/m^2
Physical Activity Status	Very Active ≥150 min/week moderate or ≥75 min/week vigorous or ≥150 min/week moderate + vigorous	Moderately active 1–149 min/week moderate or 1–74 min/week vigorous or 1–149 min/week moderate + vigorous	Inactive No reported physical activity
Fruit & Vegetable Consumption	≥ 3 servings /day	----	< 3 servings/ day
Total Cholesterol	<200 mg/dl, untreated)	200-239 mg/dL or treated to goal	≥240 mg/dL
Blood Pressure	Systolic <120 mm Hg and Diastolic <80 mm Hg	Systolic 120-139 mm Hg, Diastolic 80-90 mm Hg or treated to goal	Systolic ≥140 mm Hg or Diastolic ≥90 mm Hg
Fasting Plasma Glucose	<100 mg/ dL + no history of diabetes mellitus	100-125 mg/dL or treated to goal	≥126 mg/dL
Smoking Status	Never smoker	Former Smoker	Current smoker

Table 1: Ideal, Intermediate, and Poor Criteria for Cardiovascular Health Factors

Data from the National Health and Nutrition Examination Survey (NHANES) demonstrate that only 4.4% of the U.S. adult population aged ≥ 20 years has ideal cardiovascular health, with African Americans disproportionately less likely to have six or greater ideal cardiovascular health factors as compared to non-Hispanic whites.[1] This likely contributes to a greater burden of CVD among African Americans.[3, 14, 15] Therefore, interventions that shift at-risk individuals, particularly in the African American community, from poor toward ideal cardiovascular health are essential. Interventions designed to target BMI, physical activity and dietary intake as cardiovascular health factors can potentially facilitate this shift towards ideal cardiovascular health.

Community-Based Interventions Targeting Obesity and Cardiovascular Health

Community-based interventions serve as population approaches to target prevalent obesity and improve the cardiovascular health of at-risk populations.[16-18] Community-based interventions may also address disparities in cardiovascular health across racial/ethnic groups, particularly among those with limited access to care in clinical settings.[19] Specifically, interventions designed using principles of community-based participatory research (CBPR) can reach those most at risk due to obesity and obesity-related cardiovascular risk factors, especially in underrepresented minority populations.[20, 21]

CBPR is a complementary alternative to traditional population-based biomedical research. CBPR is defined as a collaborative approach to biomedical research that equitably involves partners from the community and academia in each stage of the research process, recognizing the unique strengths that each brings to the partnership.[22] CBPR focuses on a research topic of importance to the community and it ensures that intervention strategies designed using this approach are compatible with the culture and life circumstances of the target community and

population being studied.[23-25] CBPR approaches are also effective at identifying new research questions on which to design and implement future studies for the benefit of the community.[25, 26] Specifically, interventions based on CBPR principles occur in collaboration with community partners and are intended to serve as sustainable methods of targeting lifestyle factors.[27, 28] Moreover, the relevance of a study can be enhanced and the retention of study participants improved when community members' knowledge informs the design of the intervention and dissemination of findings.[29]

To align with CBPR principles, interventions targeting behavioral change in underrepresented minority populations and communities should address the factors affecting lifestyle choices within those communities.[30] A community-based intervention that promotes individual behavior change for weight loss and improvement of cardiovascular health, leveraging the built and social environment of the church community may have greater sustainability.[8, 23, 31] In addition, understanding psychosocial factors and cultural norms within the church community, such as perceived social support and perceptions of appropriate weight, may aid in implementing an intervention. Therefore, community assessments are necessary to contextualize community-based projects and to tailor an intervention to the needs of community members. Community assessments provide understanding of the health status of the community members, identifying health issues on which to focus intervention resources. They also aid in building capacity for future interventions by enabling community members to interpret and disseminate assessment results to broader constituencies.[29] In prior studies, community assessments have identified key social determinants of health that formed the basis of interventions targeting physical activity,[32-34] environmental health and justice,[25, 29, 35] and tobacco cessation.[36] The Institute of Medicine and Healthy People 2020 guidelines have both recognized the importance of community-based health assessments by proposing them as a potentially effective method for monitoring public health at the local level.[37, 38]

The Faith-Based Community as a Site for Developing Novel Community-Based Interventions Targeting Obesity and Cardiovascular Health

Religious settings can serve as effective sites for community-based interventions targeting lifestyle changes and weight loss to improve cardiovascular health. In a systematic review, the World Health Organization describes effective interventions in religious settings as culturally appropriate and multi-component interventions that are developed and implemented in collaboration with religious leaders.[39] Interventions in the faith-based community likely foster behavior change through the established social structure and social support within the church population. However, the World Health Organization's review noted that prior interventions in the faith-based community have been limited in both number and scale. Within the African-American community, the church is a particularly important and influential CBPR partner, having considerable influence as a social institution and being held in highest esteem by most African Americans.[40-42] The African American church has a long history of engaging in community-based health initiatives, [43-47] and leaders within the African American church can shape health perspectives and behaviors of African Americans. [48] However, it is less clear how interventions within the African American church that promote behavior change influence cultural norms, like perceptions of healthy body size. Our group has previously shown that unrealistic perceptions

of a healthy body size among those with obesity are associated with lower levels of physical activity and overly optimistic perceptions of cardiovascular risk.[49]

Our prior work suggests that the African-American, faith-based community may be an ideal setting for interventions targeting obesity. Previously, we compared health behaviors and cardiovascular risk factors among African-American participants in the Genes, Nutrition, Exercise, Wellness, and Spiritual Growth (GoodNEWS) program, a CBPR-based intervention targeting hypertension, diabetes, and dyslipidemia in churches in Dallas, Texas to the overall African-American population in Dallas County, Texas.[50] Compared to age- and sex-matched African Americans in Dallas County, the church-based population recruited for the GoodNEWS intervention had a higher prevalence of obesity and downstream obesity-related risk factors (including diabetes, low HDL, and high triglycerides) despite greater reported physical activity. Based on these findings, a church-based, behavioral weight-loss intervention for African Americans in Dallas County may be effective if providing specific tools for physical activity that promotes weight loss. However, it is much less clear the types of tools that may aid in increasing physical activity in a community-based population, similar to the population recruited for the GoodNEWS intervention. Tools to increase physical activity levels for community-based populations need further development, especially as handheld devices and web-based technology to monitor and promote physical activity become more cost-efficient and more widely available. Moreover, little is understood about the usage and efficacy of these technology-based tools in a community-based population. In the GoodNEWS intervention, the standard, group meetings with lay health promoters for the intervention population did not significantly increase physical activity as compared to the control population.[51] These findings suggest that there may be a role for incorporating technology to promote increased physical activity and behavior change in similar populations.

