DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date May 24, 2019

From Jerrell Little
IRB-Committee 2 Administrator
Human Research Protection Office

Subject CDC IRB Approval of New Protocol 7214.0, "Assessing the acceptability and adoptability of HIV-1 pre-exposure prophylaxis (PrEP) technologies with and without contraceptive formulation among African American women in the southeastern United States." (Expedited)

To Eleanor McLellan-Lemal, MA
NCHHSTP/DHAP

CDC's IRB-Committee 2 has reviewed the request for approval of new protocol 7214.0, "Assessing the acceptability and adoptability of HIV-1 pre-exposure prophylaxis (PrEP) technologies with and without contraceptive formulation among African American women in the southeastern United States." The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), categories 6 and 7. The Human Research Protection Office (HRPO) may follow up with you periodically to check the status of CDC's engagement in this research activity.

The IRB determined that the study poses minimal risk to subjects. The IRB approves the inclusion pregnant women (45 CFR 46.204).

If other institutions involved in this protocol are being awarded CDC funds through the CDC Office Financial Resources (OFR), you are required to send a copy of this IRB approval to the CDC OFR award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided OFR with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

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 your National Center Human Subjects Contact or the CDC Human Research Protection Office at (404) 639-7570 or email at huma@cdc.gov).

CC: NCHHSTP HS mailbox

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Date September 3, 2019

From Jerrell Little
IRB-Committee 2 Administrator
Human Research Protection Office

Subject IRB Approval of Amendment to CDC Protocol 7214, "Assessing the acceptability and adoptability of HIV-1 pre-exposure prophylaxis (PrEP) technologies with and without contraceptive formulation among African American women in the southeastern United States" (Expedited)

To Eleanor McLellan-Lemal, MA
NCHHSTP/DHAP

CDC's IRB-Committee 2 has reviewed and approved your request to amend protocol 7214, "Assessing the acceptability and adoptability of HIV-1 pre-exposure prophylaxis (PrEP) technologies with and without contraceptive formulation among African American women in the southeastern United States". These changes included the following:

Protocol document:

1. ***Added CDC protocol number and changed version 1.0 to version 1.1***
2. ***Version date changed from March 28, 2019 to July 29, 2019***
3. ***Page 7, added CITI number and expiration date for Janet McNicholl***
4. ***Pages 2 and reduced burden hours for informed consent and demographic and behavioral computer-assisted personal interview (CAPI) to 10 minutes and 6 minutes, respectively.***

Page 45, scheduling information: corrected duration of interview to read 60 minutes rather than 90 minutes.

Appendices document:
Based on 9 pilot interviews, minor modifications to the informed consent, the in-depth interview guide, and demographic and behavioral CAPI. Protocol number, version number, and date updated in appendices.

Informed consent

1. ***Page 46:***
    a. ***Changed burden hours from 20 minutes to 10 minutes.***
2. ***Page 47:***
    a. ***Removed sentence that read: Your total participation in the study will require about 96 minutes of your time. Pilot participants indicated that this was***

confusing and that we should only include the duration of data collection that occurs after informed consent was obtained.

3. ***Page 49***
    - ***b. Added CDC protocol number to paragraph under contact information for reporting any complaints or concerns to CDC ADS***
    - ***c. Removed line for a participant to print her name. For all other iQual protocols, the contractor has only required a signature.***

