

To: Brenda Aguilar, Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB)

From: Office of Planning, Research and Evaluation (OPRE); Administration for Children and Families (ACF)

Date: July 25, 2013

RE: NonSubstantive changes to Maternal and Infant Home Visiting Program Evaluation (MIHOPE) study materials (OMB #0970-0402)

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At the request of state and local institutional review boards, the MIHOPE team has revised the consent forms previously approved by OMB. Below we outline these state- and site-specific changes. All revised materials are included in this nonsubstantive change request.

In addition, we realized that, in order for us to randomly choose a focal child for the study, we need to ask mothers if they have twins or other sets of multiples. This would entail a change to the baseline survey, which is described below.

### **State-specific changes**

- Georgia: The state IRB's contact information has been added to the consent forms. In addition, the IRB requires that participants in Georgia be provided with a debriefing form following completion of study activities. According to the IRB application, "It is the policy of the DPH IRB to require that all research involving human subjects include a debriefing process after participants complete the study." We have proposed to the IRB that MIHOPE provide a debriefing form to study participants when field staff are in the home to collect follow-up data at 15 months. This form has been adapted from the previously approved MIHOPE brochure and consent forms, with changes only being made to the tense of the verbs used (changed from future/present to past tense), since the debriefing form describes data collection activities that happened in the past whereas the consent form and brochure describe what we will be asking participants to do if they agree to be in the study.

### **Site-specific changes**

- Los Angeles County: Los Angeles County IRB has requested that consent forms to be used in Los Angeles County add the statement: "The information we collect from you and your child will include some standardized tests. These include areas such as your child's language skills and your intelligence. These are being collected only for research purposes. We will not be sharing the results of these tests with you." In addition, the FAQs to be used in LA County have been revised to include contact information for the county IRB and to specify that video-recordings will be destroyed in 2032. The LA County IRB has not yet approved these revisions.

### **Nonsubstantive change to baseline survey**

The OMB-approved version of the survey was written as if each mother enrolled in the study postnatally had a single birth or one child at that time. We would like to add a question to determine if the mother had twins or other multiple births at time of enrollment in order to allow us to randomly choose a focal child for the study. Specifically, we're proposing to add: "Did you have a single or multiple birth?" after asking them when their due date is and then "How many babies did you give birth to?" (see SC10a. & SC10b. in attached baseline survey).

This additional question will not change the average time to complete the survey.