ATTACHMENT 4:
CDC and RTI INSTITUTIONAL REVIEW BOARD APPROVAL

CDC IRB APPROVAL

DATE: 7/31/2007

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 #5166, "Formative Research to Inform The Routine HIV Testing and Prevention Is Care (PIC) Social Marketing Campaigns" (Expedited)

TO: DONATA GREEN [DQG7]
NCHSTP/

New protocol #5166 has been approved by CDC IRB "C" for the maximum allowable period of one year and it will expire on 7/30/2008. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), category 7.

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 7/30/2008.

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.

Jennifer McCleary

cc:
NCHSTP Human Subjects
Thomas Rotnem
Laura Youngblood

RTI IRB APPROVAL

RESEARCH TRIANGLE INSTITUTE (IRB ID # 11826)
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS
Request for Exemption from IRB Review

To request approval for exemption from Institutional Review Board (IRB) review, the Project Manager (includes Project Director or Leader, Principal Investigator, or Survey Manager) must complete this form and deliver the request to an IRB Administrator. The Project Manager will be notified if more information is necessary and the results of the determination.

Date: 8/10/07 RTI Project/Proposal No.: 0208235.054.000.001/.002

Project Title: Formative Research to Inform the Routine HIV Testing, *Prevention is Care (PIC), and Partner Services (PS)* Social Marketing Campaigns

Project Manager: Jennifer Uhrig (Julia Kish Doto, Deputy Manager) Sponsor: CDC

Date Participation of Human Subjects Scheduled to Begin: October 2007 (dependent upon CDC IRB clearance and OMB approval)

A. Brief Description of Study Procedures and Participant Population:

Brief Description:
This study will be conducted as part of the development of three Centers for Disease Control and Prevention (CDC)-sponsored social marketing campaigns: Social Marketing Campaign to Make HIV Testing a Routine Part of Care (Routine HIV Testing), *Prevention Is Care* (*PIC*), and Partner Services (PS). The purpose of this study is to conduct formative research to inform the development of the campaign materials. This study's main research activity is interviews with physicians to test creative campaign materials. RTI and professional focus group recruiting firms will recruit samples of emergency medicine physicians, primary care physicians (PCP), and Infectious Disease Specialists (IDS) to participate in the interviews. To supplement the data collected during the interviews, we will ask participants to fill out a brief paper and pencil questionnaire. The questionnaire will collect basic information about the participants' and some general characteristics of their patient populations to enable us to more fully describe the participants. RTI will conduct the interviews and analyze the resulting data. The results of this study will be used by the CDC to develop the final creative campaign materials for the Routine HIV Testing, *PIC*, and PS social marketing campaigns.

Participant Population:
The Routine HIV Testing research will take place in eight cities. There will be nine interviews in each of eight different U.S. cities to test materials that are being developed for the campaign for a total sample size of about 72 participants across all eight cities.

For *PIC*, the research will take place in nine cities. There will be 18 interviews in each of nine different U.S. cities to test materials that are being developed for the campaign for a total sample size of about 162 participants across all nine cities.

For PS, the research will take place in six cities. There will be 29 interviews in each of six cities to test concepts and materials that are being developed for the campaign for a total sample size of about 174 participants.

The inclusion criteria are as follows:
Routine HIV Testing
- Speak English
- Be a licensed medical doctor (M.D.)
- Have practiced medicine for two or more years

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- Currently working full time in an emergency room setting
- Order two or more HIV tests in a month
- See two or more patients living with HIV in a month

PIC

- Speak English
- Be a licensed physician (M.D. or D.O.)
- Have practiced medicine for two or more years
- Be one of the following:
  - a primary care provider (family practice or internal medicine)
  - an infectious disease specialist
- See at least 50% of patients in a private practice setting (PCPs only)
- Diagnose at least one new case of HIV per month (PCPs only)
- Have a current caseload of at least 50 patients who are living with HIV (IDS'
- only)
- Have a current caseload of 20 or more patients who are living with HIV (PCPs
- only)

PS

- Speak English
- Be a licensed physician (M.D. or D.O.)
- Have practiced medicine for two or more years
- Be one of the following:
  - a primary care provider (family practice or internal medicine)
  - an infectious disease specialist
- See at least 50% of patients in a private practice setting (PCPs only)
- Ever diagnosed a patient with HIV (PCPs only: Yes for treat; Yes or No for non-treat)*
- Ever treated an HIV patient (PCPs only: Yes for treat; Yes or No for non-treat)*
- Number of HIV patients treated in last 12 months (PCPs only: 3 or more for treat; 0-2 for non-treat)*
- Have a current caseload of at least 50 patients who are living with HIV (IDS'
- only)

*PCPs will be segmented by whether they treat or do not treat HIV patients

Study Procedures:

Participants will be recruited by professional focus group recruiting firms and/or RTI in each of the cities. RTI staff will conduct the interviews. Interviews will last about one hour. Each participant will receive an honorarium to thank them for their time and effort in the study (Honoraria range from $150 to $250) and are dependent upon the provider type [emergency medicine, PCP, IDS]). Interviews will be audio taped. RTI staff will analyze the data and summarize the results in three separate topline reports and one final report.

The paper and pencil questionnaire will be administered either immediately before (while participants are waiting to begin their interview) or at the end of the interview when the interviewer is checking with observers about whether or not there are additional questions.

To conduct this study we will work closely with professional recruitment facilities in each city where interviews will take place. Each recruitment facility will identify, screen, and recruit potential participants using their recruitment list/database. Additional recruitment methods will be used as needed and include flyers and notices at health care venues. Individuals who meet the screening criteria and agree to participate will attend a one hour

interview. Each individual will participate in the study only once. Individuals will not be contacted after their participation in the interview has concluded.

B. Description of Physical, Psychological, Social or Legal Risks to Participants: None

C1. For educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview research with adults:

1. Is information recorded in such a manner that human subjects can be identified, directly *or through identifiers linked to the subjects?*

[X] Yes [ ] No [ ] NA

If yes, explain:

As part of the recruitment process, the recruitment firms will have the names and contact information of participants. However, RTI staff and the client will only be given their first names. During the discussions participants will be asked to use their first names only. Summary report data will be presented without individual identifiers so that individual responses cannot be linked to participants.

2. Would any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing employability or reputation?

[ ] Yes [X] No [ ] NA

If yes, explain:

C2. For research with existing data, documents, records, pathological or diagnostic specimens:

1. Are the sources of the data publicly available?

[ ] Yes [ ] No [X] NA

If no, explain:

2. Is information recorded in such a manner that human subjects can be identified, directly *or through identifiers linked to the subjects?*

[ ] Yes [ ] No [X] NA

If yes, explain:

D. Describe other categories of exempt research[1] here:

[1] Note: Categories C1 and C2 above are the most common types of research conducted at RTI that may be exempt from IRB review. For a complete list of exemption criteria, please see below.

----------Space below this line for IRB use only.----------

Decision of IRB Coordinator or Chair

Name of IRB Coordinator or Chair making exemption determination: **Juesta Caddell, Ph.D.**

Please check appropriate answer(s):

I agree that this study is exempt [45CFR46.101(b)] from IRB review based upon the information provided by the Project Manager above. (Check applicable category below.)

__(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

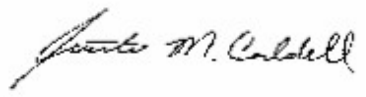
X (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

__(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

__(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

__5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

__(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.



Signature of IRB Coordinator or Chair named above

August 30,2007
Date

Version 11-30-00