The African-American, faith-based community in Washington D.C. may also serve as an ideal site for CBPR interventions to target prevalent obesity and improve the cardiovascular health of an at-risk population, particularly in African-American churches in Wards 5, 7, and 8 (of the total eight wards) in Washington D.C. Based on data from the Behavioral Risk Factor Surveillance Survey (BRFSS), a yearly assessment of the health and behaviors across the U.S., these wards are areas in Washington D.C. where the obesity prevalence is highest and resources for physical activity and healthy nutritional options are most limited.[52] In 2010, prevalent obesity ranged from 30-42% in Wards 5, 7, and 8 compared to 12-22% in the remaining five wards, as shown in **Figure 1**. In addition, less than a third of residents in Wards 5, 7, and 8 reported consumption of recommended daily fruit and vegetable servings, and adult residents in these wards reported the lowest levels of physical activity.[52] CBPR partnerships with African-American churches in Wards 5, 7, and 8 would leverage the existing social networks of these community institutions to promote behavior change for improved cardiovascular health.

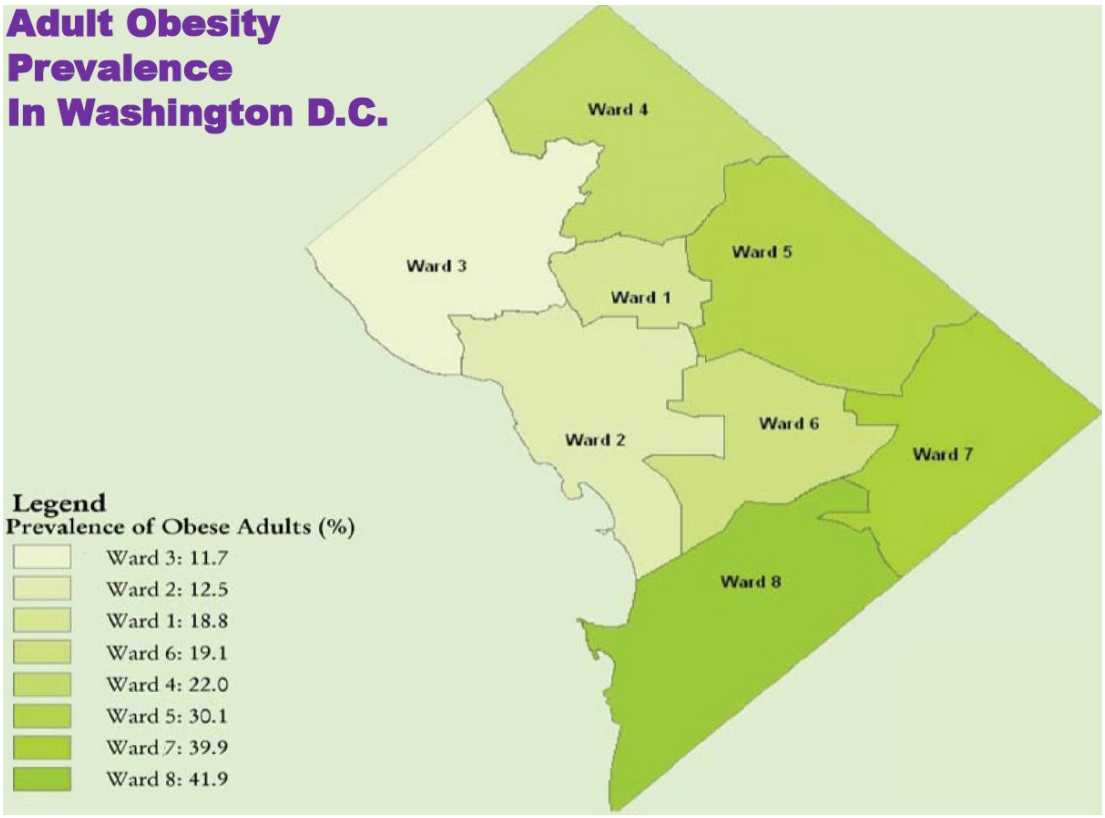

Figure 1: Obesity prevalence in Washington D.C. by ward [52]

Consequently, a community health and needs assessment would serve as a first step in establishing CBPR partnerships with African American churches in Wards 5, 7, and 8 in Washington D.C. for future implementation of a church-based behavioral weight loss intervention. First, the community assessment would allow our research team to work directly with churches in these Washington D.C. communities. This assessment would also identify cardiovascular health factors in at-risk African Americans in Washington D.C and potential methods for intervention using handheld and web-based technology. This work is timely and relevant because first, little is understood about the cardiovascular health for the population in Washington D.C.'s predominantly African-American churches. Understanding cardiovascular health factors in the population would allow us to develop specific goals for improvement in cardiovascular health for a behavioral weight loss intervention. Second, the use of technology like web-based tools for monitoring cardiovascular health factors or handheld devices for measuring physical activity and dietary intake will be evaluated in this assessment, which could identify novel methods for delivery of a future behavioral weight loss intervention. Third, this assessment will identify levels of untreated hypertension, diabetes, and hypercholesterolemia in the church-based population and evaluate methods for referral to treatment in community-based clinics. Finally, this assessment will evaluate social determinants of obesity in this population, or the psychosocial factors, cultural norms (i.e. perceptions of body size), and environmental factors that may serve as barriers to sustained behavior change in the community.

