DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date February 18, 2016

From Felecia Peterson
IRB-G Administrator, Human Research Protection Office

Subject Site-Restriction CDC IRB Approval of New CDC Protocol 6817, "Cohort study of HIV, Sexually Transmitted Infections and preventive interventions among young men who have sex with men (YMSM) in Thailand" (Expedited)

To Eileen Dunne
NCHHSTP/DHAP

CDC's IRB-G has reviewed the request for approval of new protocol #6817, "Cohort study of HIV, Sexually Transmitted Infections and preventive interventions among young men who have sex with men (YMSM) in Thailand." The IRB determined that the study involves no greater than minimal risk to subjects. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), under categories 2, 3, 4 and 7. Additional protections for children involved in research, as described in 45 CFR 46 subpart D were considered when reviewing this protocol and determined to be adequately addressed. A request for a waiver of parental permission was reviewed and approved. The protocol has been approved for the maximum allowable period of one year and CDC IRB approval will expire on **2/17/2017**.

COLLABORATOR/SITE RESTRICTIONS:

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:

1. Local IRB Approvals pending for Dept. of Disease Control Thailand and Mahidol University in Bangkok, Thailand

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 have 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 2/17/2017. Any problems of a serious nature must be brought to the immediate attention of the CDC IRB, and any proposed changes to the protocol should 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 HS mailbox (CDC)
Jon Baio