

ICR Non-Substantive CHANGE REQUEST MEMO

Study to Explore Early Development Phase 3 (SEED3)

OMB NO. 0920-1171

Expiration Date 12/31/2021

Remote Developmental Assessment During COVID-19 Pandemic

Summary:

As outlined in **Section E** and **Section H.6.** of the SEED3 protocol (Att 1), all children in the population control (POP) and potential autism spectrum disorder (ASD) workflows are scheduled for an in-person assessment during which a clinician obtains written informed consent, collects saliva samples, obtains information via a questionnaire on birth defects and genetic syndromes, and completes a standardized cognitive evaluation of the child (Mullen Scales of Early Learning, MSEL). Potential autism spectrum disorder (ASD) cases are additionally given a standardized ASD diagnostic observation (ADOS); their parent(s) complete a questionnaire on child services and treatments along with two standardized interviews (Autism Diagnostic Interview-Revised, ADI-R; and Vineland Adaptive Behavior Scales, VABS-2).

In-person clinic visits for the Study to Explore Early Development Phase 3 (SEED3) were suspended in March 2020 due to the inability to maintain safety and infection control measures necessary during the COVID-19 pandemic. Given our obligation to provide participants with as much feedback on their child as possible, remote administration and feedback would be appropriate during COVID-19.

Attachments:

Att 1 SEED 3 PROTOCOL_ amendment #6_7-21-20

Background & Justification:

Because the full developmental assessment cannot be conducted adhering to strict safety standards for COVID-19 (e.g., child assessments cannot be completed with face coverings since they assess the ability to interpret subtle facial cues), all in-person assessments have been suspended, and further enrollments will only resume at a given study site if local conditions permit implementation of the full SEED 3 protocol. For participants who have already been enrolled but have not yet completed the in-person assessment, approval is requested for remote administration of components that are feasible. Accordingly, the following procedures will be followed:

- Those who have enrolled will be informed of the potential to participate in an abbreviated remote assessment, those who do not wish to move forward with the remote assessment will be informed that they will be re-contacted if local conditions permit the in-person assessment to be completed by January 2021.

One benefit of providing feedback is to give families information on everyday skills demonstrated by their child compared to others his or her age; one potential risk is referring families for additional evaluation and treatment that may be difficult to obtain during the COVID-19 pandemic.

Effect of Proposed Changes on Current Approved Instruments:

This request only adds the ability to provide remote assessments (when possible) while in-person assessments are not an option due to the COVID-19 pandemic.

Effect on Burden Estimate:

There will be no burden change.