Purpose of Current Study

Therefore, we propose the development of a CBPR partnership with African American churches in Wards 5, 7, and 8 through a community health screening and needs assessment. In this screening and assessment, we will determine the prevalence of ideal, intermediate, and poor cardiovascular health factors based on AHA-defined goals within a church-based population in wards 5, 7, and 8 in Washington D.C. We hypothesize that fewer individuals in the church-based population will meet ideal criteria for each of the cardiovascular health factors as compared to those meeting intermediate or poor criteria. We will also evaluate the use of handheld devices, such as wearable physical activity monitors or digital cameras, for objectively measuring physical activity and dietary intake. We will examine the use of web-based technology for self-monitoring cardiovascular health markers in the population. This protocol will identify technology that may be incorporated into a future intervention. In addition, we will evaluate methods for referral for treatment of unrecognized hypertension, diabetes, and hypercholesterolemia in the community-based population. Social determinants of obesity, particularly environmental, cultural, and psychosocial factors that might help or hinder weight loss, will be evaluated in the population. The relationship between psychosocial, cultural, and environmental factors and levels of physical activity or dietary intake will be determined. Finally, we will establish a community advisory board to consult on planning the screening events, aid in dissemination and interpretation of study findings, and participate in the design of a community-based intervention. This screening and needs assessment will establish a CBPR partnership for the future design and implementation of a church-based, behavioral weight loss intervention.

3. Objectives and Specific Aims

3.1 Primary Objective

The primary objective of this study is to estimate the percentage of the population in predominantly African-American churches in Wards 5, 7, and 8 in Washington D.C. that meet ideal, intermediate, and poor criteria for each of the cardiovascular health factors (BMI, physical activity, dietary intake, blood pressure, total cholesterol, fasting plasma glucose, and cigarette smoking). This data will inform the design and implementation of a behavioral weight-loss intervention within the faith-based community immediately following this study.

3.2 Secondary Objective

The secondary objectives are to: 1) evaluate usage of handheld devices for objectively measuring physical activity and dietary intake; 2) evaluate usage of web-based technology for monitoring cardiovascular health markers, including dietary intake; 3) examine referral methods for untreated hypertension, diabetes, and hypercholesterolemia; 4) compare lifestyle behaviors across levels of psychosocial factors, cultural norms, and neighborhood environment factors; and 5) formalize a community advisory board involved in the implementation of the health screening and needs assessment program and a future behavioral weight-loss intervention.

Specific Aims and Hypotheses:

Primary Aim:

Aim 1: To determine the prevalence of ideal, intermediate, and poor levels of each of the cardiovascular health factors (BMI, physical activity, dietary intake, total cholesterol, blood pressure, fasting plasma glucose, and cigarette smoking) in a sample population from predominantly African-American churches in Wards 5, 7, and 8 of Washington D.C.

Hypothesis: We hypothesize that the percentage of the church-based population that meets ideal criteria for each of the cardiovascular health factors will be lower than the percentage meeting intermediate and poor criteria. We also hypothesize that the percentage meeting ideal, intermediate, and poor criteria will differ by sex and age.

Secondary Aims:

Aim 2a: To determine the association between physical activity levels measured by a wristband physical activity monitor to physical activity measured using a survey or a standard accelerometer in the church-based population.

Hypothesis: We hypothesize that objectively measured physical activity using a wristband physical activity monitor will differ from reported physical activity based on survey measures. We also hypothesize that physical activity measured by the wristband monitor will correlate with physical activity measured with an accelerometer.

Aim 2b: To determine the feasibility of using a handheld, digital camera to take photographs of dietary intake as a pilot for a digital food record in a subset of the study population.

Aim 2c: To evaluate usage of web-based technology for monitoring cardiovascular health markers (i.e. dietary intake, types of physical activity, weight, blood pressure, blood glucose) in the church-based population.

Hypothesis: We hypothesize that usage of web-based technology for monitoring cardiovascular health markers will differ by sex and age.

Aim 3: To examine referral methods for untreated hypertension, diabetes, and hypercholesterolemia from predominantly African-American churches in Wards 5, 7, and 8.

Aim 4: To compare physical activity and dietary intake (i.e. intake of fruits and vegetables, whole grains, sugar-sweetened beverages, prepared/processed foods, grain-based desserts) across levels of psychosocial factors, cultural norms, and neighborhood environment factors in the population from predominantly African-American churches in Wards 5, 7, and 8.

Hypothesis: We hypothesize that sub-groups of the church-based population with unfavorable psychosocial factors (i.e. lower social support) or unfavorable neighborhood environment characteristics (i.e. lower neighborhood walkability) will have lower reported physical activity or less favorable dietary intake as compared to sub-groups with more favorable psychosocial and environmental factors.

Aim 5: To formalize a community advisory board that meets quarterly to 1) consult on the planning and implementation of health screening events; 2) offer diverse expertise in evaluating the collected, de-identified data; 3) participate in the dissemination of data to their church congregations and/or community members; and 4) participate in the design and implementation of a community-based behavioral weight loss intervention.

