"Development of a Motion Comic for HIV/STI Prevention Among Young People – ages 15-24—Phase 2"

Attachment 3a. CDC IRB Approval

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date October 30, 2012

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

Subject CDC IRB Approval of Amendment #3 to CDC Protocol #6173, "Development of a Motion Comic for HIV/STI Prevention among Young People-ages 15-24", (Expedited)

To Leigh Willis, PhD, MPH
NCHHSTP/DHAP

CDC's IRB-G has reviewed and approved your request to amend protocol #6173, "Development of a Motion Comic for HIV/STI Prevention among Young People-ages 15-24." The changes included: We are requesting an amendment to our existing protocol to add a second phase of our study. The second phase of the study is needed to develop additional episodes. We would also like to be able to offer organizations who host focus groups a token of appreciation of up to $75 in the form of a gift card to cover the cost of room space and staff to host focus groups (pg. 11). Offering a token of appreciation to organizations will assist in helping us reach our target enrollment number for the second phase of the project.

Modification 1: We modified the protocol to include a second phase of the study which will consist of two additional rounds of focus groups to test content and to develop four additional episodes. We will utilize the same target populations from the first phase. We have included the focus group guides for rounds 4 and 5 (pgs. 81& 90) Would like to increase the number of study paritipants by 120, which includes 60 for round 4 and 60 for round 5.

The action was reviewed in accordance with the expedited review process outlined in 45 CFR 46.111(b)(2), minor changes to previously approved research during the period (of one year or less) for which approval is authorized.

Reminder: IRB approval of protocol #6173 will still expire on 9/12/2013.

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) 639-4721 or e-mail: huma@cdc.gov.
cc:
NCHHSTP Human Studies Review (CDC)
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