ATTACHMENT 5:

Formative Research to Inform an HIV Testing Social Marketing Campaign for African American Men Who Have Sex with Men (MSM"), formerly known as Formative Research to Inform an HIV Testing Social Marketing Campaign for African American Heterosexual Men

CDC AND RTI INSTITUTIONAL REVIEW BOARD APPROVAL

From: McCleary, Jennifer (CDC/OD/OCSO)
Sent: Wednesday, July 08, 2009 10:14 AM
To: CCID Human Studies Review (CDC)
Cc: Jones, James F. (CDC/CCID/NCZVED); Youngblood, Laura (CDC/CCID/OD)
Subject: 5176: IRB Approval of Continuation of Protocol (Expedited)

Importance: High

DATE: 7/8/2009

FROM: IRB-C Administrator
Human Research Protection Office
Office of Scientific Regulatory Services
Office of the Chief Science Officer, OD/CDC

SUBJECT: IRB Approval of Continuation of Protocol #5176, "Formative Research to Inform an HIV Testing Social Marketing Campaign for African American Men Who Have Sex with Men (AAMSM)" (Expedited)

TO: DONATA GREEN [DQG7]
NCHHSTP/DHAP

CDC's IRB "C" has reviewed and approved your request to continue protocol #5176 for the maximum allowable period of one year and it will expire on 7/23/2010. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), Category 7.

If other institutions involved in this protocol are being awarded CDC funds through the CDC Procurement and Grants Office (PGO), you are required to send a copy of this IRB approval to the CDC PGO award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided PGO with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

As a reminder, the IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk, but not less than once per year. There is no grace period beyond one year from the last IRB approval date. It is ultimately your responsibility to submit your research protocol for continuation review and approval by the IRB. Please keep this approval 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 7/23/2010.

Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes to the protocol must be submitted as an amendment to the protocol for IRB approval before they are implemented.

If you have any questions, please contact the Human Research Protection Office at (404) 639-4721 or e-mail: huma@cdc.gov.

Jennifer McCleary, BA, CIP

cc:
James Jones

Laura Youngblood

IRB ID Number: 11788

Office of Research Protection
Institutional Review Board Notice of Approval
Federalwide Assurance No. 3331

Title of Study: CDC's HIV African American Mens' Campaign-Formative Evaluation
RTI Project Number: 0208235.054 **RTI Proposal Number** (if no Project Number)
Project Leader: Jennifer Uhrig
Project Team Member Contact (if different from Project Leader):
Source of Funding for this Study: CDC
Date Submitted to IRB: May 20, 2009
Level of Review *(check one)*:
Full ☐, IRB Meeting Date:
Expedited ☒, category: 9: Cont. Rev. minimal risk research

Type of Review *(check one)*:
- ☐ Preliminary review (Do not involve human subjects or data until pretest or full study is approved.)
- ☐ Pretest/Pilot Test
- ☐ Full Implementation
- ☐ Amendment, describe:
- ☐ Add study site(s):
- ☒ Renewal
- ☐ Study Closure

IRB Approval of Special Conditions *(check all that apply)*:
- ☐ Waiver of Signed Informed Consent/Parental Permission
- ☐ Participation of Pregnant Women (**Worksheet B** submitted by project team)
- ☐ Participation of Prisoners (**Worksheet C** submitted by project team
- ☐ Participation of Prisoners in DHHS-funded studies (OHRP acknowledgement received)
- ☐ Participation of Minors (**Worksheet D** submitted by project team)
- ☐ IRB Agreement of Nonsignificant Risk Device Study Determination

Please note the following requirements:
- If **unexpected problems** or **adverse events** occur, the project team must notify the IRB.
- If there are **changes** in study procedures or protocol or any data collection materials (brochures, letters, questionnaires, etc.) the project team must notify the IRB before they are implemented.
- The project team is required to apply for **continuing review** as long as the study is active, which includes participation of human subjects or possession of human data or specimens.

Expiration Date of IRB Approval: 12-19-2009
(No human subjects research can occur after this date without continuing review and approval.)

Wendy Visscher — 05-20-2009

Signature - IRB Member or Chair — **Date of IRB Approval**

Wendy Visscher, PhD
Name - IRB Member or Chair (print or type)

☐ Copy sent to project leader
☐ Entered into MIS

Office of Research Protection, Institutional Review Board
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