4. Investigational Plan

4.1 Description of Study Population and Recruitment

The purpose of this study is to evaluate cardiovascular health factors, psychosocial factors, cultural norms, and neighborhood environment characteristics in the predominantly African-American church-based population in Wards 5, 7, and 8 in Washington D.C. This study will also evaluate the feasibility and acceptability of using technology in this community-based population for objectively measuring physical activity and dietary intake and monitoring cardiovascular health markers. This cardiovascular health and needs assessment will serve as the basis for a community-based behavioral weight loss intervention in this community. Participants will be congregants of a church located in Wards 5, 7, or 8 in Washington D.C. Study participants will be recruited from each of the participating churches using posted flyers and announcements during church meetings and services. Individuals interested in participating in the assessment will contact either an investigator in the study or a designated church representative so that they can be scheduled for the screening event. All testing for the cardiovascular health and needs assessment will be completed during scheduled events where up to 25 consented participants will undergo testing. All potential participants will speak with a research coordinator or the principal investigator to make certain they meet inclusion criteria prior to being scheduled for a health assessment event. Informational sessions will be conducted with potential participants prior to the health screening event and a copy of the IRB-approved informed consent will be provided to potential participants at that session.

4.2 Eligibility Assessment

4.2.1 Inclusion Criteria

Individuals eligible for this protocol are aged 19 - 85 years, attend one of the participating churches, and are able to provide informed consent independently. Eligible participants should also speak and read English at the 8th grade level.

4.2.2 Exclusion Criteria

Women in their second or third trimester of pregnancy at the time of enrollment will be excluded from the protocol.

4.3 Study Design and Methods

This observational study will involve cardiovascular health factor screening, administration of a survey, and evaluating usage of handheld and web-based technology related to physical activity, dietary intake, and cardiovascular health for one month for a convenience sample of participants recruited from churches in Wards 5, 7, or 8 in Washington D.C. Potential participants recruited for the screening events will be asked to fast at least 12 hours prior to blood testing. Potential participants will also receive the informed consent document at the informational sessions or by e-mail or U.S. mail prior to the screening event so that they can read the document prior to the screening event. Participants will undergo informed consent on

the same day prior to starting any testing during the screening event. Study participants will also undergo off-site registration to register them as an active outpatient for the Clinical Center. During a single appointment at their respective churches, study participants will undergo blood pressure testing and a capillary blood sample (obtained with a fingerstick) will be taken to measure fasting blood glucose, hemoglobin A1c, and blood lipids. Participants will also undergo anthropometric measures (height, weight, waist circumference, and hip circumference). Participants will complete a detailed survey of socio-demographic characteristics, medical history including weight history, health care access, health behaviors (physical activity, dietary intake), psychosocial measures (social support and social isolation, perceived stress, spiritual health locus of control), cultural norms (body size perception), and measures of neighborhood environment (perceptions of neighborhood environment). We will measure neighborhood walkability from each participant's home and work addresses using Walk Score. The survey will evaluate current usage of web-based and handheld device technology, which may be used in implementing a behavioral weight loss intervention. Finally, the survey will ascertain participants' beliefs about and preferences for a future church-based intervention.

To objectively measure physical activity and sleep duration, each participant will be given a FitBit® Flex wireless activity and sleep wristband to wear and self-monitor physical activity and sleep duration for one month after the screening event. Participants' usage of www.FitBit.com, a website associated with the FitBit® device and available for monitoring cardiovascular health markers, including dietary intake, types of physical activity, weight, blood pressure, blood glucose, will also be evaluated. A subset of the study population will be given an Actigraph GT3X accelerometer to wear for one month in addition to the FitBit® Flex to correlate physical activity levels measured by each device. Use of the Actigraph GT3X accelerometer will be optional for up to 15 study participants.

A subset of the study population will also be provided with a digital, handheld camera to measure a three-day digital food record. For those given digital cameras, they will be asked to take pictures of their meals for three days (two weekdays and one weekend day). The three-day digital food record will be optional for up to 15 study participants.

Once participants have undergone health factor screening at the church event, they will be given a cardiovascular disease risk assessment during the event. In partnership with Community Health Partnership, Inc., a community-based health organization located at Nativity Catholic Church in Washington D.C., participants will utilize a web-based, cardiovascular risk assessment tool entitled "Healthy? Find Out!".[53] This web-based tool was developed by Community Health Partnership in collaboration with the Harvard School of Public Health, Washington University's Siteman Cancer Center, the Washington D.C. Cancer Consortium, and D.C. Department of Health.

Study participants found to have untreated hypertension, diabetes, or hypercholesterolemia will be referred to a local primary care facility for further evaluation and treatment. Untreated hypertension will be defined as systolic blood pressure ≥ 140 mmHg and/or diastolic blood pressure ≥ 90 mmHg on no anti-hypertensive medications. Untreated diabetes will be defined

as fasting blood glucose ≥ 126 mg/dL and/or hemoglobin A1c ≥ 6.5% on no medications for diabetes. Untreated hypercholesterolemia will be defined as an LDL cholesterol ≥ 190 mg/dL on no lipid-lowering medications. Participants referred for treatment will be re-contacted one month after screening to determine if they have scheduled an appointment for follow-up evaluation. Participants with critical values for blood pressure (i.e. systolic blood pressure ≥ 180 mmHg and/or diastolic blood pressure ≥ 120 mmHg) or blood glucose ≥ 500 mg/dl will be referred for emergency evaluation.

Fifteen to twenty-five participants will undergo screening in one day at each of the churches. Aggregate, de-identified results of prevalent cardiovascular health factors of study participants will be provided to each of the congregations and to members of the community advisory board during scheduled events. This will be done to obtain feedback on interpreting the results and how the results can inform the design of a behavioral weight loss intervention. **Figure 2** is a workflow diagram and description of the work stations that would be set up at the church location for gathering each type of data. Student volunteers from Howard University or church-based volunteers will help in directing participants through stations at the events.

