

Note to File - 18 Month - Administration of Ages and Stages 3 Questionnaire (ASQ-3)

At present, the NCS is approved to administer the ASQ-3 at 18 months. In practice, if the 18-Month Interview is scheduled outside of the 18-Month ASQ-3's window of administration, then the ASQ-3 would not be administered during the visit. Therefore, we also request approval for use of the 14-, 16-, 20-, and 22-Month Ages and Stages Questionnaires (ASQ) Self-Administered Questionnaire in addition to the currently approved 18-Month ASQ in order to broaden the window of administration for the 18-Month Interview. As a point of information, the ASQ-3 may only be administered once for a given visit. For example, if the ASQ-3 was administered at 14 months, it would not be administered again.

For more details, please see Supporting Statement B.2.