

**Understanding HIV/STD Risk and Enhancing PrEP Implementation Messaging in a Diverse Community-Based Sample of Gay, Bisexual, and Other Men Who Have Sex with Men in a Transformational Era (MIC DROP)**

**OMB # 0920-1421**

**Approved November 29, 2023**

**Summary of Changes**

We are requesting a non-substantial change to the information collection request (ICR) for the MIC DROP Study (OMB #0920-1421).

Specifically, we are requesting a revision to one screening question in order to notify participants that their email address will be collected as part of the study. We are requesting the addition of a response to allow ineligible participants to provide their email if they are interested in being contacted about future studies. We are requesting the addition of a question to collect personal pronouns so that we may address participants by their preferred pronouns. We are also requesting several administrative changes including a formatting change; correction to a grammatical (capitalization) error; the addition of messages to the administrator/programmer; and the revision of existing instructions to the participant for clarity. We have also revised our consent forms to clarify participation options for the current and future studies and added language to notify participants about tax information collection requirements.

We are requesting these changes in order to be more consistent and responsive to participants, and to adhere to the institutional requirements of the awardee of the cooperative grant, Emory University. These changes are consistent with stakeholder input and align with the goals and plans of this project.

The changes are summarized in Table 1 below. The change affects the following attachments:

- Att 4a\_Eligibility Screener English / Spanish
- Att 4b\_Registration Contact Information Form English / Spanish
- Att 5a\_Consent to Participate English / Spanish
- Att 5b\_Focus Group Consent English / Spanish
- Att 5c\_In-Depth Interview Consent English / Spanish

There are no changes to the burden table. Changes to Attachment 4a included the following:

- A formatting change: Moving the location of a question on the screener (Q1)
- Adding instructions to the administrator/programmer:
  - o After question 1 (if Q1 [LANGUAGE] = NO, then show disqualification message)
  - o After question 9 (if Q9 [PHONE] = YES then display Q10)
- A grammatical correction: Capitalizing the first letter of the word "Choose" (Q8)
- Adding the word "email" (Q17)
- Adding an option for ineligible participants to provide their email address
- Rephrasing existing participant instructions to complete registration

None of the above revisions changed the average estimated time it took to complete the instrument; therefore, there were no changes to the burden table.

One question was added to Attachment 4b (Q8. What pronouns should we use for you?). When we tested the revised questionnaire, the addition of the single question did not change the average estimated time it took to complete the instrument; therefore, there were no changes made to the burden table.

Consent documents are not included in the calculation of participant burden; therefore, changes to the consent documents will not change the burden calculation.

**Table 1. Summary of Changes**

<b>Instrument and Summary of Changes</b>	<b>Original Question</b>	<b>Change Proposed</b>	<b>Reason for Change Proposed</b>
<b>Att 4a Eligibility Screener (English and Spanish)</b>  Question 1 was moved to the top of the screener.	1. Are you able to read and understand [English/Spanish] without assistance? Yes No	1. Are you able to read and understand [English/Spanish] without assistance? Yes No  [No change to question content. Move Question 1 to the top of the screener]	Key stakeholder input, project goals.  Question 1 was moved to indicate that, depending upon their response to question 1, the respondent will receive either an immediate welcome or disqualification message.
<b>Att 4a Eligibility Screener (English and Spanish)</b>  Administrator / Programmer instructions were added after question 1.	1. Are you able to read and understand [English/Spanish] without assistance? Yes No	1. Are you able to read and understand [English/Spanish] without assistance? Yes No  [Administrator/Programmer instructions] If no: disqualify and show "Sorry, you do not qualify to take this survey."	Key stakeholder input, project goals.  Administrator / Programmer instructions were added after question 1 to display a disqualification message to the participant if they answer 'No' to question 1.
<b>Att 4a Eligibility Screener (English and Spanish)</b>  Grammatical (capitalization) error correction to question 8.	8. What race or races do you consider yourself to be? (choose all that apply)	8. What race or races do you consider yourself to be? (Choose all that apply)	Key stakeholder input.  A correction was made to a capitalization error on question 8.