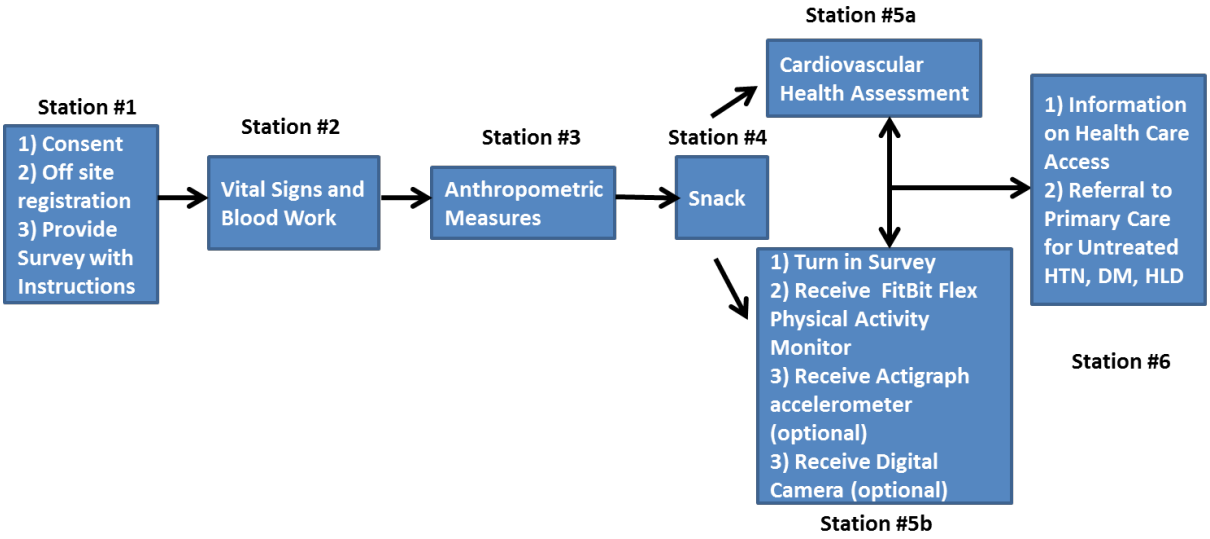

Figure 2: Diagram of Cardiovascular Health Screening and Assessment

Station #1 – The study consent will be obtained by a research coordinator. After obtaining consent, the research nurse would complete an off-site admission registration packet for the participant to register the participant as a Clinical Center outpatient. The research coordinator would then provide instructions for completing the study survey instrument to each participant.
Station #2 – A research nurse will obtain vital signs and blood work.
Station #3 – Anthropometric measures will be obtained by a post-baccalaureate IRTA.
Station #4 – A snack will be provided for participants after fasting blood work is completed.
Station #5a - Participants will receive a cardiovascular health assessment using a web-based tool. Participants will also receive counseling on cardiovascular risk from the principal investigator. Participants with untreated hypertension, diabetes, or hypercholesterolemia will be identified by the principal investigator.

Station #5b – While participants are waiting to receive anthropometric measures and cardiovascular health assessment, they will have time to complete the study survey. They will also receive instructions on how to use the wearable physical activity monitor and how to access the website www.FitBit.com. The website provides feedback on data collected by the device and allows users to monitor additional cardiovascular health markers. A subset of the study population will also receive the Actigraph GT3X accelerometer and/or a digital camera for a digital three-day food record.
Station #6 – Participants will have the opportunity to get information on health care access for primary care. Those with untreated hypertension, diabetes, or hypercholesterolemia will be referred to a primary care facility.

A community advisory board composed of community leaders, church leaders, and co-investigators on the project will meet quarterly to review and provide recommendations for the implementation of the community assessment. Members of the advisory board will be selected based on experience and expertise in Washington D.C. around issues of community health, program development in the faith-based community, physical activity, or nutrition. Leaders from each of the participating churches will be representatives on the advisory board. The board will also discuss assessment findings, how best to communicate data from the assessment to the community, and how to use the information learned from the assessment in the design of a behavioral weight loss intervention. Members of the board who are not co-investigators of this study will serve on the advisory board for the duration of the assessment with possible extensions of terms on the advisory board. The community advisory board will meet in Washington D.C. in churches or at other civic locations.

The limitations of this protocol must be acknowledged. Because the community health and needs assessment is based in Washington, D.C., the generalizability of the study findings is limited. However, the study findings may inform the development of interventions through faith-based organizations in other urban areas. Additionally, this study is limited in the cardiovascular phenotyping of the study participants, such as collection of blood samples for measurement of biomarkers related to obesity and cardiovascular risk. However, we have deliberately designed this health assessment to be as non-invasive as possible in an effort to foster trust between the community and our research team.

4.4 Medical History and Physical Examination

A medical history, including information on health behaviors, existing cardiovascular risk factors, and cardiovascular disease history, will be gathered in the study. Vital signs and anthropometric measures will be taken on each participant. There will be no detailed physical examination completed during this health assessment.

4.5 Laboratory Tests and Parameters

Capillary blood will be tested for fasting blood glucose, hemoglobin A1c, and blood lipids (total cholesterol, HDL, LDL, TG). Participants will be provided with blood testing results on-site during counseling about cardiovascular risk in the screening event. Any laboratory test result that the Investigator considers clinically significant will be repeated at the discretion of the

investigator to rule out laboratory error. Per Clinical Center policy, no more than 550 mL of blood will be collected over an 8-week period.

4.6 Procedures

All tests will follow NIH Clinical Center policies, and clinical consent forms for individual tests requiring these will be obtained in addition to the study protocol consent.

i) **Off-Site Registration:** Once a participant has signed up for a screening event, a member of the research team will enter an Admissions request in the ATV. The admissions office will process the request and generate a medical record number in CRIS for the participant so that the participant is in pre-registration status. Once a participant has consented to the study, the research coordinator will complete the off-site admissions registration packet with the participant, including a patient registration form, the General Admissions Consent (NIH-1225-1), and the Information Practices form (NIH-2753). The completed off-site registration packet will be returned to the Clinical Center Admissions office and the participant will be assigned as an active outpatient for the study. The research coordinator will obtain training for performing off-site registration. The study participant will be given copies of completed consent documents and the research team will maintain the original documents.

