Supporting Statement A

for

Cardiovascular Health and Needs Assessment in Washington, DC - Development of a Community-Based Behavioral Weight Loss Intervention (NHLBI)

Date

Revised May 7, 2014

Tiffany M. Powell-Wiley, MD, MPH
National Heart, Lung, and Blood Institute
National Institutes of Health
Building 10-CRC, 5-3340
Bethesda, MD 20892
Phone: 301-594-3735

Table of contents

LIST OF ATTACHMENTS:

- Attachment 1: National Heart, Lung, and Blood Institute Protocol 13-H-0183
- Attachment 2: Letter of Protocol Approval from NHLBI Institutional Review Board
- Attachment 3: NHLBI Protocol 13-H-0183 Survey Instrument
- Attachment 4: NHLBI Protocol 13-H-0183 Consent Document
- Attachment 5: Community Advisory Board Meeting Notes - Dated May 6, 2013
- Attachment 6: Community Advisory Board Meeting Notes - Dated July 22, 2013
- Attachment 7: 13-H-0183_Heart Health Screening Ad Posting
- Attachment 8: NIH Clinical Center Patient Registration Form
- Attachment 9: Health Data Monitoring Login Screen Shots

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

Responding to a Legislative Mandate: The objective of the information collection is within the National Heart, Lung and Blood Institute's (NHLBI) mandate described in the PHS Act, Section 421 (42USC 285b-3) and specifies provision of "investigation into the epidemiology, etiology and prevention of all forms and aspects of heart, blood vessel, lung, and blood diseases, including investigations into the social, environmental, behavioral, nutritional, biological, and genetic determinants and influences involved in the epidemiology, etiology, and prevention of such diseases".

Why the need to collect these study data? : The purpose of this collection of information is to conduct a community health and needs assessment for individuals in predominantly African-American churches in Washington, District of Columbia (DC), based on principles of community-based participatory research (CBPR). African Americans disproportionately have poorer cardiovascular health and a greater burden of cardiovascular disease as compared to other racial and ethnic groups. Therefore, interventions that improve cardiovascular health in the African American community are essential. Past studies suggest that community-based interventions are needed to improve cardiovascular health in the African-American community. Interventions based on CBPR principles develop in collaboration with community partners and allow an intervention's components to be tailored to the unique needs of the 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. Most of all, community assessments provide context for community-based projects and foster trust with community members. To remain consistent with CBPR principles, a community health and needs assessment is necessary to understand the needs of the target population. This assessment is being conducted in partnership with DC community leaders.

Religious settings can serve as effective sites for community-based interventions targeting lifestyle changes and weight loss to improve cardiovascular health[1]. Interventions in the faith-based community likely foster behavior change through the established social structure and social support within the church population. 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. The African American church has a long history of engaging in community-based health initiatives[2-6], and leaders within the African American church can shape health perspectives and behaviors of African Americans[7]. Our prior work suggests that the African-American, faith-based community may be an ideal setting for interventions targeting obesity and a church-based, behavioral weight-loss intervention for African Americans may be effective if providing specific tools for physical activity that promotes weight loss [8]. However, it is much less clear the types of tools that may aid in increasing physical activity in a community-based

population. 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.

The African-American, faith-based community in Washington, DC may 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, DC. Based on data from the Behavioral Risk Factor Surveillance Survey (BRFSS), a yearly assessment of the health and behavior across the United States (US) conducted by the US Centers for Disease Control and Prevention (CDC), these wards are areas in Washington, DC where the obesity prevalence is highest and resources for physical activity and healthy nutritional options are most limited. 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 (Please see page 8 in Attachment I). 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. Finally, African-Americans in Wards 5, 7, and 8 have the the highest incidence and prevalence for cardiovascular disease in Washington D.C.

Overall, data collection from this project will aid in developing a behavioral weight loss intervention based on the principles of CBPR in the faith-based community in Washington D.C to promote increased physical activity and improve dietary intake among at-risk individuals using web-based technology and handheld devices.

Why should the Federal Government sponsor this research?
This data collection is to achieve a result within the statutory mission of the Intramural Program of NHLBI, which is to conduct investigator-initiated research that utilizes unique resources and environment of the NIH and its Clinical Center that are not available in other research institutions. The information collected in this study is vital to advancement of the NHLBI's objective of developing novel devices to benefit patients. This mission includes conducting studies that can later be translated into the broad clinical practice, enabling advances to have a public health impact. Studies suggest that communities are more receptive to CBPR projects after their input was included in the study design and implementation, likely building trust with the studied population and increasing participant retention [9]. Engaging community partners and participants in formal discussions from the preliminary phase of the study through implementation may accelerate the translation of findings into improved clinical outcomes[10].

