Form Approved
OMB No. 0920-XXX
Expiration Date
XX/XX/20XX

ATTACHMENT 5:
CDC AND RTI INSTITUTIONAL REVIEW BOARD APPROVAL

DATE: 7/24/2007

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

SUBJECT: Site Restricted - IRB Approval of New Protocol #5176, "Formative Reserch to Inform an HIV Testing Social Marketing Campaign for African American Heterosexual Men" (Expedited)

TO: DONATA GREEN [DQG7]
NCHSTP/

New protocol #5176 has been approved by CDC IRB "C" for the maximum allowable period of one year and it will expire on 7/23/2008. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), category 7. The Board determined that the study poses no greater than minimal risk to subjects.

The Board also approved a waiver of documentation of informed consent for the telephone screener in accordance with 45 CFR 46.117(c)(2).

Collaborator Site Restriction: Study activities may not begin with the following collaborator/site until documentation indicating current IRB approval has been received by CDC's Human Research Protection Office and is on file:

RTI International

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 7/23/2008.

Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes to the protocol should 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) 639-4954 or e-mail: huma@cdc.gov.

Jennifer McCleary

cc:
Jim Jones
NCHSTP Human Subjects
Laura Youngblood

RTI

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: July 6, 2007 (revised)

Level of Review *(check one)*:
Full ☒, IRB Meeting Date: June 19, 2007
Expedited ☐, category: None

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: 04-06-08
(No human subjects research can occur after this date without continuing review and approval.)

Juesta M. Caddell

Signature - IRB Member or Chair

July 13, 2007
Date of IRB Approval

Juesta M. Caddell, PhD
Name - IRB Member or Chair (print or type)

☒ Copy sent to project leader on: July 13, 2007
☐ Entered into MIS

Office of Research Protection, Institutional Review Board
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