ii) **Blood Pressure Testing:** Blood pressure will be measured using the protocol established by the JNC-VII guidelines[54] and the average of two blood pressure measurements will be taken using recently calibrated automatic blood pressure cuffs. If the first two blood pressure measurements vary by > 20 mmHg systolic or 10 mmHg diastolic, a third measurement will be performed and the average recorded.

iii) **Capillary Blood Sample for Blood Glucose, Lipid Panel and Hemoglobin A1c:** Fingerstick capillary blood will be used for analyses of fasting plasma lipids and blood glucose using a Cholestech LDX point-of-care analyzer (Alere, Inc., Waltham, MA) and for hemoglobin A1c (HgbA1c) using a DCA Vantage Analyzer (Siemens, Inc. – Laboratory Diagnostics, Tarrytown, NY).

iv) **Anthropometric Measures:** Dr. Amber Courville, an associate investigator on the protocol, will provide training for post-baccalaureate IRTAs and students completing anthropometric measures for this study. Participants will be asked to wear lightweight, loose-fitting clothing with empty pockets for the event. Height will be measured using a stadiometer. Weight will be measured using a calibrated scale. Waist circumference (at the level of the iliac crest) and hip circumference (at the maximum protuberance of the buttocks) will be measured in triplicate with a flexible tape measure.

v) **Survey:** A survey instrument will be completed by each of the participants. The survey will provide detailed data on health care access, and psychosocial,cultural, and environmental factors that may influence the design of an intervention. This survey is patterned after a health assessment survey used during the GoodNEWS intervention. The questionnaire is more extensive than the prior survey used in the GoodNEWS study because it now includes questions on social support, social isolation, neighborhood environment, spiritual locus of control, and utilization of technology. This protocol will provide pilot data on the feasibility of gathering this

additional survey data in the study population and aid in refining the survey tool for future studies. The specific elements of the survey are as follows:

a. **Socio-demographics:** Participants will respond to questions about demographics and socioeconomic status such as age, race/ethnicity, address data for characterizing walkability of neighborhood and work environment using Walk Score (www.walkscore.com), educational attainment, annual income, and marital status.
b. **Medical History/Perceptions of Health/Health Care Access:** Participants will respond to questions about prevalent hypertension, hypercholesterolemia, diabetes, and cardiovascular disease. Questions abstracted from the 2011 Behavioral Risk Factor Surveillance System (BRFSS) [55] and the 2009-2010 National Health and Nutrition Examination Survey (NHANES) dietary screener questionnaire [56] will be used to assess health behaviors and perceived health status. Study participants will respond to questions about health behaviors, such as dietary habits (including fruit and vegetable, whole grains, and sugar-sweetened beverage intake), physical activity, tobacco use, and alcohol consumption. Information about health care access and utilization will also be collected from the participants.
c. **Weight History and Body Size Perception**: Self-reported weight history will be surveyed using questions abstracted from the BRFSS [55] and the 2011 NHANES weight history questionnaire.[57] Participants will indicate their maximum and minimum weight in pounds, and provide information about any recent changes in their weight. Body size perception will be evaluated using the Pulvers Scale for African American Adults.[58, 59] Using the scale, study participants will select a female or male figure that they believe best reflects 1) their ideal figure, 2) their current figure, and 3) three figures that represent their three closest same-sex friends.
d. **Social Support and Social Isolation**: Participants will respond to questions about social support and various dimensions of social isolation including general isolation,[59] perceived loneliness,[60] depression,[61] and perceived stress.[62]
e. **Neighborhood Environment**: Perception of neighborhood environment will be assessed using questions abstracted from the Project on Human Development in Chicago Neighborhoods, including questions on neighborhood violence, physical environment and social cohesion.[63] Home and work address data will be used to determine the walkability of the home and work environment by calculating a Walk Score for each location. A Walk Score is a number from 0 to 100 that demonstrates how walkable the area around an address may be, with a higher score indicating greater walkability.
f. **Spiritual Health Locus of Control**: The Spiritual Health Locus of Control Scale[64] will be used to assess participant beliefs regarding the role of God in one's health. Participants will respond to a series of questions on a 5-point Likert scale (strongly disagree to strongly agree).

g. **Technology Utilization:** Utilization of the internet and mobile phone technology will be evaluated with questions abstracted from the Computer-Email-Web Fluency Scale.[65]

vi) **Physical Activity Monitoring:** Each participant will be provided with a FitBit® Flex Activity wireless activity and sleep wristband (FitBit® , Inc., San Francisco, CA) to wear and self-monitor physical activity and sleep duration for one month during the study. Evaluation of the use of the FitBit® Flex device and web-based tools is exploratory to gather pilot data about independent levels of utilization in this population and to determine whether similar technology may be incorporated into a future intervention. The FitBit® Flex monitor is designed to provide objective, accelerometer-based data about the amount and intensity of physical activity (i.e. calories burned) and sleep duration for participants. During the screening event, each participant will be provided with an account on www.FitBit.com (using a de-identified username and password) and will be instructed on how to select physical activity goals and self-monitor physical activity as measured by the device. This monitor will be for the participant to keep. Participants will be encouraged to sync data from the FitBit® to the website at least weekly for one month. There will be one computer provided to each of the churches where participants can wirelessly upload recorded physical activity and sleep. Each church will have a study participant designated as a contact for any questions related to the use of the Fitbit® device. Using the FitBit® website, participants will also be able to log self-reported types and duration of physical activity, weight, dietary intake, heart rate, blood pressure and blood glucose, if measured. Self-reporting of these measures will be optional for participants. For one month after receiving physical activity and sleep wristband, investigators will monitor usage of the FitBit® Flex device and website by collecting de-identified data at least weekly from www.FitBit.com. The investigators will determine the proportion of the population that 1) uploads physical activity data to the website, 2) monitors physical activity on the website, 3) logs and monitors other health factors on the website. There will be no monitoring of FitBit® device and website usage after a one month period. The collected data will be correlated with the baseline characteristics of the participants. For instance, we will compare baseline characteristics between participants based on frequency of FitBit® device and website usage. The use of the FitBit® Flex in this study is designed to determine the feasibility of including this type of physical activity monitor in a future weight loss intervention.