Instrument and Summary of Changes	Original Question	Change Proposed	Reason for Change Proposed
<b>Att 4a Eligibility Screener (English and Spanish)</b>  Administrator / Programmer instructions were added after question 9.	9. Do you own and use an Android or iOS smartphone? <input type="checkbox"/> Yes <input type="checkbox"/> No [PHONE]	9. Do you own and use an Android or iOS smartphone? <input type="checkbox"/> Yes <input type="checkbox"/> No [PHONE]  [Administrator/Programmer instructions] If PHONE = YES.	Key stakeholder input, project goals.  Administrator / Programmer instructions were added after question 9 to indicate that, if the participant answers YES to question 9, question 10 will be displayed.
<b>Att 4a Eligibility Screener (English and Spanish)</b>  Email was added to the list of contact information in question 17.	17. Are you willing to provide contact information, including phone number and mailing address so that we can send you study materials, including HIV/STI testing kits and any tokens of appreciation?	17. Are you willing to provide contact information, including phone number, email, and mailing address so that we can send you study materials, including HIV/STI testing kits and any tokens of appreciation?	Key stakeholder input, project goals.  This addition lets participants know that their email address will be collected in this study. The study has been approved by OMB to collect participant email address, but this information was accidentally omitted from this screening question.

Instrument and Summary of Changes	Original Question	Change Proposed	Reason for Change Proposed
<p><b>Att 4a Eligibility Screener (English and Spanish)</b></p> <p>A section was added to allow ineligible participants the option to enter their email address if they would like to be contacted about other studies.</p>	<p>End 1. If the participant is Not Eligible:</p> <p>Thank you so much for answering all of the questions; we really appreciate your time.</p> <p>Unfortunately, you are not eligible for this particular research study.</p> <p>Would you like to be contacted about other studies you may potentially be eligible for?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>	<p>End 1. If the participant is Not Eligible:</p> <p>Thank you so much for answering all of the questions; we really appreciate your time. Unfortunately, you are not eligible for this particular research study.</p> <p>Would you like to be contacted about other studies you may potentially be eligible for?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>If YES:</p> <p>1) You indicated that you would like to be contacted about other studies you may potentially be eligible for. Please provide your email address below. We will use this to contact you about any future studies you may be eligible for.</p> <p>_____</p> <p>Thank You!</p>	<p>Key stakeholder input.</p> <p>Many important research studies have difficulty finding participants. This option allows respondents who were ineligible to participate in this study, the option to be contacted about other studies. This benefits respondents who are interested in participating in research as well as other research studies who are recruiting potential participants.</p>

Instrument and Summary of Changes	Original Question	Change Proposed	Reason for Change Proposed
<p><b>Att 4a Eligibility Screener (English and Spanish)</b></p> <p>Participant instructions for completing registration were clarified.</p>	<p>(No question number, change applies to the participant instructions for completing registration at the end of the screener)</p> <p>Please click on the following link to complete the registration process [link to registration survey]. Thank you for your time.</p>	<p>Please click the “Next” button below to complete your registration.</p>	<p>Key stakeholder input, project goals.</p> <p>Participant instructions for completing registration were clarified for easier reading and better comprehension.</p>
<p><b>Att 4b Registration Contact Information Form (English and Spanish)</b></p> <p>A question was added to request participants’ preferred pronouns.</p>	<p>[New question]</p>	<p>8. What pronouns should we use for you?</p> <p>He/him/his</p> <p>She/her/hers</p> <p>They/them/theirs</p> <p>Ze/Zir/Zirs</p> <p>Xe/Xir/Xirs</p> <p>Something else: _____</p> <p>[PRONOUNS]</p>	<p>Key stakeholder input, project goals.</p> <p>Pronouns will be used by study staff to address participants by their preferred pronouns.</p>

