

**Date** February 27, 2019

**To** Josh Brammer  
Office of Information and Regulatory Affairs (OIRA)  
Office of Management and Budget (OMB)

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Office of Information and Regulatory Affairs (OIRA)  
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**From** Aleta Meyer and Tia Brown  
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**Subject** Non-Substantive Change Request: Multi-Site Implementation Evaluation of Tribal Home Visiting (MUSE) (OMB #0970-0521)

This non-substantive change request includes updates to materials for the Multi-Site Implementation Study of Tribal Home Visiting (MUSE). Changes include submission of updated instruments as agreed upon during passback; updates to attachments to reflect minor procedural changes; and revisions to the supporting statements to incorporate changes related to instruments, minor procedural changes, and very minor edits.

This memo describes the changes to materials, including the location of related changes. The following revised materials are included with this submission:

- Updated Instruments 1-10, 15, and 16
- Attachment A: Informed Consents Document Attachment D: Documentation of Initial IRB Approval and Amendment Approval for Waiver of Parental Consent for Minor Caregivers (Ages 14-17) –
- Attachment F Caregiver Flyer
- Attachment G Staff Survey Invitation Email
- Attachment J Program Data Collection Reminders Emails
- Attachment L – Intro to MUSE Video Script (NEW Attachment)
- Supporting Statement A
- Supporting Statement B

### **Updated Instruments**

Between the initial submission and review by OMB, the MUSE study team systematically reviewed all study instruments to identify opportunities to reduce respondent burden and improve clarity of items or instructions. In addition, the adoption of a more secure data collection software and refined data collection procedures required updates to quantitative instruments. The edits made as a result of these processes did not increase burden estimates nor did they change the nature of data being collected. Instruments 1-10, 15, and 16 were updated, as summarized here:

- Data entry fields were added to the beginning of most quantitative instruments in order to track data collection and link data for individuals across data sources (e.g., Caregiver Program ID, Staff Member Name or ID). These fields were not included on instruments previously submitted because the data collection software determines the fields, and the software had not been selected by the time of initial submission. This change does not affect the original burden estimates because those estimates included time for logging in to data collection software and entering identification data entry fields in the initial estimate.
- Question wording and response options were standardized across questions and instruments where possible. Questions and response options were aligned to increase efficiency and effectiveness of data analyses. This standardization ensures respondent burden is minimized and within the current estimated time per response.
- Response options were refined to be mutually exclusive and exhaustive.
- Home visiting content categories across instruments were refined in response to stakeholder feedback. Examples were added to facilitate consistent respondent interpretation of the categories.
- Introductory text, question wording and response options were revised for clarity.
- Survey skip patterns were simplified to reduce the number of questions asked.
- Instructional text was revised to reflect changes to data collection technology.
- For some instruments, questions were added after realizing that we had omitted an important variable. For other instruments, questions were deleted after realizing the question was not necessary or after receiving stakeholder feedback on the appropriateness of the question. More questions were deleted than added through this process; thus, these changes do not increase burden.
- Additional revisions to Instruments 2 and 3 are detailed in a following section.

## Updated Attachments

- **Attachment A. Informed Consents:** Parental consent/assent forms were removed because the Colorado Multiple Institution Review Board (COMIRB) no longer requires consent from the parents of minor caregivers participating in Tribal MIECHV programs (as described in Non-Substantive Change SSA p. 16-17 – Changes to Consent), language was added to reflect that the study team has applied for a certificate of confidentiality, estimated number of study participants was updated, fills for specific program names were deleted, the PI's email address was added, the description of topics covered in surveys was expanded, and the text was edited for clarity.
- **Attachment D. Documentation of Initial IRB Approval and Documentation of Amendment Approval for Waiver of Parental Consent for Minor Caregivers (14-17):** The amendment was added to document approved changes to consent procedures
- **Attachment F. Caregiver Flyer:** The names and contact info for study personnel were edited and a link to the Introduction to MUSE Video was added
- **Attachment G. Staff Survey Invitation Emails:** the reminder email template was deleted because we will use the same email for the initial invitation and subsequent reminders, text was added indicating that grantees may use staff IDs instead of names, the Administration for Children and Families was named more specifically as the study sponsor, and the text was edited for clarity
- **Attachment J. Program Data Collection Reminder Emails:** text was added indicating that grantees may use staff IDs instead of names, the name of one of the implementation logs was updated, text was updated to reflect further developed study procedures, and the text was edited for clarity

