



DATE: January 4, 2018

TO: Steph Tatham, Desk Officer, Office of Management and Budget, Office of Information and Regulatory Affairs

FROM: Amy Madigan, Program Officer, Administration for Children and Families, Office of Planning, Research, and Evaluation

SUBJECT: Non-substantive change for the Early Head Start Family and Child Experiences Survey (Baby FACES 2018) OMB control number 0970-0354

The Baby FACES institutional review board (Health Media Lab IRB) required changes to several documents as a condition of approval. HML IRB is authorized by the U.S. Department of Health and Human Services, Office of Human Research Protections (IRB #00001211, IORG #0000850), and has DHHS Federal-Wide Assurance approval (FWA #00001102). We believe that these changes are minor and non-substantive. Specifically, HML IRB asked that all consent forms and information letters/emails use consistent phrasing to address the following five elements:

- 1) A clear statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- 2) A description of any risks or benefits to the subject or to others which may reasonably be expected from the research;
- 3) A statement that participation is voluntary and negotiable, refusal to participate or to not respond to any question will involve no penalty or loss of benefits, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
- 4) A statement describing the extent to which privacy and confidentiality of records identifying the subject will be maintained, and any limitations to confidentiality (e.g., mandatory reporting of abuse, etc.);
- 5) An explanation of who to contact for answers to questions about the research and research subjects' rights, and who to contact in the event of a research-related injury to the subject.

We made adjustments to the letter and consent form that will go to parents as well as the introductory materials that explain the study to staff, program directors, and center directors. All documents now describe all five elements using consistent wording.

We also made a slight change to the forms we use for sampling classrooms and home visitors (Classroom/Home Visitor Sampling Form), as well as children (Child Roster Form). The instructions for completing the forms are revised to clarify that we are requesting information about children funded by Early Head Start and the staff serving them.

Updated materials with this nonsubstantive change request include: Attachments 1-3 and Appendix E.