Explanation of COVID related GenIC Change

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 (2ADoPT) OMB # 0920-1091 (21AG)

We are requesting a change in the information collection request (ICR) entitled, "*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 (2ADoPT)*". This GenIC was approved under OMB # 0920-1091 (CDC#0920-19BSO), under Generic ICR, "*Using Qualitative Methods to Understand Issues in HIV Prevention, Care and Treatment in the United States"* (abbreviated as "iQual", OMB # 0920-1091, expiration 9/30/2021). The Government awarded a Firm Fixed-Price Task Order to Research Support Services (Contract # 200-2013-57341) as a result of a request for a task order proposal under terms and conditions set forth in the iQual Indefinite Delivery/Indefinite Quantity (IDIQ) Task Order multi-award contracts.

This formal request to change this OMB approved GenIC from an in-person information collection to a virtual collection as a result to the COVID19 pandemic, is resulting from the OMB's requirement to address the issue managing ongoing CDC collections to convert approved ICRs from in-person collection to online/virtual collection in a more streamlined fashion.

Clinical trials of HIV-1 PrEP technologies with and without contraceptive formulation among women are mostly being conducted outside of the United States (US); thus, it is critical that we have a better understanding on how and if how these products may benefit US African American women at risk for HIV infection. To date, limited research has been conducted among African American women of North American ancestry residing in this geographical region. There is a need for research that examines the following: 1) how well a biomedical intervention will be received (acceptability) as well as 2) the perceived extent to which new biomedical intervention might meet the needs of African American women and real-world organizational settings (adoptability).

Due to COVID19, all in-person human subjects activities for this study were suspended early March 2020. We planned to initiate data collection as soon as it was safe to do so. As the pandemic continues, funding considerations warrant that we take a different approach. Per 45 CFR 46.108(a)(3)(iii) under the 2018 Requirements and 45 CFR 46.103(b)(4)(iii) under the pre-2018 Requirements, we propose shifting from in-person data collection to virtual interviews. The completion of this exploratory qualitative study is high priority given its potential contribution to identifying acceptability, delivery, or uptake considerations associated with HIV prevention biomedical technologies being developed or undergoing clinical trial testing. Given that African American women are most risk for HIV infection, their input is critical in better understanding which options are viewed as practical and suitable for them.

Virtual data collection will use a video-enhanced teleconference computer-mediated interview approach. The in-depth interview (IDI) is comprised of a qualitative interview and a brief demographic and behavioral computer-assisted personal interview (CAPI) using SurveyGizmo. A private online Zoom® conferencing platform will be used to conduct the IDIs. The virtual meeting room will be password-enabled with interviewer-controlled entry. All IDIs would be collected as synchronous-only (live) sessions. Video capture of an interview will not be incorporated as study data. Only audio recording of the open-ended qualitative portion of the IDI will be undertaken. The demographic and behavioral CAPI will not be audio recorded.

Written informed consent has been replaced with verbal informed consent. A waiver of documentation of informed consent was approved for this study, as it meets the requirements of 45 CFR 46.116 (d) which states that an IRB may waive the requirement for the investigator to obtain a signed consent form if the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Specifically, data will be collected, managed, and archived (temporarily until end-of-study destruction) in a manner where participants cannot be identified.

Recruitment Materials & Data Collection Tools Changes

Attachment 2_Recruitment Flyer:

Original Text	New Text
18 years and older	18-34 years of age
one-on-one in person interview	one-on-one, virtual, audio-recorded interview
90 minutes or less	70 minutes or less
$40 cash	$40 gift card or e-cash
1-888-XXX-XXXX	1-888-617-8522
OMB No.: XXXX-XXX	OMB # 0920-1091
Expiration Date: XX/XX/XXXX	Expiration Date: 09/30/21

Attachment 3a_Screener:

Location	Old Text	Next Text
Narrative FAQ	face-to-face	virtual
Narrative FAQ	in a place convenient to you	
Narrative FAQ	90 minutes	70 minutes
Narrative FAQ		The interview is done using Zoom, an Internet-based video conference platform. If you qualify to take part in the study, we will give you an Internet link that connects you to your interview. We can give you a WIFI on-demand pass that gives you temporary Internet access for the interview or you can choose to use your own WIFI. Your own laptop, tablet, or phone is required to connect to the interview. While you and the person conducting the interview will be able to see one another, only your voice will be recorded during the interview. The interview will not record video of you and the interviewer.
Question 13	If you are eligible, would you be willing to participate in an in-person interview at a time and a place convenient to you?	If you are eligible, would you be willing and able to participate in videoconference virtual interview at a time convenient for you?
Checklist	ABLE TO COMPLETE IN-DEPTH INTERVIEW (DOES NOT SOUND/APPEAR TO BE UNDER THE INFLUENCE OF DRUGS OR ALCOHOL/DISORIENTED/CONFRONTATIONAL/ HAS MUCH TROUBLE WITH SCREENER QUESTIONS/ ANGRY)	
Checklist		WILLING TO TAKE PART IN A VIRTUAL INTERVIEW
FAQs/if they ask	no more than an hour	no more than 70 minutes
FAQs/if they ask	$40 cash	$40 e-cash or gift card