a. **Accelerometer data:** Up to fifteen study participants will have the option to receive an Actigraph GT3X accelerometer (Actigraph, LLC, Pensacola, FL) in addition to the Fitbit® device. The Actigraph GT3X accelerometer will be worn at the waist for up to 30 days to measure level of physical activity. The accelerometer will be collected from participants after 30 days of usage. The physical activity data will be uploaded from the device and categorized as sedentary, light,moderate, or vigorous physical activity using ActiLife software (Actigraph, LLC, Pensacola, FL). The collected data will be correlated with physical activity data measured by the Fitbit® device in these participants.

vii) **Digital Food Record:** Up to fifteen participants will have the option to receive a digital camera to take pictures of their meals for a three-day digital food record. They will be instructed to take pictures before and after each meal for three days (2 weekdays and 1 weekend day). Participants will be instructed to take date and time-stamped photos. Each participant will be given a fiducial marker (4 cm x 4 cm card) to place by their meal when taking pictures as a reference image in determining portion size.[66] The digital cameras will be collected from participants after completing the three-day digital food record. The number of photos captured before and after eating for the three-day food record will be determined for the subset of participants to evaluate the feasibility of this tool for the population. Reported fruit and vegetable consumption will be compared to fruit and vegetable consumption recorded in the digital pictures for the subset of the population using cameras._

viii) **Evaluation of Referral for Untreated Cardiovascular Risk Factors**: For those with untreated hypertension, diabetes, or hypercholesterolemia, they will receive a phone call from the research coordinator one month after screening to determine if they followed up with a primary care clinic for assessment and/or treatment.

4.7 Schedule of Events

Table 2 depicts the timeline for the cardiovascular health and needs assessment.

	Baseline Measurements (3 months to collect data at all churches)	**Analysis of Results** (3 months)
Informed consent	√	
Anthropometric measures	√	
Blood pressure	√	
Blood glucose	√	
Hemoglobin A1c	√	
Lipid panel	√	
<u>Survey Assessments</u> -Socio-demographic characteristics -Physical activity -Dietary intake -Cardiovascular risk factors -Health beliefs and behaviors -Healthcare access and utilization -Psychosocial and environmental factors -Cultural Norms -Use of technology -Perceptions about needs for church-based weight loss intervention	 √ √ √ √ √ √ √ √ √ √	
Cardiovascular risk assessment	√	
Self-monitoring physical activity and usage of FitBit® Activity Tracker	1 month	

	Baseline Measurements (3 months to collect data at all churches)	**Analysis of Results** (3 months)
Self-monitoring of cardiovascular health factors with FitBit® website (duration of physical activity, weight, dietary intake, heart rate, blood pressure and blood glucose)	1 month	
Actigraph accelerometer data (OPTIONAL)	1 month	
Digital food record (OPTIONAL)	3 days	
Evaluation of referral for untreated HTN, DM, HLD	1 month	
Dissemination of community assessment results to churches		√
Community Advisory Board meetings	Quarterly	

Table 2: Timeline and Components of Cardiovascular Health and Needs Assessment

5. Data Collection and Management Plan

All blood testing for this study will be point-of-care testing without any blood collected for storage. All results will be presented to the participants and all participants will be counseled on the results. Data will be kept on the NHLBI P:drive, accessible through password-protected computers. Only the members of the research team will have access to the samples and data. Community advisory board members and participating churches will be presented with de-identified, aggregate data from the community health and needs assessment.

All human subjects personally identifiable information (PII) as defined in accordance to the Health Insurance Portability and Accountability Act, eligibility and consent verification will be recorded in DIR's Clinical Data System (CDS) database. Primary data obtained during the conduct of the protocol will be kept in secure network drives that comply with NIH security standards. Primary and final analyzed data will have identifiers so that research data can be attributed to an individual participant.

At the completion of the protocol (termination), samples and data will be destroyed consistent with journal or NIH policies.

End of study procedures: Data will be stored in locked cabinets and in a password protected network servers until they are no longer of scientific value.

Loss or destruction of data: Should we become aware that a major breech in our plan to protect subject confidentiality and trial data has occurred, the IRB will be notified.
Data will not be sent outside NIH without IRB notification and an executed agreement.

6. Statistical Considerations

6.1 Statistical Methods

The percentage of community-based participants meeting ideal, intermediate, and poor criteria for each of the cardiovascular health factors will be compared using Chi-square testing. Comparison of the distribution of cardiovascular health factors between men and women will also be done using the Chi-square test. Dietary intake and self-reported physical activity will be compared across levels of social support, social isolation, perceived health, perceived spiritual locus of control, and perceived neighborhood environment, using analysis of variance (ANOVA) or Student's t-test for continuous variables and Chi-square testing for categorical variables. Dietary intake and self-reported physical activity will also be compared across levels of neighborhood walkability for the population.

Objectively measured physical activity using the records from the FitBit® Flex will be used to categorize participants' activity time as "sedentary", "lightly active, "fairly active" or "very active". Among the subset of participants given Actigraph accelerometers, correlations will be performed between time spent in each category of physical activity as measured by the Fitbit® Flex as compared to activity measured by the accelerometer. Usage of the FitBit® Flex device (i.e. number of times uploading data from device to website) and usage of website health monitoring tools (i.e. number of times logged into website) will be determined for age and sex groups.

6.2 Sample Size Calculation

Sample size calculations for this study are based on the primary aim to estimate proportions of the study population in ideal, intermediate, and poor categories for each of the cardiovascular health factors. With a sample size of 100, the maximum width of the confidence interval for each estimate would be ± 10%, or the proportion of the population within each category for the cardiovascular health factors could be estimated within 10% of the true value. Therefore, to obtain a sample size of 100 individuals, we propose recruiting a sample population for the community health screening and assessment of no more than 50 individuals from each of the participating churches, or 150 individuals in total. This sample size would account for up to 33% of individuals who may be recruited for a health screening, but who may not show up for an appointment.