The NIH's intramural research programs are undergoing an accreditation process through the Association for the Accreditation of Human Research Protection Programs' (AAHRPP), and NIH leadership is requesting that all intramural divisions consider involving some community perspective in developing research studies. CBPR projects are within the scope of work requested by the NIH Intramural Divisions and are in

support of the AAHRP accreditation process. Additionally, this research falls within the National Institutes of Health's (NIH) mission to "seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability."

A.2 Purpose and Use of the Information Collection

The purpose and use of the information collection for this project is to determine the prevalence of ideal, intermediate, and poor cardiovascular health factors based on American Heart Association (AHA)-defined goals within a church-based population in wards 5, 7, and 8 in Washington, DC**.** The definition for community, as referenced in this study, is a church community or a religious institution that includes congregational member participants, as well as the persons and entities served by this institution. The information collected will also evaluate data from handheld devices, such as wearable physical activity monitors or digital cameras, to objectively measure physical activity and dietary intake from selected community members. This protocol will then identify technology that may be incorporated into future interventions. In addition, the collected information will be examined for methods of referral for treatment for 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. This information from the screening and needs assessment will establish a CBPR partnership for the future design and implementation of a church-based, behavioral weight loss intervention.

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 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 Institution Review Board (IRB)-approved informed consent will be provided to potential participants at that session. This process exhibits very little burden on participants. The following information lists some of criteria for this study:

- **Eligibility Assessment**

    i) **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.

ii) **Exclusion Criteria**: Women in their second or third trimester of pregnancy at the time of enrollment will be excluded from the protocol.

- **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.

Specific Aims for the study:

Aim 1: To determine the prevalence of ideal, intermediate, and poor levels of each of the cardiovascular health factors (Body Mass Index - 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, DC

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

Aim 2b: To determine feasibility in using a handheld, digital camera to take photographs to capture dietary intake for digital 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) within a church-based population.

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: Too 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

Aim 5: To formalize a community advisory board that would meet 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

A.3 Use of Information Technology and Burden Reduction

Data Technology

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 Admissions, Travel and Voucher (ATV) system. The ATV system at the NIH Clinical Center (CC) will process the information from the participant into the CRIS Clinical Research Information System **(**CRIS) to produce a NIH CC medical record number required for study participants. The information will be stored on a secure server at the NIH CC.

ii) **Physical Activity Monitoring:** Each participant will be provided with a wireless physical activity and sleep monitoring wrist band device to wear and self-monitor physical activity and sleep duration for <u>one month</u> during the study. Evaluation of the use of a wrist band 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 wireless wrist band 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 a password-protected website connected to the device (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 wireless monitor 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 wireless wrist band device. Using the 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 wireless wrist band device and website by collecting de-identified data at least weekly from the password-protected website connected to the device. 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 wireless wrist band 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 the wireless wrist band device and website usage. The use of the wireless wrist band 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 wireless physical activity and sleep monitoring wrist band 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 wireless wrist band device in these participants.

iii) **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. 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._

A.4 Efforts to Identify Duplication and Use of Similar Information

The information collected in this protocol is unique to the populations of predominantly African-American churches in Washington, DC. Content from the 2009-2010 National Health and Nutrition Examination Survey (NHANES) dietary screener questionnaire was used in designing the survey instrument for the study; however, the NHANES data collection is not specific to populations in Washington DC. Additionally, similar elements of data (i.e. data on dietary intake, physical activity, and prevalent cardiovascular risk factors) were collected from residents of Washington, DC as a part of the Centers for Disease Control and Prevention's BRFSS. However this data may not necessarily be representative of populations in the African-American faith-based communities in Washington, DC. In addition, the BRFSS does not provide detailed information on psychosocial and environmental factors for the population in Washington, DC. Finally, the collection of this data will involve the development and enhancement of

community partnerships, which are imperative for the creation of future interventions tailored to the needs of the Washington, DC community.

