

ICR Non-Substantive CHANGE REQUEST MEMO

Study to Explore Early Development Phase 3 (SEED3)

OMB NO. 0920-1171

Expiration Date 12/31/2021

Supplemental COVID-19 Impact Assessment

Summary:

Change #1: Cover sheet for COVID-19 Impact Survey

- The cover sheet contains 4 questions to confirm eligibility and interest in participation.
- This ICR includes a 10 minute burden for reviewing materials over the phone. However, it is anticipated that some participants will choose to complete the survey independently without the need for guidance to complete the survey, in which case responses to these questions will be needed.

Change #2: COVID-19 Impact Survey

- Minor wording changes to questions #2, 6, 8, 11, 16, 18, 19, 20, 22, 33
- These changes are to improve clarity of the questions.

Attachments:

List them with their corresponding numbers

- ITEM #6 Appendix C.3_COV-IMP Survey (clean and track changes versions)
- ITEM #6.5 Appendix C.3_COV-IMP COVER sheet for Survey

Background & Justification:

The Study to Explore Early Development (SEED) is a collaborative multi-phase, multi-site case-control study of children with ASD as compared to children with other DDs and from the general population (POP). Currently in the third phase of data collection, the objectives of SEED since initiation in 2006 have been to assess the etiologic risk factors for ASD, and to describe the phenotypic variability and health and service needs of children with ASD and other DDs. To meet these objectives, SEED has collected detailed data on the development and functioning of children using a number of standardized assessments (Child Behavior Checklist [CBCL], Social Responsiveness Scale [SRS], Vineland Adaptive Behavior Scales [VABS], Autism Diagnostic Interview-Revised [ADI-R], Mullen Scales of Early Learning [MSEL], Autism Diagnostic Observation Schedule [ADOS]). Some of these assessments must be administered during an in-person visit (e.g., the ADOS relies on fluid face-to-face interactions). Others can be readily administered through mail or phone surveys. Thus, while it is not currently possible to administer assessments that must be completed in person for new participants, for children who have data prior to the end of March 2020, re-administration of some of these assessments provides a unique opportunity to assess changes from before to after implementation of COVID-19 mitigation efforts. Additionally, because SEED 3 has a case (ASD) and two control arms (children with other developmental disabilities [DDs] and children from the general population [POP]), surveying the children in SEED 3 about their experiences related to COVID-19 and mitigation efforts provides a unique opportunity to inform preparedness guidance and reveal effective coping strategies now and in future public health emergencies.

Key Outcomes

- Comparison of COVID-19 impacts among children classified as ASD, DD, and POP in SEED 3, including: impacts on education and use of remote learning; changes in use of services and telemedicine; experiences with testing and mitigations strategies; and changes in routines and well-being.

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- Comparison of COVID-19 impacts on mothers of children classified as ASD, DD, and POP in SEED 3, including: changes in household structure, finances, employment and health insurance; changes in routines and support; and experiences with COVID-19 infection.
- Pre-COVID-19 and post-COVID-19 assessment of behavior problems (for ASD, DD, and POP), and everyday living skills (post-COVID-19 for ASD, DD and POP, including; pre-post assessment for ASD and for DD and POP as data are available).

Effect of Proposed Changes on Current Approved Instruments:

Form	Current/Question Item	Requested Change
ITEM #6.5 Appendix C.3_COV-IMP COVER sheet for Survey	#1-4	Questions added to replace phone script for participants who return survey by mail with no assistance over the phone
ITEM #6 Appendix C.3_COV-IMP Survey	#2, 6, 8, 11, 16, 18, 19, 20, 22, 33	Small wording changes to improve clarity

Effect on Burden Estimate:

Form	Approved Burden	Requested Burden
ITEM #6.5 Appendix C.3_COV-IMP COVER sheet for Survey	10 minutes	No change
ITEM #6 Appendix C.3_COV-IMP Survey	25 minutes	No change
Total		
		No change