Instrument and Summary of Changes	Original Question	Change Proposed	Reason for Change Proposed
<p><b>Att 5a_Consent to Participate (English and Spanish)</b></p> <p>Consent for future contact was revised to include all study sites. Consent to participate in the current and future studies were separated to make the participants' choices clear. Yes/No options were added to make the participants' options clear.</p>	<p>Consent and Authorization</p> <p>Consent for Contact for Optional Study/Studies:</p> <p>Please check the box below if you consent to be contacted for future studies conducted by Emory University. Only your contact information would be kept for this purpose. The data you provide today will not be used as a part of future Emory University studies for which you may be contacted.</p> <p><input type="checkbox"/> Checking this box indicates your consent to be contacted for participation in future Emory University studies.</p> <hr/> <p>TO BE FILLED OUT BY SUBJECT ONLY</p> <p>If you would like to enroll and participate in the MIC-DROP study, please proceed to the survey.</p>	<p>Consent for Future Contact for Optional Study/Studies:</p> <p>Please indicate below if you consent to be contacted for future studies conducted by Emory University, San Diego State University, and University of Chicago. Only your contact information would be kept for this purpose. The data you provide today will not be used as a part of future Emory University, San Diego State University, and University of Chicago studies for which you may be contacted.</p> <p>I would like my contact information stored for potential contact about participation in future Emory University, San Diego State University, and University of Chicago research studies.</p> <p>( ) YES ( ) NO</p> <p><i>Consent for MIC-DROP Study</i></p> <p>Being in this study is entirely your choice. You have the right to refuse to participate or to stop taking the baseline survey at any time.</p> <p>Please indicate if you agree to voluntarily participate in this study.</p> <p>( ) Yes, I agree to participate in this study ( ) No, I do not agree to participate in this study</p> <p><u>If Yes, send to landing page stating: STOP AND LET STAFF KNOW YOU CONSENTED</u> <u>If No, send to landing page stating: THANK YOU FOR YOUR TIME!</u></p>	<p>Key stakeholder input, project goals.</p> <p>These changes will simplify and clarify the consent process for participants and optimize consent tracking in the study.</p>

Instrument and Summary of Changes	Original Question	Change Proposed	Reason for Change Proposed
<p><b>Att 5b_Focus Group Consent (English and Spanish)</b></p> <p><b>Att 5c_In-Depth Interview Consent (English and Spanish)</b></p> <p>Language notifies participants at the San Diego and Chicago sites that tax information will be collected.</p>	[New section]	<p>You will be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.</p>	<p>Key stakeholder input, project goals.</p> <p>This is language is required by the lead study site, Emory University. The University is required by law to collect and report taxpayer information if participant incentives exceed a stipulated dollar amount. This section informs persons who are considering enrolling in the study of this requirement.</p>

**Attachments:**

- Att 4a\_Eligibility Screener English\_clean
- Att 4a\_Eligibility Screener English\_tracked
- Att 4a\_Eligibility Screener Spanish\_clean
- Att 4a\_Eligibility Screener Spanish\_tracked
- Att 4b\_Registration Contact Information Form English\_clean
- Att 4b\_Registration Contact Information Form English\_tracked
- Att 4b\_Registration Contact Information Form Spanish\_clean
- Att 4b\_Registration Contact Information Form Spanish\_tracked
- Att 5a\_Consent to Participate English\_clean
- Att 5a\_Consent to Participate English\_tracked
- Att 5a\_Consent to Participate Spanish\_clean
- Att 5a\_Consent to Participate Spanish\_tracked
- Att 5b\_Focus Group Consent English\_clean
- Att 5b\_Focus Group Consent English\_tracked

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- Att 5b\_Focus Group Consent Spanish\_clean
- Att 5b\_Focus Group Consent Spanish\_tracked
- Att 5c\_In-Depth Interview Consent English\_clean
- Att 5c\_In-Depth Interview Consent English\_tracked
- Att 5c\_In-Depth Interview Consent Spanish\_clean
- Att 5c\_In-Depth Interview Consent Spanish\_tracked
- IRB approval for change to the screener
- IRB approval for change to the contact information form
- IRB approval for change to the study consent form
- IRB approval for change to the focus group consent form
- IRB approval for change to the in-depth interview consent form
- MIC DROP burden table (no changes)

There are no changes to the SSA, SSB, or other attachments.