The information collected about handheld and web-based technology usage collected in this study is also unique to other community-based participatory research projects. Efforts are ongoing to incorporate handheld technology for promoting and monitoring lifestyle change as a part of behavioral weight loss interventions; however, much of this work is limited to primary care settings [11-13] or predominantly Caucasian populations.[14-17] This protocol is novel in its evaluation of handheld technology for measuring physical activity and dietary intake by an underserved population in resource-limited environment. These findings will translate into a community-based intervention using technology-based tools specifically tailored to the needs of the community members.

.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

A.6 Consequences of Collecting the Information Less Frequently

The health and needs assessment is being conducted once with only a one-day assessment session which will last up to four hours for study participants. Thirty days of data collection from physical activity monitors and a website for measuring cardiovascular health factors will hold minimal burden on study participants. Selected study participants will be re-contacted during the 30-day period to determine if they made an appointment with a primary care provider for follow-up evaluation of an uncontrolled cardiovascular risk factor that was identified during the assessment. Participants who volunteered to conduct digital food records or accelerometer testing will be contacted to obtain the devices back from them.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

One limitation of this community health and needs assessment is that the study population is a convenience sample of the population in predominantly African-American churches in D.C. Therefore, we cannot guarantee that results can be generalized to the universe of the study. However, this limitation is justified to provide assessment information to those who may be most likely to be involved in a subsequent intervention. Otherwise, this study fully complies with **guidelines of 5 CFR 1320.5.**

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

The Federal Register 60-Day Notice for this study, Volume 79, Issue Number 1, Pages 141-142 was published on January 2, 2014. One response was submitted as a comment.

The study held community advisory board (CAB) meetings on May 6th and July 22nd, 2013, to discuss the specific aspects of the protocol. The CAB consists of representatives from the faith-based community, including pastors of participating churches, DC Department of Health, U.S. Department of Agriculture, other various DC community organizations and churches, health care organizations, NIH, and academia with expertise in nutrition and community health. The CAB members provided consultation on the design of the study. The CAB members received all study documents a few days prior to the CAB meetings. Specific comments included: recommendations on the study design and instrument design, and participant recruitment and retention (Please see Attachments 5 and 6). These recommended changes were incorporated into the protocol prior to submission to the NHLBI IRB. Those in attendance are included in the meeting notes.

A.9 Explanation of Any Payment of Gift to Respondents

The decision to provide a stipend for study participants is to ensure participant retention and full cooperation with the protocol procedures. Remuneration for participants is designed not to induce participation and is consistent with prior NIH intramural protocols. Alternatives, such as small gifts like water bottles or t-shirts, are not likely to produce the level of reliability necessary for the purpose and need for this data collection. Moreover, there is a possibility that individuals will benefit from participating in this study by getting an evaluation of their cardiovascular health. This may assist in managing their blood pressure, blood sugar, cholesterol, and body weight.

Participants will be compensated as described in the table A.9 – 1. Based on the compensation plan, up to 100 people can receive the $25 gift card for completions of testing at the screening event, including the blood draw, requiring that $2500 be budgeted for this remuneration. Up to 100 people can receive a $25 gift card for completion of the one-month data collection with the physical activity monitor; $2500 must be budgeted for this type of remuneration. A subset of the study population (15 participants) can take part in testing the accelerometer and/or digital camera in the study, and those participants that return these devices can receive a $25 gift card for each device returned. $750 ($25 X 15 participants X 2 devices) must be budgeted for this remuneration. In total, $5750 will be budgeted for remuneration to account for the maximum compensation amount.

A.9 - 1 Participant Compensation Table

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

A.10 Assurance of Confidentiality Provided to Respondents

Participants are provided with the following information in the consent form for the study: "In this protocol, we will obtain heart-related health factor data and questionnaire data that will be stored. We will also include certain information in your medical record. Other information will be for scientific research, publication, and teaching. Name and other personal information of study participants will not be revealed and will remain private to the extent permitted by law. In doing so, the information will identified by a code to link test samples with the name and other personal information of the participant. The code will be stored in a secret password-protected database under the control of principal investigator, Dr. Powell-Wiley. If any data is shared or published, the names or personal information the study participants will not be told to ensure identity protection and confidentiality."

Arrangements for Handling, Storage, and Disposition of Study Information: 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 Division of Intramural Research's (DIR) 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.

This study was approved by the OPRR-authorized NHLBI IRB on July 25, 2013.

