

To: Quinn Hirsch
Office of Information and Regulatory Affairs (OIRA)
Office of Management and Budget (OMB)

From: Tara Rice
Office of Population Affairs (OPA)
Office of the Assistant Secretary for Health

Date: January 5, 2022

Subject: NonSubstantive Change Request – Components Study of REAL Essentials (REA)
(OMB #0990-0480)

This memo requests approval of nonsubstantive changes to the approved information collection, Components Study of REAL Essentials (REA) (OMB #0990-0480).

Background

OMB approved the Components Study of REAL Essentials (REA) on October 18, 2021. The information collection included the following data collection activities: administering a youth outcome survey, holding focus groups with youth, administering youth engagement exit ticket surveys after each class session, collecting fidelity logs from and interviewing REA program facilitators; and interviewing leaders at the district, community organization, or school level. To date, no sample has been enrolled and no data have been collected.

Overview of Requested Changes

We are requesting approval for a modification to an existing item (H16d) in the youth survey (Instrument 1). We propose changing the wording of h16 on the survey instrument from “I felt respected by the facilitator” to “The REA facilitator responded to questions without judgement.” The proposed change is being made to better align with feedback we received when observing the REA facilitator training around the importance of respecting students by responding to questions without judgement.

We do not expect the proposed changes to affect the approved burden.

We are also proposing the following revisions to the parental consent, and youth survey and focus group assent forms (Attachments C, D, and E in the initial submission):

- Adding language around the risks and benefits of participating in the study (Attachments C, D, and E)
- Adding language that participation is voluntary (Attachment E)
- Adding identity and contact information for investigators (Attachment E)
- Adding text to clarify the study activities (Attachment C)
- Adding language to the parent consent form (Attachment C) on how to complete the form

electronically and including an option for parents to opt out of the recording if their child's site is participating in the youth engagement study, and where youth will be placed in the classroom if they opt out of the recording.

The requested changes to consent forms come at the request of our Institutional Review Board (IRB), Health Media Lab, and the continued impact of the pandemic on in-person schooling.

We have also created two versions of the parent consent form: one for sites participating in the youth engagement study (C2) and one for the other sites (C1). The content of the form(s) has not changed from the approved version other than what is indicated above; we have adjusted formatting and split them into two separate versions to accommodate the different sites.

Time Sensitivities

OPA requests approval as soon as possible since sample enrollment is estimated to begin January 24th, 2022.