Attachment 3b_Contact Information:

Location	Old Text	Next Text
Item 2	contact number	contact phone number
Item 7	SPECIFY:	EMAIL:
	if you would still like to	if you would still like to do so
Points to cover	An interview is a like a conversation where someone on our team will serve as the interviewer. The interviewer will ask you questions and you will provide your thoughts, experiences, and feelings related to each of the questions. At the end, we will ask you a short set of questions so that we better understand you.	The audio-recorded part of the interview will take about 60 minutes and is a like a conversation where someone on our team will serve as the interviewer. The interviewer will ask you questions and you will provide your thoughts, experiences, and feelings related to each of the questions. At the end, we will ask you a short set of questions so that we better understand you. This part of the interview will not be audio recorded and will take about 6 minutes to complete.
Points to cover	• The interview needs to be in person. We'll have an interviewer in • [AREA] at • [LOCATION] on • [DATES]	

To establish technology access and needs required for virtual IDI participation, the following six new questions have been added to the contact information form:

Question	Description	Valid Values
The interview is done virtually. Because you and the person conducting the interview will need to be able to see one another and we have some products to show you, the device you use to connect to the interview will need a camera. What type of device will you be using for the interview?	Participant identifies the type of device that she intends to use for the virtual IDI.	Check all that apply: 1 = Mobile phone 2 = Tablet such as an iPAD 3 = Laptop or computer 4 = Other device (e.g., Kindle, Chromebook) SPECIFY OTHER: _____
Does your device have a built-in camera?	Determine whether participant's device will enable visual participation?	1 = Yes 2 = No
Does your device have a microphone?	Determine what type of microphone the participant intends to use for the IDI.	1 = Yes 2 = No SPECIFY ALTERNATIVE (e.g., earphones with built-in microphone, laptop built-in sound and audio):_____
Will you need a WIFI on-demand pass?	Determine if	1 = Yes

	participant will require an on-demand WIFI passcode or if she will use her own Internet.	2 = No
Will you need assistance with the Zoom link, your device's camera, or WIFI access?	Determine participant's familiarity with Internet hyperlinks on her device. Specify what type Include specific type of assistance needed.	1 = Yes 2 = No SPECIFY: _____
You will receive $40 following the interview. You can choose to receive it as either a gift card or an electronic cash transfer.		1 = gift card 2 = electronic cash transfer

Attachment 3c_IDI Guide and Showcards:

The interview guide was mainly restructured to ensure that products were presented the same across interviews:

- Objectives were replaced with interviewer instructions.
- Added "sexually transmitted diseases" after STDs in case participants were unfamiliar with the acronym.
- Added section header per interviewer request to alert them to ready materials for presenting product-specific questions.
- Added explanation to the participant of process for discussing prototype products.
- Three questions asked for each product are now presented separately on the interview guide for each product as opposed to presented once at the beginning of this section.

Showcard #0:

- Common traits were extracted from each of the product showcards and presented as a new showcard (Showcard #0) to reduce redundancy.

Showcard #1:

- Both interviewers and in-person mock interview participants had a difficult time with Long-acting Cabotegravir Injection. This was changed to Long-acting Injection.

Showcard #2: "cut" was revised to "small cut" and added 3 bullets:

- Once the wound has healed, knocking or hitting the implant will not do it, or you, any harm.
- Although the implant is not visible, it is possible that its outline under the skin can be felt and seen.
- It is possible that the area around the implant could be bruised and tender for a few days.

Showcard #3:

- Split up some of the lengthier bullet items into sub-bullets
- Added and slightly revised modified text:
  - A ring for only preventing pregnancy is licensed in the US.

- Some women using the contraceptive-only ring have reported that they or their sexual partners are able to feel the ring during sex.
- The same may be true of a ring that prevents both pregnancy and HIV.

NEW: Optional suggested probes added to questions 6 and 7 so that some follow-up could occur if participant had neither or these experiences:

- 6a (If R cannot describe "sexual health services") What about women's health services?
- 7a If no steps are taken, ask: Please tell me what makes you <not at risk>/<not take any steps>." or What steps do you think other women who are at risk STDs or sexually transmitted diseases might take?"

Attachment 3d_Demographic Behavioral CAPI

No changes were made to this data collection instrument.

Changes in Estimates of Annualized Burden Hours

Burden calculations for the study are anticipated to remain unchanged (98 total hours). This exploratory qualitative study will be conducted in the same three locales as originally proposed (Atlanta, GA; Jackson, MS; and Baton Rouge, LA. A total of 75 IDIs will be conducted (25 per locale).

Type of Respondent	**Form Name**	**No. of Respondents**	**No. of Responses Per Respondent**	**Average Burden Per Response (in Hours)**	**Total Burden Hours**
General Public- Adults	Attachment 3a.Screening CAPI	150	1	5/60	12.5
General Public- Adults	Attachment 3b. Contact Form	90	1	2/60	3
General Public- Adults	Attachment 3c. In-depth Interview Guide and Product Information Showcards	75	1	1	75
General Public- Adults	Attachment 3d. Demographic and Behavioral CAPI	75	1	6/60	7.5
Total					**98**