A.11 Justification for Sensitive Questions

Sensitive questions that will be collected in the survey instrument include:

Income: Income has been related to obesity and, in most studies, individuals with a higher socioeconomic status (SES) tend to be less obese. Because income may influence behavior modification, it is critical to collect this information.

Alcohol Consumption: Alcohol intake has shown to be an important factor in weight distribution, especially weight gain, and physical activity. Because alcohol consumption may influence lifestyle adaptations, it is critical to collect this information.

Psychological Factors: Psychological factors (Perceptions of Health, Weight History and Body Size Perception, Social Support and Social Isolation, Center for Epidemiologic Studies Depression Screen, Perceptions of Neighborhood Environment, Spiritual Health Locus of Control) have shown to influence physical activity and dietary intake. All these types of measures have been demonstrated to associate with behavior change and weight loss, making them important to data collection. Because psychological factors are vital social determinants of health, it is important to collect this information. If this information is not collected, the study will have insufficient information on barriers to weight loss that might influence the development of a behavioral weight loss intervention.

As described in Section A.10 (Assurance of Confidentiality Provided to Respondents), appropriate measures to safeguard respondent privacy have been instituted. In addition, both adult respondents will be informed that they can decline to answer any question that they do not wish to answer.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

There are no costs to respondents other than their time. The total estimated annualized burden hours are 2385. The estimated hourly wage was retrieved from the Bureau of Labor Statistics in the U.S. Department of Labor.

A.12 - 1 ESTIMATES OF HOUR BURDEN

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response	Annual Hour Burden
Registration/ Consent Process (Protocol)	100	1	15/60	25
Clinical Evaluation (Protocol)	100	1	30/60	50
Survey Instrument	100	1	1	100
Device Training (Protocol)	100	2	1	200
Health Data Monitoring	100	2	10	2,000
Digital Camera Return (Protocol)	15*	1	18/60	5
Accelerometer Return (Protocol)	15*	1	18/60	5
Totals				2385

*Participants who receive an accelerometer or digital camera as a part of the health assessment will be instructed to return these devices at the end of the study.

A.12 - 2 ANNUALIZED COST TO RESPONDENTS					
Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Respondents	Hourly Wage Rate	Respondent Cost
Registration /Consent Process (Protocol)	100	1	15/60	$10.00	$250.00
Clinical Evaluation (Protocol)	100	1	30/60	$10.00	$500.00
Survey Instrument	100	1	1	$10.00	$1000.00
Device Training (Protocol)	100	2	1	$10.00	$2000.00
Health Data Monitoring	100	2	10	$10.00	$20,000.00
Digital Camera Return (Protocol)	15*	1	18/60	$10.00	$50.00
Accelerometer Return (Protocol)	15*	1	18/60	$10.00	$50.00
Totals					$23,850

*Participants who receive an accelerometer or digital camera as a part of the health assessment will be instructed to return these devices at the end of the study.

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

No capital start-up, operational or participant costs or charges to any individuals will occur in this study.

A.14 Annualized Cost to the Federal Government

The annualized cost of monitoring the project by NHLBI is estimated at $169,400. This information is itemized in the Table A.14-1. Please note that there are no costs associated with the accelerometers. The program will be borrowing accelerometers for use from a collaborating group at NCI (the Applied Research Program).

Table A.14 -1 Estimate of Annualized Cost to the Government			
Type of Cost	**Contract**	**Other**	**Total**
Study Mgmt. & Operations			
NIH Project Oversight Officer (Federal Scientist): NHLBI Assistant Clinical Investigator (Title 42) ($158,000 @ 30% effort)		$47,400	
Community Outreach/Research Coordinator (Contractor)	$65,000	$0	
Physical Activity Monitors (100 devices)	$8000	$0	
Digital Cameras (15 cameras)	$3000	$0	
Development and Support of Web-Based Platform for Device Training for Participants and Participant Monitoring of Cardiovascular Health Factors	$35,000	$0	
Equipment for Blood Testing, Blood Pressure Measurements, Anthropometric Measures, and Survey Administration	$0	$5250	
Remuneration	$0	$5750	
Total			**$169,400**

A.15 Explanation for Program Changes or Adjustments

This is a new information request.

