DEPARTMENT OF HEALTH & HUMAN SERVICES

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

# Memorandum

Date September 25, 2020

From LaShonda Roberson, DHSc, MPH
CDR, USPHS
Sr. IRB Administrator
Human Research Protection Office

Subject IRB Approval of CDC Protocol #7224.0, Amendment #1, "Quantitative research to understand consumer opinions and preferences for emerging HIV prevention products among MSM in Atlanta" (Expedited)

To Ayana Stanley, DrPH
NCHHSTP/DHAP

CDC IRB Committee 1 has reviewed and approved your request to amend protocol **7224.0**, "Quantitative research to understand consumer opinions and preferences for emerging HIV prevention products among MSM in Atlanta". The modification includes the following changes:

We are recommending an expansion of sites for the 2PM study, from Atlanta solely to three separate sites including Atlanta. This would reduce the burden on Atlanta where there is research fatigue in the population and competition for research subjects. As Atlanta has a considerably large MSM population, there are also many research projects that also seek to recruit, enroll, and retain this group in studies. At Emory University, for example, there are thousands of MSM enrolled in the 20 PRISM (Programs, Research, Innovation in Sexual Minority Health) studies. Additionally, there are other active investigators throughout the Atlanta metropolitan area who are recruiting the same populations for their studies at Emory University, Georgia State University, the University of Georgia, Mercer University, GA Tech, as well as research teams at other universities, colleges, community-based and AIDS-service organizations, government and non-governmental agencies. Currently, there are 7 active and planned clinical trial investigations listed on clinicaltrials.gov, including those examining biomedical prevention options, including those being conducted as multisite studies (e.g.,

https://clinicaltrials.gov/ct2/show/NCT03729570?term=gaymen&recrs=ab&map_cntry=US&map_state=US%3AGA&draw=2&rank=4).

We would like to add two new jurisdictions: Houston, TX and Miami, FL, both cities are part of Ending of the Epidemic. (p 15 & 16 of protocol)

Due to the study being conducted virtually, audio recording of verbal consent will be requested prior to conducting the short survey and the IDI or FG (p. 21 & 30 in protocol, Appendix B)

Conduct virtual data collection instead of in-person due to the COVID-19 pandemic. (p 25 in protocol)

The action was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(2) category 7, minor changes to previously approved research during the period of one year for which approval is authorized.

**Reminder: IRB approval of protocol #7224.0 will still expire on 12/21/2030.**

**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 Subjects Review (CDC)