ATTACHMENT 3A: CDC 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: September 12, 2007

CDC IRB Protocol Approval

-----Original Message-----
From: Nakano, Connie (CDC/OD/OCSO)
Sent: Wednesday, May 23, 2007 1:24 PM
To: Gunter, Dorothy (CDC/CCID/NCHHSTP)
Cc: Milton, Micah (CDC/CCID/OD); Merritt, Robert (CDC/CCHP/NCCDPHP); Dodson, Janella (CDC/CCID/NCHHSTP); Vann, Jerrell (CDC/CCID/NCHHSTP)
(CTR)
Subject: IRB Approval of New Protocol #5127, (Expedited)

DATE: 5/23/2007

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

SUBJECT: IRB Approval of New Protocol #5127, "Qualitative Evaluation of HIV Counseling, Testing, and Referral Services in Non-Health Care
Settings: Eliciting Consumer Views" (Expedited)

TO: DOROTHY GUNTER [DCG0]
CCID/NCHHSTP/DHAP

New protocol #5127 has been approved by CDC IRB B for the maximum allowable period of one year and it will expire on 5/21/2008. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), categories 6 & 7 and determined that the study involves no greater than minimal risk to subjects. The Board also approved the inclusion of children in the study in accordance with
45 CFR 46.404 and approved the incidental inclusion of pregnant women in the study in accordance with 45 CFR 46.204. The Board granted a waiver of documentation of consent for the screener for adult participants under 45 CFR 46.117(c)(2); waiver of parental permission under 46.116(d) and 46.408(c); waiver of documentation of assent for the screener for adolescent participants under 45 CFR 46.408(d).

PLEASE NOTE: We understand that CDC PIs will wait to request IRB review and approval from Research Triangle International (RTI) after CDC releases IRB approval. Please forward RTI IRB approval to our office as it becomes available. Human subjects research activities cannot begin at RTI until IRB approval is obtained.

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 5/21/2008.

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
Micah Milton
Rob Merritt