A.16 Plans for Tabulation and Publication and Project Time Schedule

A.16 - 1 Project Time Schedule	
Activity	**Time Schedule**
Study Announcement	2 weeks - 1 month after OMB approval
Information Session and Participant Recruitment	6 weeks - 2 months after OMB approval
Health Assessment and Survey Administration	2 - 3 months after OMB approval
Data Collections from Participants	2 1/2 - 3 1/2 months after OMB approval
Data Collections and Device Deposit	3 - 4 months after OMB approval
Analyses Publication	7 – 8 months after OMB approval
Publication	12 months after OMB approval

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB Expiration Date will be displayed on all documents.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to certification for paperwork.

A.19 References

1. The World Health Organization. Interventions on diet and physical activity: What works. 2009;2013
2. Tuggle RM. *It is well with my soul*. Washington D.C.: Magnificent Publications, Inc; 2000.
3. Thomas SB, Quinn SC, Billingsley A, Caldwell C. The characteristics of northern black churches with community health outreach programs. *Am J Public Health*. 1994;84:575-579
4. Hale WD, Bennett RG. *Building healthy communities through medical-religious partnerships*. Baltimore & London: Catherine J. McGinnis Family Foundation; 2000.
5. Foege W, O'Connell U. *Healthy people 2000: A role for america's religious communities*. Chicago: Park Ridge Center and The Carter Center 1990.
6. Chatters LM, Levin JS, Ellison CG. Public health and health education in faith communities. *Health Educ Behav*. 1998;25:689-699
7. Corbie-Smith G, Goldmon M, Isler MR, Washington C, Ammerman A, Green M, Bunton A. Partnerships in health disparities research and the roles of pastors of black churches: Potential conflict, synergy, and expectations. *J Natl Med Assoc*. 2010;102:823-831
8. Powell-Wiley TM, Banks-Richard K, Williams-King E, Tong L, Ayers CR, de Lemos JA, Gimpel N, Lee JJ, Dehaven MJ. Churches as targets for cardiovascular disease prevention: Comparison of genes, nutrition, exercise, wellness and spiritual growth (goodnews) and dallas county populations. *J Public Health (Oxf)*. 2012
9. Lapan S, Quartaroli, MT. Research essentials: An introduction to design and practices. 2009:60-83
10. Wallen GR, Middleton KR, Miller-Davis C, Tataw-Ayuketah G, Todaro A, Rivera-Goba M, Mittleman BB. Patients' and community leaders' perceptions regarding conducting health behavior research in a diverse, urban clinic specializing in rheumatic diseases. *Prog Community Health Partnersh*. 2012;6:405-415
11. Appel LJ, Clark JM, Yeh HC, Wang NY, Coughlin JW, Daumit G, Miller ER, 3rd, Dalcin A, Jerome GJ, Geller S, Noronha G, Pozefsky T, Charleston J, Reynolds JB, Durkin N, Rubin RR, Louis TA, Brancati FL. Comparative effectiveness of weight-loss interventions in clinical practice. *N Engl J Med*. 2011;365:1959-1968
12. McDoniel SO, Wolskee P, Shen J. Treating obesity with a novel hand-held device, computer software program, and internet technology in primary care: The smart motivational trial. *Patient Educ Couns*. 2010;79:185-191
13. Spring B, Duncan JM, Janke EA, Kozak AT, McFadden HG, DeMott A, Pictor A, Epstein LH, Siddique J, Pellegrini CA, Buscemi J, Hedeker D. Integrating technology into standard weight loss treatment: A randomized controlled trial. *JAMA Intern Med*. 2013;173:105-111

14. Acharya SD, Elci OU, Sereika SM, Styn MA, Burke LE. Using a personal digital assistant for self-monitoring influences diet quality in comparison to a standard paper record among overweight/obese adults. *J Am Diet Assoc*. 2011;111:583-588
15. Burke LE, Styn MA, Sereika SM, Conroy MB, Ye L, Glanz K, Sevick MA, Ewing LJ. Using mhealth technology to enhance self-monitoring for weight loss: A randomized trial. *Am J Prev Med*. 2012;43:20-26
16. van der Mark M, Jonasson J, Svensson M, Linne Y, Rossner S, Lagerros YT. Older members perform better in an internet-based behavioral weight loss program compared to younger members. *Obes Facts*. 2009;2:74-79
17. Wang J, Sereika SM, Chasens ER, Ewing LJ, Matthews JT, Burke LE. Effect of adherence to self-monitoring of diet and physical activity on weight loss in a technology-supported behavioral intervention. *Patient Prefer Adherence*. 2012;6:221-226

Updated: 04/04/2011 by: MPC