

**Summary of Proposed Changes in the ICR for Web-Based Approaches to Reach Black or African American and Hispanic/Latino MSM for HIV Testing and Prevention Services OMB# 0920-1284**

**Summary of Changes**

We are requesting non-substantive modifications to the information collection request (ICR) for Web-Based Approaches to Reach Black or African American and Hispanic/Latino MSM for HIV Testing and Prevention Services OMB# 0920-1284. The changes requested for this ICR are non-substantive modifications to include: 1) an additional method for HIV testing to be added to at-home HIV testing kits; and 2) the removal of one of the study arms. 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 an Additional Testing Method to At-Home HIV Testing Kits**

This study utilizes DBS cards as the primary method for laboratory testing of participant blood samples. Another form of sample collection, microtainer collection, is a proposed addition to the study. The purpose of microtainer collection is to evaluate the feasibility of self-collection of microtainers among untrained MSM in the US and analyze samples for their HIV infection (viral load) and HIV medications (PrEP or ART). The addition of microtainer testing at home will serve as evidence in providing individuals a means to be clinically monitored from home. In future, this could alleviate the need for patients to visit a medical clinic for PrEP, ART and viral load monitoring.

For the microtainer collection, the participant will perform a single finger-stick to provide enough blood to fill at least half (250 uL) of the microtainer. The participant will return the microtainer in a provided mailing envelope directly to the CDC DHAP lab. The packaging will not contain identifiable information and participants who choose to return the microtainer will receive a \$10 token of appreciation in the form of a gift card. There are no changes or additions to survey instruments regarding the microtainer collection.

**Table 1. Proposed Testing Method Modifications to Web-based Approaches to Reach Black or African American and Hispanic/Latino MSM for HIV Testing and Prevention Services**

Doc, Page, Section, Variable	Change Proposed	Reason for Change Proposed
<b>Microtainer collection</b>		
SSA, Page 6, Purpose and Use of Collection, content change	<b>Added</b> (as indicated here in bold highlight): “At the end of the 4-month follow-up period, participants will be sent dried blood spot (DBS) <b>and microtainer collection kits</b> for research purposes and another rapid HIV self-test kit for their use.”	To note the addition of another specimen collection added to the self-test kit.
SSA, Page 7, Purpose and Use of Collection, content change	<b>Added: “The purpose of the microtainer collection is to evaluate the feasibility of self-collection of microtainers among</b>	This information describes the research purpose for adding microtainer

	<b>untrained MSM in the US and analyze samples for HIV infection and HIV (PrEP or ART) medications. This may serve as a proof of principle in providing individuals a means to be clinically monitored from home which could alleviate the need for PrEP and VL monitoring clinic visits.”</b>	collection to this study.
SSA, Page 7, Purpose and Use of Collection, content change	<b>Added</b> under sub-heading “Mail-out Testing Kit Only Arm”: <b>“Microtainer collection is estimated to take 10 minutes.”</b>	This information clarifies changes to the estimated amount of time that participants will need to complete the test kit.
SSA, Page 8, Purpose and Use of Collection, content change	<b>Added</b> under sub-heading “Healthmindr Arm”: <b>“Microtainer collection is estimated to take 10 minutes.”</b>	This information clarifies changes to the estimated amount of time that participants will need to complete the test kit.
SSA, Page 10, Explanation of Any Payment or Gift to Respondents, content change	<b>Added:</b> “Participants in this trial will be provided with up to <b>\$80</b> over the study period.”	This information updates tokens of appreciation totals to reflect the addition of the microtainer.
SSA, Page 10, Explanation of Any Payment or Gift to Respondents, content change	<b>Added:</b> <b>“Participants who return completed microtainers will be provided an additional \$10 upon receipt of the microtainer.”</b>	This information clarifies changes to the estimated amount of time that participants will need to complete the test kit.
SSB, Page 6-7, Procedures for the Collection of Information, content change	<b>Added:</b> <b>“Microtainer samples will be mailed directly to CDC. Microtainer will be delivered pre-labeled and will not need to be registered (name and contact information will not be provided).</b>	Updated to indicate that collection kits will provide both a DBS and microtainer specimen collection supply.
SSB, Page 6, Procedures	<b>Added:</b> <b>“Microtainer samples will be mailed</b>	Updated to indicate how

