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Date July 21, 2014

From Jason Abel
IRB-A Administrator, Human Research Protection Office

Subject IRB Approval of CDC Protocol #6531, "Context Matters: Measuring Provider and Community Factors in The Sustainable Health Center Implementation PrEP Pilot (SHIP) Study"
(Expedited)

To Dawn Smith, MD,MS, MPH
NCHHSTP/DHAP

CDC's IRB-A has reviewed the request for approval of new protocol #6531, "Context Matters: Measuring Provider and Community Factors in The Sustainable Health Center Implementation PrEP Pilot (SHIP) Study" and has approved the protocol for the maximum allowable period of one year. CDC IRB approval will expire on 07/20/2015. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), Category 7. The IRB determined the study to be not greater than minimal risk to subjects.

The IRB has approved the inclusion of pregnant women under 45 CFR 46.204
The IRB has approved the waiver of documentation of consent under 45 CFR 46.117(c)(2)

Institutions that receive federal support who are engaged in human subjects research are required to obtain and provide documentation of IRB approval. CDC investigators who interact with institutions that have failed to meet these requirements are collaborating with noncompliant institutions. Study activities may not begin with the collaborators listed below until documentation indicating current IRB approval has been received by CDC's Human Research Protection Office (HRPO) and the PI has been notified by HRPO that this restriction has been lifted and study activities may begin:

- **Access Community Health Network**
- **Newark Community Health Centers**
- **Central Care Community Health Center**

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 along with available IRB approvals from all collaborators. 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 along with all completed supporting documentation at least six weeks before the protocol's expiration date of 07/20/2015.**

Any problems of a serious nature must be brought to the immediate attention of the CDC IRB, and any proposed changes to the protocol are required to be submitted as an amendment to the protocol for CDC IRB approval before they are implemented.

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office (404) 639-7570 or e-mail: huma@cdc.gov.

cc:
NCHHSTP Human Subjects (CDC)