## **New Attachment**

**Attachment L. Intro to MUSE Video Script:** The MUSE Study Team developed an Introduction to MUSE Video that program staff can share with caregivers when introducing the MUSE study. The video was developed based on the content in the caregiver flyer and is intended to support a broader introductory conversation between home visiting program staff and caregivers about the study.

## **Revisions to Instruments 2 & 3**

### **Revision to reflect reduction in number of items from Social Provisions Scale**

The number of items used to measure social support was reduced from 24 to 12 items by using an abbreviated version of the Social Provisions Scale. The number of items added by MUSE to measure specific support around parenting was reduced from 5 to 2. Members of the Technical Work Group provided feedback on this scale, expressing concern about the negative frame of some of the items. There were concerns about how Caregivers would respond to negative items and whether they were necessary to measure social support. In response to these concerns, the MUSE Team reviewed recent literature on the Social Provisions Scale and consulted with colleagues with experience measuring similar constructs with AIAN populations. Evidence suggested that 12 negative-coded items could be omitted without likely compromising the reliability and validity of this measure. Thus, the decision was made to include only the 12 positive-coded items on the Social Provisions Scale. The decision was also made to frame the parenting support items added by MUSE positively; 2 of the 5 items were retained, with one revised to a positive frame. Revisions were made within SSA (pp. 6-7) and Instruments 2 & 3. These changes ensure respondent time is within the current burden estimates.

## **Minor edits to Supporting Statement A (SSA)**

### **Cover page, Date**

Additional dates were added to reflect the initial request for approval and this non-substantive change request.

### **Changes to Table of Contents (p. i-ii)**

The Table of Contents was updated to reflect the page numbers for the content.

### **Changes to List of Exhibits (p.iii)**

The List of Exhibits was updated to reflect the page numbers for the content.

### **Updated Attachment Letter (p. 2)**

The Attachment label was updated to reflect the change in lettering with the new Attachment L.

### **Acronym written out (p.2)**

The acronym for American Indian / Alaska Native (AI/AN) was written out, given it was the first time used in the document.

### **Dates for Tribal MIECHV Renewal Packages Updated (p. 11 & 17)**

The dates for Tribal MIECHV Renewal Packages were updated in the footnotes.

### **Changes to Language for Incentives for Respondents (p. 13)**

The language describing incentives was revised to indicate present tense.

## **Non-substantive Changes to Supporting Statement A – p. 10-11, Additional Improvement of Technology to Reduce Burden**

### **Non-Substantive Change**

The description of the approach for obtaining data was revised to accurately represent current procedures. The scanning and uploading of files for some assessments will no longer be necessary. This change to procedure did not change attachments or instruments.

## **Non-substantive Changes to Supporting Statement A – p. 16-17, Changes to Consent**

### **Non-Substantive Change**

The language regarding consent was changed to omit the phrase ‘or assent’ given changes to the review by the Colorado Multiple Institution Review Board (COMIRB). As reflected in Attachment D, COMIRB no longer requires consent from the parents of minor caregivers participating in Tribal MIECHV programs. Instead, minor caregivers will provide their consent to participation, rather than the combined parental consent and minor caregiver assent.

## **Non-substantive Changes to Supporting Statement A – p. 17, Changes to Collection of Direct Identifiers**

### **Non-Substantive Change**

Changes have been made to the collection of direct identifiers to address concerns regarding the release of names of participants to the MUSE team. All caregiver data will be submitted with a program ID instead of caregiver names. Grantees will also have the option of submitting staff data with an ID instead of staff name. This change in procedure does not change attachments or instruments.