7. Data and Safety Monitoring

7.1 Safety Monitoring

Accrual and safety data will be monitored by the Principal Investigator, Tiffany Powell-Wiley, who will provide oversight of the conduct of this study.

Accrual and safety data will be monitored and reviewed annually by the Institutional Review Board (IRB). Prior to implementation of this study, the protocol and the proposed subject informed consent document will be reviewed and approved by the properly constituted IRB operating according to the 21 CFR 56. This committee must approve all amendments to the

protocol or informed consent document, and conduct continuing annual review so long as the protocol is open to accrual or follow up of participants.

7.2 Adverse Event Reporting

Adverse events are defined as any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome, or disease which either is diagnosed during participation in the health screening event or occurs during the study participation.

The principal investigator (and medical advisory investigator) will be responsible for assessing adverse events. Information on adverse events will be solicited from participants through questions from study personnel and information volunteered by the subject.

The following adverse events will be listed in the consent and not reported to the IRB:

- *Vasovagal symptoms during capillary blood testing.*
- *Psychological distress caused by newly diagnosed diabetes, hypertension, or hypercholesterolemia*

The following adverse events will be listed in the consent and reported to the IRB at the time of continuing review:

- *Death from any cause during the data collection period*

7.3 Serious Adverse Events

A serious adverse event (SAE) is defined by federal regulation as any AE occurring at any dose that results in any of the following outcomes: death, life-threatening AE, hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect.

Serious adverse events that are determined to be possibly, probably or definitely associated with the research activities of this protocol will be reported to the Principal Investigator of this study. Serious adverse events that are deemed possibly, probably or definitely related to the participants baseline disease, undiagnosed conditions, or concurrent therapies will not be reported.

Serious adverse events will be reported to the IRB using the NHLBI IRB Serious Adverse Event Form. The NHLBI IRB will receive a written report of the SAE within 7 calendar days of a death or 15 calendar days of any serious adverse events as outlined in the Interim Guidelines for Adverse Event Reporting.

Because there is no intervention in this study and because the risk of testing during the screening protocol represents only a minor increase over minimal risk, no DSMB is requested. The principal investigator will be responsible for reporting all adverse events to the IRB.

8. Human Subjects Protections

8.1 Rationale for Subject Selection

Subjects of both genders will be considered for inclusion in this study. There will be no racial, ethnic, or gender discrimination. Cognitively impaired and institutionalized persons will not

participate in this study. Criteria for exclusion or withdrawal from the study are based on the presence of other disease processes that may be harmful to the health of participants.

8.2 Participation of Children

Subjects under 18 years of age will not be considered for inclusion in this protocol.

8.3 Risk/Benefit Assessment

Overall Risk/Benefit Analysis of the Study: The research involves no more than minimal risk to subjects, with the prospect of direct benefit. Participants are provided a cardiovascular risk assessment during the screening and may benefit from a new diagnosis of hypertension, diabetes, or hypercholesterolemia, and/or a greater understanding of their cardiovascular disease risk. If newly diagnosed or poorly controlled hypertension, hypercholesterolemia, or diabetes is found during testing, participants will be referred to their own primary care provider or will be referred to a local clinic to establish primary care.

Specific Risks*:*

- **Capillary Blood Testing**: The finger stick required to do capillary blood testing may lead to transient discomfort and minor bruising may occur at sites of phlebotomy. Participants may briefly feel lightheaded and nauseated (faint).
- **Cardiovascular Health Factor Screening**: Participants with newly diagnosed or poorly controlled hypertension, hypercholesterolemia, or diabetes may experience psychological distress upon learning the results of testing during the screening event.

Benefits: Participants will be provided reports of lab work, anthropometric measures, and a detailed cardiovascular disease risk assessment during the testing that can be taken to their primary care provider. They will also be referred to a local clinic to establish primary care if they do not already have a primary care provider.

8.4 Risks and Discomforts

- **Capillary Blood Testing**: The finger stick required to do capillary blood testing may lead to transient discomfort and minor bruising may occur at sites of phlebotomy. Participants may briefly feel lightheaded and nauseated (faint).
- **Cardiovascular Health Factor Screening**: Participants with newly diagnosed or poorly controlled hypertension, hypercholesterolemia, or diabetes may experience psychological distress upon learning the results of testing during the screening event.

8.5 Consent Processes and Documentation

Each participant will receive an oral and written explanation of the goals, procedures, and risks of this study. The Principal Investigator and those Associate Investigators who are listed on the cover page of the protocol with an asterisk next to their name may obtain informed consent from research participants. Consent will be obtained at the church site for the screening and assessment event. The original, signed informed consent document will be placed in the medical record, and the subject will receive a signed copy of the informed consent document.

8.6 Subject Advocate

A subject's rights representative is available to participants on this protocol. The representative can be reached at 301-496-2626 and is located in Building 10. Participants may ask any questions about the study and may withdraw their consent at any time.

9. Conflict of Interest

The National Institutes of Health reviews NIH staff researchers at least yearly for conflicts of interest. The following link contains details on this process http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf.
None of the members of the research team reported a potential conflict of interest.

10. Reimbursement for Travel

Reimbursement for local travel will be in accordance with NHLBI travel policy and reimbursement will be consistent with NIH and NHLBI guidelines.

11. Financial Compensation

Participants will be compensated as described in the table below:

Description of tests or procedures	Compensation
Completion of Testing at Screening Event, including blood draw	$25 Visa gift card
Completion of 1 month of data collection with physical activity monitor	$25 Visa gift card
Return of accelerometer to research team (up to 15 participants)	$25 Visa gift card
Return of digital camera to research team (up to 15 participants)	$25 Visa gift card

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