An Economic Empowerment Intervention to Reduce Risk of HIV among Impoverished High-Risk African American Women in the Southeastern US: Exploratory Research and Feasibility Assessment

APPENDIX C: Centers for Disease Control and Prevention (CDC) IRB Approval for Research Involving Human Research Participants and Supporting Documents

From: McCleary, Jennifer (CDC/OD/OCSO)
Sent: Tuesday, July 25, 2006 10:41 AM
To: Stratford, Dale (CDC/NCHSTP/DHAP)
Cc: NCHSTP Human Subjects (CDC); Bialek, Stephanie R. (CDC/NCID/DVH); Milton, Micah (CDC/CCHP/NCBDDD)
Subject: 4871: Site Restricted - IRB Approval of New Protocol (Expedited)

DATE: 7/25/2006

FROM: IRB 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 #4871, "An Economic Empowerment Intervention to Reduce Risk of HIV among Impoverished High-Risk African Amercian Women in the Southeastern US: Exploratory Research and Feasibility Assessment" (Expedited)

TO: Billie (Dale) Stratford [BBS8]
NCHSTP/DHAP/IRS

New protocol #4871 has been approved by CDC IRB "C" for the maximum allowable period of one year and it will expire on 6/20/2007. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), category 7.
Please Note: Study activities may not begin with the following collaborators/sites until the following conditions have been met:

Florida
- Florida Department of Health: Current IRB approval documentation has been received by CDC and is on file with this office.
- Manilla Consulting: Current IRB approval documentation has been received by CDC and is on file with this office.
- EPICC: Collaborator must apply and receive a FWA from OHRP and the IRB Authorization Agreement between this collaborator and CDC has been approved. [Both of these conditions were met – see attached]

North Carolina
- North Carolina Department of Health and Human Services: Current IRB approval documentation has been received by CDC and is on file with this office.
- Manilla Consulting: Current IRB approval documentation has been received by CDC and is on file with this office.
- CBO - Once determined, collaborator must have current FWA and current IRB approval documentation has been received by CDC and is on file with this office.

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 research participants 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 6/20/2007.

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:
Stephanie Bialek
Micah Milton
NCHSTP Human Subjects

From: Paul_Moore@doh.state.fl.us
Sent: Tuesday, August 01, 2006 9:48 AM
To: Stratford, Dale (CDC/NCHSTP/DHAP)
Subject: FW: Electronic FWA Application for EPICC, Inc. Approved by OHRP as FWA00010426

Fyi,

Paul A. Moore, MSW
Program Director
HIV/AIDS Education, Prevention,
Intervention and Care Coalition (EPICC)
(561) 540-1100
Cell: (561) 635-4325

-----Original Message-----
From: jmakle@osophs.dhhs.gov [mailto:jmakle@osophs.dhhs.gov]
Sent: Tuesday, August 01, 2006 9:44 AM
To: Moore, Paul; krabec@bellsouth.net; Moore, Paul
Cc: jmakle@osophs.dhhs.gov
Subject: Electronic FWA Application for EPICC, Inc. Approved by OHRP as FWA00010426

This is an automated message from an unmonitored address. Please do not reply.

Your institution's electronic submission of a Federalwide Assurance (FWA) has been approved by the Office for Human Research Protections (OHRP), and the FWA number assigned to your institution, EPICC, Inc., is FWA00010426. You will find this approval listed on our website at http://ohrp.cit.nih.gov/search/asearch.asp#ASUR. Funding agencies use this website to verify that an institution holds an active OHRP-approved FWA.

Whenever information provided to OHRP changes for your institution's FWA, you must submit an update/renewal. You may do this electronically by going to the OHRP Electronic Submission System at http://ohrp.cit.nih.gov/efile/. Your FWA must be renewed at least every 3 years.

Effective February 1, 2005, OHRP stopped mailing copies of approved Federalwide Assurance (FWA) documents to filing institutions. This was necessitated by the volume of FWA documents OHRP is managing. Over 10,000 FWAs have been approved. OHRP encourages FWA institutions to continue to submit documents (new and updates/renewals) electronically (http://ohrp.cit.nih.gov/efile). When an electronic submission is processed, an automatically generated e-mail notifies the Human Protections Administrator and Signatory Official, as well as the person submitting the electronic record, that the FWA document has been approved. This, of course, is dependent upon the electronic file submitted to OHRP providing e-mail addresses as requested.

Sincerely,

Division of Policy and Assurances
Office for Human Research Protections
U.S. Department of Health and Human Services

1101 Wootton Parkway, Suite 200
Rockville, MD 20852
(240) 453-6900
Toll-Free within the U.S. (866) 447-4777

From: McCleary, Jennifer (CDC/OD/OCSO)
Sent: Wednesday, August 09, 2006 10:02 AM
To: Stratford, Dale (CDC/CCID/NCHSTP); 'Glenn Krabec, PhD'
Cc: NCHSTP Human Subjects (CDC)
Subject: 4871: IRB Authorization Agreement Approval for EPICC, Inc.

Importance: High

The IRB Authorization Agreement for study #4871, "An Economic Empowerment Intervention to Reduce Risk of HIV Among Impoverished High-Risk African American Women in the Southeastern US: Exploratory Research and Feasibility Assessment", to allow EPICC, Inc. to rely on CDC IRB review for this study has been approved.

The original signed agreement will be maintained by CDC in the study file. A copy of the approved agreement will be sent to you directly.

Any additional questions, please let me know.

Thanks,
Jennifer

Jennifer McCleary
IRB-C Administrator
Human Research Protection Office/OCSO
Phone: 404-639-4954
Fax: 404-639-4901
MS: D73

From: McCleary, Jennifer (CDC/OD/OCSO) on behalf of Human Subjects Review-OD (CDC)
Sent: Thursday, August 10, 2006 12:57 PM
To: Stratford, Dale (CDC/CCID/NCHSTP)
Cc: NCHSTP Human Subjects (CDC)
Subject: 4871: Partial Site Restricted Lifted - IRB Approval of New Protocol (Expedited)

The Human Research Protection Office has received the requested documentation from EPICC, Inc. The site restriction for this collaborator is hereby lifted.

Thanks,
Jennifer

Jennifer McCleary
IRB-C Administrator
Human Research Protection Office/OCSO

From: McCleary, Jennifer (CDC/OD/OCSO)
Sent: Tuesday, July 25, 2006 10:41 AM
To: Stratford, Dale (CDC/NCHSTP/DHAP)
Cc: NCHSTP Human Subjects (CDC); Bialek, Stephanie R. (CDC/NCID/DVH); Milton, Micah (CDC/CCHP/NCBDDD)
Subject: 4871: Site Restricted - IRB Approval of New Protocol (Expedited)

DATE: 7/25/2006

FROM: IRB 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 #4871, "An Economic Empowerment Intervention to Reduce Risk of HIV among Impoverished High-Risk African Amercian Women in the Southeastern US: Exploratory Research and Feasibility Assessment" (Expedited)

TO: Billie (Dale) Stratford [BBS8]
NCHSTP/DHAP/IRS

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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:
Stephanie Bialek
Micah Milton
NCHSTP Human Subjects