ATTACHMENT 3B: RTI IRB PROTOCOL APPROVAL

for

Qualitative Evaluation of HIV Counseling, Testing, and Referral Services in Non-Health Care Settings: Eliciting Consumer Views

New OMB Application

Technical Monitor: Dorothy Gunter, MPH
Senior Advisor, Science and Program Integration

Address:
1600 Clifton Rd, NE
MS D21
Atlanta, GA 30333

Telephone: 404-639-6436
Fax: 404-639-1950
E-mail: dorothy.gunter@cdc.hhs.gov

Date: October 17, 2007

RTI INTERNATIONAL

IRB ID Number:11813

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

Title of Study: Qualitative Evaluation of HIV Counseling, Testing, and Referral Services in Non-Health Care Settings: Eliciting Consumer Views
RTI Project Number: 0208235.052 **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 9, 2007

Level of Review *(check one)*:
Full ☒, IRB Meeting Date: 6/4/07
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: June 4, 2008
(No human subjects research can occur after this date without continuing review and approval.)

Angela M. Greene

06-13-2007

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

Angela Greene, M.S. M.B.A.
Name - IRB Member or Chair (print or type)

☐ Copy sent to project leader on:
☐ Entered into MIS

Office of Research Protection, Institutional Review Board
3040 Cornwallis Road, Research Triangle Park, NC 27709-2194, USA
Telephone: 919-316-3358 Fax: 919-316-3897 orpe@rti.org