

**“Research and Evaluation Survey for the Public Education Campaign on Tobacco among LGBT Young Adults (RESPECT)”
(OMB Control Number 0910-0808)**

Change Request (83-C)

January 22, 2021

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to incorporate minor edits in the documents for the Research and Evaluation Survey for the Public Education Campaign on Tobacco among LGBT Young Adults (RESPECT).

The purpose of this change request is to make the following minor modifications to the study documents by:

- Making minor wording changes to the study documents for clarity
- Clarifying the incentive process and amount
- Updating the vendor information
- Updating the contact information for questions about the survey
- Updating the number of participants planned for the study noted in the public documents

Details of the changes are included in the table below, and in the two supporting documents.

In conversations with OMB in the past, we noted that we expected to have non-substantive changes to our instruments based on the development/changes to the campaign creative.

Contents of the Change Request Package for OMB No. 0910-0808
IC Documents

Att #	Document	IC Title	Edits
1	Baseline Web Survey  Attachment 1_BaselineWebSurvey	<ul style="list-style-type: none">• Outcome baseline via social media• Outcome baseline in person	<ul style="list-style-type: none">• Changed procedure for “Prefer Not to Answer” response option for questions; minor wording changes requested by FDA.• Updated electronic nicotine product definition to be more consistent with PATH.• Additional information in final thank you screens that was missing.
3	Screeners  Attachment3_Screener TC.docx	<ul style="list-style-type: none">• Pilot of in-person recruitment• Media tracking screener• Outcome screener via social media• Outcome screener in person	<ul style="list-style-type: none">• Intercept and social media screeners have been split into two questionnaires to ensure survey responses stored separately from contact information.• Minor wording adjustments.• Included screens that were missing prior to survey programming.
5	Screeners Informed Consent	<ul style="list-style-type: none">• Pilot of in-person recruitment• Media tracking screener• Outcome screener via social media	<ul style="list-style-type: none">• Changed estimated number of screener respondents to be total across social media and intercept recruiting.• Removed reference to \$5 early bird bonus for intercept respondent; information provided in web survey informed consent.

Att #	Document	IC Title	Edits
	 Attachment5_ScreenerInformedConsentT	<ul style="list-style-type: none"> • Outcome screener in person 	
6	 Attachment6_WebSurveyInformedConsent	<ul style="list-style-type: none"> • Outcome baseline via social media • Outcome baseline in person 	<ul style="list-style-type: none"> • Updated “Financial Considerations” with new incentive vendor information: incentives must be distributed via email and new vendor offers over 50 gift card options. • Removed language in “Future Contacts” referencing \$5 early bird bonus. Participants will be notified of bonus upon re-contact for follow-up.
8	 Attachment8_ScriptforRecruitingIntercept	<ul style="list-style-type: none"> • Pilot of in-person recruitment • Outcome screener in person 	<ul style="list-style-type: none"> • Removed reference to \$5 early bird bonus to reduce confusion. Details in web survey informed consent. • Replaced number of intercept participants to be screened with total number of participants to be screened • Added telephone number (if they choose) as identifying information to be requested in “What about Privacy?”
11	 Attachment11_EmailsandTextMessagesTo	Supplemental study document (no burden)	<ul style="list-style-type: none"> • Minor wording adjustments to more clearly describe how respondents will receive the incentive, and how they can opt out of future emails or text messages. • Updated language to clarify that participants will receive bonus incentive if complete survey within 48 hours of receiving initial email. • Removed references to unique access code for accessing baseline survey, unique links will be used instead. • Clarified that messages will come from RESPECT staff. • Changed vendor for incentives, additional/new information provided in incentive email pertaining to new vendor
	 Rationale for Item Changes to the RESP	Supporting document for change request	Rationale for item changes to the RESPECT baseline instrument
	 Rationale for Item Changes to the RESP	Supporting document for change request	Rationale for item changes to the RESPECT screener instrument