Summary of Proposed Changes in the ICR for Qualitative Research to Understand Consumer Opinions and Preferences for Emerging HIV Prevention Products among MSM in Atlanta, Houston, and Miami OMB# 0920-1091

Summary of Changes

We are requesting non-substantive modifications to the information collection request (ICR) for Qualitative Research to Understand Consumer Opinions and Preferences for Emerging HIV Prevention Products among MSM in Atlanta, Houston, and Miami (OMB# 0920-1091). The changes requested for this ICR are to modify the data collection methods from in-person focus groups and in-depth interviews to virtual focus groups and in-depth interviews using internet-based video conferencing software to mitigate risks for person-to-person transmission of SARS CoV-2. No changes are requested to survey/data collection instruments and there are no changes to the burden hours calculated for the study.

Changes to Include a Modification from Conducting In-person to Virtual Focus Groups and In-depth Interviews via Internet-based Video Conferencing Software

The advent of the COVID-19 pandemic has required in-person studies to modify data collection procedures to mitigate risk and transmission of the coronavirus. As a result, this study will implement virtual in-depth interviews (IDIs) and focus groups (FGs).

Potential participants may see online social media sites, print media, online ads, or electronic flyers which contain a number to call if interested. When they call, they will reach a research team recruiter who will describe the study and then screen the participant. Alternatively, local individuals within each site will promote the study through their networks and share the flyers. If they meet the eligibility criteria, they may be asked for contact information and scheduled to participate in either a virtual IDI or FG. 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. Prior to beginning verbal informed consent, interviewers will ask for permission to audio record the consent process as documentation of informed consent. If agreed, the interviewer will turn on recorder and read the verbal consent script aloud, which includes an explanation of the study, risks and benefits of participation, duration of participation, contact information for individuals who can answer questions about the research study or about participant rights and protections, the voluntary nature of participation, and the right to withdraw without penalty. Participants will be given an opportunity to ask questions and receive additional information before consenting to proceed. At the conclusion of the recorded verbal informed consent process, the interviewer will then sign a copy of the verbal consent script acknowledging that they have audio recorded, read and explained the consent form to the participant before receiving the participant's consent, and the participant had knowledge of its contents and appeared to understand it. After the participant provides verbal consent, they will be asked to complete a 5-minute quantitative survey prior to the start of the qualitative portion (IDI or FG). Contractor staff will verbally administer the surveys via video teleconference for IDIs. For FGs, contractor staff will call participants on their personal phones to conduct the survey which will ensure privacy.

All data collection activities will be carried out by trained contractor staff. Interviews and focus groups will all be conducted online via video conferencing software, e.g., Zoom. For IDIs (which will last approximately 60 minutes), we will work with each participant to establish a convenient time. For FGs, we will consider participant availability and preference to decide into which group to schedule a participant. No aspect of obtaining verbal consent or implementing IDI/FG data collection will be video recorded. These processes will be audio recorded only.

Table 1. Proposed Virtual Modifications to Qualitative Research to Understand Consumer Opinions and Preferences for Emerging HIV Prevention Products among MSM in Atlanta, Houston, and Miami

Doc, Page, Section, Variable	Change Proposed	Reason for Change Proposed
SSA, Page 3, Overview Box	Added virtual data collection	Mitigate COVID-19 risks
SSA, Page 4, Justification	Removed references to in-person data collection	Mitigate COVID-19 risks
SSA, Page 7, Use of Improved Information Technology and Burden Reduction	Removed references to in-person data collection	Mitigate COVID-19 risks
SSA, Page 7, Use of Improved Information Technology and Burden Reduction	Added statement of no video recording of virtual interviews	Participant privacy protection
SSA, Page 8, Explanation of Any Payment or Gift to Participants	Added virtual data collection	Mitigate COVID-19 risks
SSA, Page 13, Project Time Schedule	Updated project timetable	Updated project timetable due to Change Request
SSB, Page 4, Target Population	Added virtual data collection	Mitigate COVID-19 risks
SSB, Page 5-6, Procedures for the Collection of Information	Removed references to in-person data collection and written informed consent. Added verbal informed consent	Mitigate COVID-19 risks
SSB, Page 8, Individuals	Removed references to in-person data	Mitigate COVID-19 risks

Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data	collection	