Attachment 6 of Supporting Statement

IRB Letters of Approval for Research Involving Human Subjects

for

Evaluation of the *Successful Business Strategies to Prevent Heart Disease and Stroke Toolkit*

CDC Task Order Officer (TOO): Dyann Matson Koffman
National Center for Chronic Disease Control and Health Promotion
TOO Contact Information: 770-488-8002 (phone), 770-488-8151(fax)

Copy of Letter of Approval from the Office of the Director, Human Research Protection Office, CDC:

DATE: 1/18/2007

FROM: IRB Administrator Office of Chief Science Officer, OD Human Research Protection Office, CDC

TO: Dyann Matson Koffman, NCCDPHP

SUBJECT: Approval to continue relying on the American Inst for Research in Behavioral Sciences' IRB for review of Protocol # 4914: Evaluating the Heart Disease and Stroke Prevention Toolkit: Employer Evaluations

Your request to continue Protocol #4914 has been approved utilizing the American Inst for Research in Behavioral Sciences IRB. CDC has approved this protocol for review by American Inst for Research in Behavioral Sciences' IRB in accordance with the process outlined in 45 CFR 46.114 and the signed/approved IRB Authorization Agreement (IRB AA) on file with CDC and American Inst for Research in Behavioral Sciences.

This protocol was reviewed and approved by the American Inst for Research in Behavioral Sciences' IRB **with an expiration date of 11/27/2007. CDC is authorizing you 30 additional days from the expiration to submit a CDC 'Request for Continuing Review of Protocol' form (CDC 0.1251) with copies of the American Inst for Research in Behavioral Sciences' IRB approval letter/report and copies of the current consent forms. If the reviewing IRB does not approve this protocol by the actual expiration date, this protocol will be considered out of compliance. You are required to notify me immediately should this happen and CDC will be required to suspend the protocol.**

Please keep this approval letter in your protocol file as proof of IRB approval and as a reminder of the expiration date. To avoid lapses in approval of your research and the possible suspension of subject enrollment and/or termination of the protocol, please submit your continuation request at least six weeks before the **protocol's expiration date of 11/27/2007.**

You must then submit a 'Request for Continuing Review of Protocol' form (CDC 0.1251) to continue the protocol IRB Authorization Agreement between CDC and the American Inst for Research in Behavioral Sciences' IRB. Please include the following documents:

1. a current letter of IRB approval by the American Inst for Research in Behavioral Sciences
2. copy of the relevant meeting minutes
3. copy of current consent forms (if applicable), and
4. any changes or amendments to the protocol or other required documents.

Serious problems must be immediately reported to this office. Any proposed changes to the existing protocol must be submitted as an amendment to the protocol and must be approved by the IRB before they are implemented. Once the amendment is approved by the American Inst for Research in Behavioral Sciences IRB, please submit to us the 'Request for Amendment Approval of Protocol' form (CDC 0.1252) along with a copy of the amended protocol, changed consent forms, any relevant meeting minutes and a copy of the current American Inst for Research in Behavioral Sciences IRB approval letter. Changes cannot be initiated until CDC has also approved the amendment(s) to the protocol.

Please forward a copy of this e-mail to the local American Inst for Research in Behavioral Sciences investigator and if you have any questions, please send an e-mail referencing the protocol number to ahsubject@cdc.gov.

Please direct all emails regarding assurances and human subject issues to the ahsubjects@cdc.gov mailbox.
Thank You,

Constance M. Bonds, MPA
IRB Administrator, Assurances and Reliance Relationships
Centers for Disease Control
Office of the Chief Science Officer
Human Research Protection Office
1600 Clifton Rd. NE, M/S D-73
Atlanta, GA. 30033
Phone: (404) 639-4967 Fax: (404) 638-5333

Copy of Letter of Approval from the American Institutes for Research IRB:

REVIEW OF SAFEGUARDS FOR HUMAN SUBJECTS

American Institutes for Research
1000 Thomas Jefferson Street, NW
Washington, DC 20007

Institutional Review Board
IRB00000436

Project number: 02031.004.02
Project Director/Proposal Author: PD-Margarita Hurtado/PM-Anna Levin
Project/Proposal title: Evaluating The Toolkit: Successful Business Strategies to Prevent Heart Disease and Stroke

1. Type of review:

(Check one)
☒ Expedited review
☐ Full IRB review

(Check one)
☐ Initial review
☐ Scheduled re-review (e.g., annual)
☒ Requested re-review (e.g., new data collection component, research plan change)

2. Review determination:

After reviewing the above-referenced project, the Institutional Review Board (or member signing below) has determined the following:

☐ Determination of Exemption: the project is exempt from further IRB review because it does not constitute research or because it does not involve human subjects.

☐ Provisional Approval: the submitted project is approved pending development of the research plan (45CFR46.118), which must be reviewed before enrollment of subjects or collection of data can begin. Proposed date of review: __

☐ Conditional Approval: data collection for the project can proceed after meeting the following conditions:

☒ **Approval: Approval is granted for the above referenced project to conduct data collection and analysis in relation to a post-intervention state survey. In keeping with our Federalwide Assurance mandate the IRB must conduct reviews at least annually for each project. This project will be reviewed again on 1/3/07.**

☐ Approval Denied: approval of the project is denied and data collection may not proceed for the following reasons:

3. Consent Procedures

The Institutional Review Board has determined that consent procedures:

☐ are not applicable to the project.

☐ must be reviewed on .

☒ **are approved as submitted.**

☐ are approved under the following conditions:

☐ are not approved for the following reasons:

4. Individually Identifiable Information Safeguards

The Institutional Review Board has determined that the safeguards planned for individually identifiable information:

☐ are not applicable to the project.

☐ must be reviewed on .

☒ **are approved as submitted.**

☐ are approved under the following conditions:

☐ are not approved for the following reasons:

5. Comments

Approval for the above referenced project to conduct data collection and analysis in relation to a post-intervention state survey. There is minimal risk to participants involved in this data collection effort. The procedures in place to provide consent-related information are adequate and commensurate with this level of risk. The implied request for approval of a waiver of documentation of consent is granted (i.e., completing the web survey can serve as an indication of consent and a signed consent form is not needed from participants).

6. IRB Signature(s):

11/7/06
Date

Andrea S. Burling

Andrea S. Burling
IRB Representative

Please keep in mind that any material changes made to the study or the study procedures require the submission of an updated IRB package.