Attachment 9

Nurse Delivered Sexual Risk Reduction Intervention for HIV-Positive Women in the South

0920-XXXX

Attachment 9 CDC IRB Approval

From: McCleary, Jennifer (CDC/OD/OCSO)
Sent: Tuesday, August 12, 2008 12:37 PM
To: Williams, Kim (CDC/CCID/NCHHSTP)
Cc: NCHSTP Human Subjects (CDC); Sandul, Amy (CDC/CCID/NCHHSTP)
Subject: 5401: IRB Approval of New Protocol (Expedited)

DATE: 8/12/2008

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

SUBJECT: IRB Approval of New Protocol #5401, "Brief Nurse Delivered Intervention Study (Trial)" (Expedited)

TO: KIM WILLIAMS [KTW5]
NCHHSTP/DHAP/IRS

New protocol #5401 has been approved by CDC IRB "C" for the maximum allowable period of one year and it will expire on **8/11/2009**. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), categories 6 and 7. The IRB determined that the study poses no greater than minimal risk to subjects and approved a waiver of documentation of informed consent for screening in accordance with 45 CFR 46.117(c)(2).

IRB NOTE: In regards to the revisions made to the protocol and appendices at the request of the local IRB, please note that if women elect not to take with them a copy of the consent document they should still be provided with contact names and numbers in case they have questions about the study, feel they have been harmed, or want information about their rights as participants in research. Please consider providing them with contact information in the form of a business card or some other subtle means.

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 8/11/2009.

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 Review
Amy Sandul

Attachment 10(b) University of North Carolina, Chapel Hill – Local IRB Approval

----- Original Message -----

From: IRB

To: cfogel@email.unc.edu

Cc: nabrown@email.unc.edu

Sent: Friday, August 08, 2008 2:09 PM

Subject: IRB Notice

A paper copy of the approval memo and any relevant documents are being mailed today.

To: Catherine Fogel
School of Nursing
CB: 7460

From: Public Health-Nursing IRB

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Authorized signature on behalf of IRB

Approval Date: 8/07/2008
Expiration Date of Approval: 4/27/2009

RE: Notice of IRB Approval by Full Board Review
Submission Type: Initial
Study #: 08-0668

Study Title: Trial for Reducing Sexual Risk in Southern HIV Positive Women
Sponsors: The Centers for Disease Control and Prevention

This submission has been approved by the above IRB for the period indicated.

Study Description:

Purpose: The study will test the efficacy of an HIV prevention intervention designed to reduce high-risk sexual behaviors in HIV-positive women living in the Southeastern United States. The Intervention Trial, which employs a randomized wait-list comparison design with a three-month follow-up period includes 330 HIV-positive women attending HIV clinics in Durham, Guilford, and Mecklenburg counties who will be assessed using behavioral risk measures; in addition, a subset of 25-30 Trial arm participants participate in in-depth, semi-structured interviews designed to assess social and environmental factors contributing to HIV behavioral risks.

Regulatory and other findings:

The Board agreed that this research involves no more than minimal risk and future reviews may be done on an expedited basis, under Expedited Review, Category 9.

Investigator's Responsibilities:

Federal regulations require that all research be reviewed at least annually. It is the Principal Investigator's responsibility to submit for renewal and obtain approval before the expiration date. You may not continue any research activity beyond the expiration date without IRB approval. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.

When applicable, enclosed are stamped copies of approved consent documents and other recruitment materials. You must copy the stamped consent forms for use with subjects unless you have approval to do otherwise.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented (use the modification form at ohre.unc.edu/forms). Should any adverse event or unanticipated problem involving risks to subjects or others occur it must be reported immediately to the IRB using the adverse event form at the same website.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:
Niasha Brown, School Of Nursing

IRB Informational Message—please do not use email REPLY to this address