for the Collection of Information, content change	<b>directly to CDC. Microtainer will be delivered pre-labeled and will not need to be registered (name and contact information will not be provided)."</b>	sample will be sent to CDC.
SSB, Page 6, Procedures for the Collection of Information, content change	<b>Removed</b> horizontal perforation on the form that separates the Patient Identification section from the remainder of the form.	It is no longer necessary to separate the Patient Identification section from the remainder of the form.
SSB, Page 8, Procedures for the Collection of Information, content change	<b>Changes</b> in highlight to heading: "DBS and Microtainer Testing". Similar minor changes made throughout the rest of the document.	To make references to the microtainer kit along with the DBS samples consistent throughout.
SSB, Page 8-9, Procedures for the Collection of Information, content change	<p><b>Added: "Participants who return the DBS card and report taking PrEP or ART will be sent a microtainer collection after they return their DBS card.</b></p> <p><b>The microtainer collection kit includes: an instruction booklet in English, a microtainer collection tube, a plastic bag, an alcohol wipe, two gauze pads, two safety lancets (BD, 2 mm), a bandage and a return envelope. Microtainers will be pre-labeled with the participant ID and do not need to be registered by the participant. Microtainers will be returned directly to CDC.</b></p> <p><b>For the microtainer collection, the participant will perform a single finger-stick to provide enough blood to fill at least half (250 uL) of the microtainer. The participant will return the microtainer in the provided mailing envelope. The packaging will not contain identifiable information and it will be mailed to the CDC DHAP lab."</b></p>	This information provides more detail concerning the microtainer collection kit and the specimen collection process.
SSB, Page 8-9, Procedures for the Collection of Information, content change	<b>Added: "Similarly, for the microtainer collection kit, participants will receive \$10 for sending in their specimen."</b>	This clarifies that participants will receive an additional \$10 for the microtainer kit.

**Changes to remove the Health MPowerment Study Arm**

The original design of the study included an arm of participants that would be exposed to an app called Health Mpowerment. The purpose of the health Mpowerment arm was to understand its effects on participants in the study and to compare results from this arm to another app intervention arm, Health Mindr. Unfortunately, the sub-contractor for this work was unable to produce the app as originally planned. All references to Health Mpowerment have therefore been removed as part of this amendment.

**Table 2. Proposed Intervention Arm Modifications to Web-based Approaches to Reach Black or African American and Hispanic/Latino MSM for HIV Testing and Prevention Services**

Page, Section, Variable	Change Proposed	Reason for Change Proposed
<b>Removal of Health Mpowerment Arm</b>		
SSA, Page 6, Purpose and Use of Collection, content change	<b>Removed:</b> “either an online website, called healthMpowerment, that provides community support, HIV information, discussion boards, and interaction with healthcare and prevention professionals or”	Changed to remove reference to the arm that is being taken out of the study.
SSA, Page 6, Purpose and Use of Collection, content change	<b>Removed:</b> “either the interactive HIV prevention mobile-optimized website (healthMpowerment, University of North Carolina) and mobile app (“	Changed to remove reference to the arm that is being taken out of the study.
SSA, Page 6, Purpose and Use of Collection, content change	<b>Changed:</b> “They will be assigned to one of <b>two</b> groups:”	Changed to reflect accurate number of study arms.
SSA, Page 8, Purpose and Use of Collection, content change	<b>Removed:</b> “ <b>healthMpowerment Arm: The estimated burden for participants depends on the condition they are randomized to and the activities in which they participate. For the healthMpowerment arm, the estimated burden for participants is 3 hours and 45 minutes. In total, reading the consent form for eligibility screening (Attachment 4a), completing the online eligibility screener (Attachment 3a), completing the study registration process (Attachment 3b), consenting to participate in the study (Attachment 4b), and completing the baseline assessment (Attachment 3c) is estimated to be 20 minutes. Completing the 4-month follow up</b>	Changed to remove reference to the arm that is being taken out of the study.

	<p>assessment will take approximately 30 minutes (Attachment 3e). Completion of the HIV self-testing kit is estimated to take 30 minutes (10 minutes to read the instructions and collect a sample and 20 minutes to wait for the test results to be processed). Estimates times for completion of the DBS sample collection is 15 minutes and the HIV self-testing is 30 minutes. Completion of the first test result survey (Attachment 3d) will take 5 minutes, and completion of the second test result survey will take 5 minutes (Attachment 3f). Interaction with healthMpowerment is estimated at 5 minutes per week over 4 months, or 80 minutes.”</p>	
SSA, Page 10, Protection of the Privacy and Confidentiality of Information Provided by Respondents, content change	<p><b>Removed: “PII is also used for follow-up HIV video counseling and to initiate engagement with the health Mpowerment website in order to encourage linkage to care after HIV testing.”</b></p>	Changed to remove reference to the arm that is being taken out of the study.
SSB, Page 6, Procedures for the Collection of Information, content change	<p><b>Removed: “and health MPowerment arm,”</b></p>	Changed to remove reference to the arm that is being taken out of the study.
SSB, Page 6, Procedures for the Collection of Information, content change	<p><b>Removed: “healthMpowerment: Participants assigned to the healthMpowerment arm will receive access to an interactive mobile-optimized website. As participants interact with healthMpowerment, data about features used, pages visited, functions used, postings made, content contributed, and time spent will be captured and stored in the administrative portals of the healthMpowerment website. Data are stored with alphanumeric strings unique to participants. Emory study staff hold the link between alphanumeric strings and contact information for participants.”</b></p>	Changed to remove reference to the arm that is being taken out of the study.