## **Non-substantive Changes to Supporting Statement A – p. 21, Changes to Estimated Range for Honoria**

### **Non-Substantive Change**

The language describing honorarium was revised to present tense and the estimated range for Honoria amount updated. The initial range for honorarium was based on the size of the grantee team and did not

reflect the number of caregivers enrolled in home visiting that were served by the grantee, a number which varies substantially from grant to grant. To more closely parallel the size of each grant site, the range for the honoraria was revised from \$1,200-1,600 to \$1,560-3,110 per site. This change reflects the size of the grantee staff team and number of caregivers enrolled in home visiting. The honoraria is less than the anticipated cost of the staff time needed to facilitate MUSE data collection with caregivers.

### **Minor edits to Supporting Statement B (SSB)**

#### **Cover page, Date**

Additional dates were added to reflect the initial request for approval and this non-substantive change request.

#### **Changes to Table of Contents (p. i-ii)**

The Table of Contents was updated to reflect the page numbers for the content.

#### **Changes to List of Exhibits (p.iii)**

The List of Exhibits was updated to reflect the page numbers for the content.

#### **Clarification of Goals of Strategies to Mitigate Non-response Bias (p. 10)**

In the previous revision to Supporting Statement B, the phrase ‘obtaining a representative sample of caregivers and’ should have been omitted to reflect the purpose of the incentives, which is to mitigate nonresponse bias. It is now omitted.

### **Non-substantive Change to Supporting Statement B – p. 6, Reference to Video aid added (Attachment L)**

#### **Non-substantive Change**

Reference to a video that has been developed to introduce the MUSE study to caregivers was added (new Attachment L described above). This video will be used along with the informational flyer (Attachment F). The script for the introduction video is provided in new Appendix L. This script is based on the content of the informational flyer, which has been approved.

### **Non-substantive Changes to Supporting Statement B – p. 7, IRB-approved Waiver of Consent for Minor Caregivers.**

#### **Non-Substantive Change**

The MUSE study obtained an IRB-approved waiver of parental consent for minor caregivers (as described above as non-substantive changes to SSA – p. 16-17). Reference to this approval was added.

### **Non-substantive Changes to Supporting Statement B – p. 7, Change to Approach for Caregivers with Limited Literacy or Visual Impairment**

#### **Non-Substantive Change**

A phone survey option has been developed for Caregivers with limited literacy or visual impairment. A member of the MUSE Study Team will conduct phone surveys with these participants. Text was edited to reflect this update.

### **Non-substantive Changes to Supporting Statement B – p. 8, Change to Number of Email Reminders**

#### **Non-Substantive Change**

The text was updated to reflect that MUSE Team will send four email reminders (instead of three, as previously proposed) to encourage participation. This change in procedure does not change attachments or instruments.

### **Non-substantive Changes to Supporting Statement B – p. 9, Change to Web-based Data System for Implementation Logs**

#### **Non-Substantive Change**

The text was updated to reflect that web-based data system will allow grantees to access data entry for each component of the Implementation Logs. This change in procedure does not change attachments or instruments.

### **Non-substantive Changes to Supporting Statement B – p. 10, Change to Staff Who Will Recruit Caregivers**

#### **Non-Substantive Change**

The text was updated to reflect that caregivers will be recruited to participate in MUSE by other program staff in addition to home visitors (as previously described). This change in procedure does not change attachments or instruments.

### **Non-substantive Changes to Supporting Statement B – p. 11, Changes to Maximizing Response Rates**

#### **Non-Substantive Change**

The range for the honoraria was revised to \$1560-3,110 per site to reflect the size of the grantee staff team and number of caregivers enrolled in home visiting (as described above as changes to estimated range for honoraria – p. 21). The text was updated to reflect this revision.

### **Non-substantive Changes to Supporting Statement B – p. 12, Changes to Data Entry for Rapid Reflect Self-Completed Home Visit Questionnaires**

#### **Non-Substantive Change**

Data entry will occur on the tablet. There will not be a paper backup option. Should there be any challenges with the tablet on a particular home visit, no Rapid Reflects will be collected. This change in procedure is updated in the text and does not change attachments or instruments.