Attachment 4

CDC and RTI International Institutional Review Board Approvals

DATE: 1/25/2007

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

SUBJECT: IRB Approval of New Protocol #5021, ""Examining the Efficacy of the HIV Testing Social Marketing Campaign for African American Women"" (Convened Board - B)

TO: Jami Fraze

New protocol #5021 has been approved by CDC IRB B for the maximum allowable period of one year and it will expire on 1/10/2008. The IRB determined that the study involves minimal risk to subjects. The Board also approved a waiver of documentation of informed consent for study eligibility screening and online survey participation in accordance with 45 CFR 46.117(c)

NOTE: Please forward local approval documentation with regards to Research Triangle International and Knowledge Networks, Inc. as they become available.

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 1/10/2008.

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 4721 or e-mail: huma@cdc.gov.

Connie Nakano

cc:
Janella Dodson

Jerrell Vann
Scott Damon
Rob Merritt

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IRB ID Number:11750

Office of Research Protection and Ethics

Institutional Review Board Notice of Approval

Federalwide Assurance No. 3331

Title of Study: Examining the Efficacy of the Take Charge, Take the Test Social Marketing Campaign
for African American Women
RTI Project Number: 0209353.004 **RTI Proposal Number** (if no Project Number)
Project Leader: Kevin Davis
Project Team Member Contact (if different from Project Leader):
Source of Funding for this Study: CDC
Date Submitted to IRB: March 16, 2007 (revised)
Level of Review *(check one)*:
Full , IRB Meeting Date: February 28, 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 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: February 28, 2008
(No human subjects research can occur after this date without continuing review and approval.)
03-20-2007
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 on:
Entered into MIS