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Office of Management and Budget (OMB)

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**Date:** August 13, 2020

**Subject:** Non-Substantive Change Request – Multi-Site Implementation Evaluation of Tribal Home Visiting (MUSE) (OMB #0970-0521)

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This memo requests approval of non-substantive changes to materials for the Multi-Site Implementation Evaluation of Tribal Home Visiting (MUSE) (OMB #0970-0521) that will allow us to proceed safely with data collection during the COVID-19 pandemic.

### ***Background***

The MUSE study received OMB approval in December of 2018 and is approved through December 31, 2021. A non-substantive change request was previously approved in March of 2019. The information collection is currently underway; however, data collection was put on hold for 4 months due to COVID-19. In response to the pandemic, Tribal Home Visiting programs have modified their service delivery strategy from in-person home visits to home visits made virtually using telephone or videoconference. The change in service delivery mechanism necessitates changes to MUSE data collection procedures; we are proposing updates to shift data collection from an in-person to a virtual format. We are also proposing to collect a limited amount of additional information that describes how home visiting services are being provided virtually during the pandemic.

### ***Overview of Requested Changes***

For details on the changes to data collection protocols, instruments and attachments, please see Table 1.

Updates to allow virtual data collection:

- 1) Adding the option for home visitors to consent caregivers into the study over the phone or via videoconference
- 2) Adding options for study participants to complete the Caregiver Survey electronically or over the phone
- 3) Adding procedures for conducting qualitative interviews virtually

Updates to gather information about virtual home visiting services:

- 4) Adding questions to qualitative interview protocols about the impact of COVID-19 on home visiting services and parenting (Instruments 11, 12, 13 and 14)
- 5) Adding a data element to Instrument 16 Administrative Data Elements to capture visit mode

### ***Time Sensitivities***

The requested updates to our data collection procedures, instruments and other study materials are needed before the MUSE Team and our local study partners can resume consenting and enrolling participants into the study, administering surveys to caregivers, and conducting qualitative interviews. These study activities have been on hold for several months while our study partners adjusted to providing virtual

home visits and the MUSE Team identified feasible options for continuing data collection in a virtual home visiting environment. We plan to restart these activities in September of 2020 or whenever we have obtained all of the necessary approvals.

### ***Updated Materials***

The following revised materials are included with this submission:

- Updated Supporting Statement A
- Updated Supporting Statement B
- Updated Instrument 11 Home Visitor Interview Questions
- Updated Instrument 12 Program Coordinator-Manager or Program Director Interview Questions
- Updated Instrument 13 Program Evaluator Interview Questions
- Updated Instrument 14 Caregiver Interview Questions
- Updated Instrument 16 MUSE Administrative Data Elements
- Updated Attachment A Informed Consent Documents
- Updated Attachment E Caregiver Interviewee Selection Guide
- Updated Attachment I Caregiver Interview Invitation Phone Script

**Table 1. Proposed Changes to Data Collection Procedures, Instruments, and Attachments**

#### **Changes to Data Collection Procedures to Accommodate Virtual Data Collection**

The previously approved MUSE data collection procedures rely on home visitors to conduct informed consent and surveys with caregivers in person during home visits. In response to COVID-19, Tribal Home Visiting grantees have discontinued in-person home visits and are now providing home visits over the telephone or video conference. MUSE has made modifications to our data collection procedures to allow us to continue collecting data from caregivers while services are provided virtually. Additionally, we will no longer conduct site visits to collect qualitative data in order to protect the communities and the MUSE study staff. We have updated our qualitative interviewing procedures to allow for interviews with caregivers and staff to be conducted virtually.

#### Informed Consent

We have updated our data collection procedures to allow home visitors to obtain informed consent for study participation over the phone or videoconference. Program staff will provide a copy of the consent form to the caregiver prior to administering consent via email, no-contact drop-off, or mail. During a virtual home visit, the home visitor will read the consent form to the caregiver, document the caregiver's response on the electronic consent form using the MUSE iPad, and enter their initials into the form to indicate that verbal consent was administered. We expect to receive a waiver of written consent for study participation from our IRB of record as well as local research review entities.

#### Caregiver Surveys

We have created an electronic version of the Caregiver Survey that can be sent via email or text in lieu of being completed during an in-person home visit on a MUSE iPad. Home visitors will email or text the link to caregivers at the opening of the data collection window for the baseline, 6-month and 12-month surveys. Caregivers can opt to take the survey by phone instead of on a personal electronic device. Program staff will be able to provide gift cards upon completion of the survey via email, no-contact drop-off, or mail in lieu of handing caregivers gift cards during in-person home visits. In addition to previously approved incentives, we will also be offering a \$5 gift card to caregiver respondents who access the survey via text or email to reimburse them for any costs incurred for the use of cellphone data. Caregivers receiving Tribal Home Visiting services typically rely on cellphone data plans to access the internet, and

not offering reimbursement for these costs could prove detrimental to survey response rates and attitudes towards the study amongst our program partners more generally.

#### Qualitative Interviews

We have updated our qualitative interviewing procedures to describe how qualitative interviews will occur over the phone or videoconference. No changes are needed to interviewee recruitment procedures. Our informed consent procedures have been updated to include obtaining verbal consent at the beginning of the interview. The interviewer will read the consent form to the participant, document the response on the paper consent form, and sign the form to indicate that verbal consent was administered. We expect to receive a waiver of written consent for qualitative interviews from our IRB of record as well as local research review entities. Interviews will be conducted and recorded using secure technology. Incentives will be provided to caregiver interview participants via email, no-contact drop-off, or mail.

#### **Revisions to Instruments 11, 12, 13, 14**

We updated the qualitative interviewing instruments (Instruments 11, 12, 13, 14) to contain a limited number of questions about the impact of COVID 19 on home visiting services and parenting. Burden is not affected because the interviewer will keep the interview to the allotted time.

#### **Revisions to Instrument 16**

We made one minor refinement to the planned administrative data collection elements (Instrument 16). We added the data element “Visit type” which will provide information on whether the home visit occurred in-person or virtually. While this update adds a data element, the burden estimate remains the same as our previously approved estimate of 24 hours. In our previous non-substantive change request, we reduced the total number of administrative data elements by 1, so the updated instrument still contains the original number of data elements used to calculate our approved burden estimate (43 data elements).

#### **Revisions to Attachment A**

We have updated the Caregiver Qualitative Consent Form and the Professional Qualitative Consent Form to state that interviews will be conducted in-person in a private office or virtually over a private telephone or videoconference call.

#### **Revisions to Attachment E**

We have updated the caregiver interview invitation phone script to include a script for inviting caregivers to participate in virtual interviews.

#### **Revisions to Attachment I**

We have updated the caregiver interviewee selection guide to reference in-person or virtual interviews.