In-depth guide

1. ***Page 50:***
    - ***a. Added in detail to second sentence.***
    - ***b. Omitted explanation that a transcript is a typed out record of the interview since this is already explained in the informed consent.***
    - ***c. Moved instructions to the interviewer to verbally label audio recording after informing participant that recording will start.***
    - ***d. Since the participant already consented to audio recording, replaced While you have signed the informed consent, I will like to get your permission verbally to record the interview. Are you okay with the interview being an audio recorded? with I will begin audio-recording the interview now. Is that okay?***
2. ***Page 51:***
    - ***a. Replaced I will usually ask my questions in terms of your personal thoughts, behaviors, and feelings with I am asking questions in terms of your personal thoughts, behaviors, and feelings.***
    - ***b. Replaced to give advice to with talking.***
    - ***c. Replaced the word this with your description of reproductive health***
    - ***d. Replaced So that we are on the same page, we define with For the purposes of this study, think of.***
    - ***e. Omitted the sentence that read: Sexual health in our definition is not just about diseases, dysfunctions or illness.***
    - ***f. Added you think to two questions to the first two questions regarding sexual health.***
    - ***g. Replaced pronoun they with women moved the word is to the end of the question.***
    - ***h. Replaced Tell me about any with Describe, and omitted the words or wellness and might.***
    - ***i. Replaced STIs with STDs on this page as well as for the remainder of the document.***
    - ***j. Omitted question regarding pregnancy protection given that in all pilot cases responses emerged organically from earlier questions.***
    - ***k. Moved question about steps taken to protect oneself from HIV infection to the beginning of the next section.***
    - ***l. Omitted the question, Imagine that we have available a means of effectively protecting women against unwanted pregnancy, HIV, and STDs. For simplicity let's call this a solution. What form would you want this solution to take?***
3. ***Page 52:***

a. ***Added new transition statement indicating that discussion would shift to HIV, added question from item 2k, added Imagine that we have available a means of effectively protecting women against unwanted pregnancy, HIV, and STDs to the second transition statement, and removed the example of oral contraceptives given that pilot participants thought it created the potential for confusion.***
b. ***Removed all follow up questions regarding products that would be appealing unappealing. Pilot participants indicated that target sample would be unlikely to understand or respond to these types of questions.***
c. ***Changed the order of Showcards to correspond with the card ordering, and added instructions to the interviewers to display the showcard alone to get participants' responses before showing them prototype product.***
d. ***Simplified follow-up questions and made them optional probes given that in many pilot interviews, participants had already included related responses to these questions in their initial responses.***

4. ***Page 53:***
   a. ***Simplified question wording.***
   b. ***Omitted the question What would be needed to women to seriously consider using this product?***
   c. ***Removed from transition statement: what adopting use of these products involves. By adoption, I am talking about and In other words, going beyond finding these products acceptable and just stating a possible willingness to use them.***
   d. ***Replaced of their use with these 3 products.***
   e. ***Replaced lend itself with help to.***
   f. ***Added closing question Is there anything else you'd like us to know?***
   g. ***Replaced about you with on the tablet***
   h. ***Added interviewer reminder instructions to turn off audio recorder(s) before proceeding with demographic and behavioral CAPI.***

Demographic and Behavioral CAPI

1. ***Page 54:***
   a. ***Changed burden duration from 10 minutes to 6 minutes.***
2. ***Page 55:***
   a. ***For question #3, replaced get with earned.***
3. ***Page 56:***
   a. ***Added response options Pull out and Other to question #8.***
   b. ***Omitted question #9.***
   c. ***Replace STIs with STDs and removed examples of common STIs from transition statement.***
4. ***Page 57-58:***
   a. ***Removed explanation of vaginal and anal sex from transition statement. Pilot participants indicated that explanations should only be added if participant had not already mentioned these sexual acts in the in-depth interview and presented separately with their corresponding questions (new questions #12 and #13).***
   b. ***Added three sometimes use response options***

c. ***Omitted questions #16 and #17 since PrEP is covered in the in-depth interview.***

Showcards

1. ***Showcard #1, page 60, replaced the word would with does and added periods to the acronym US.***
2. ***Showcard #2, page 61, added This device is a little like a tattoo needle and added periods to the acronym US.***
3. ***Showcard #3, page 62:***
    a. ***Added new bullet, It is intended to only provide HIV protection for vaginal sex. It does not provide protection from HIV if a woman has oral or anal sex.***
    b. ***Correct verb to be past tense.***
    c. ***Added periods to the acronym US.***
    d. ***Removed redundant bullet It is approved for use by the US government.***

The action was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), under categories 6, and 7 to previously approved research during the period (of one year or less) for which approval is authorized.

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 Human Studies