

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:

The project is associated with the COVID-19 response given that the results of the study may inform preparedness guidance and coping strategies related to COVID-19 and associated mitigation efforts. During the recent COVID-19 pandemic, a focus on infection containment may have unintended influences on children with developmental disabilities (DDs) due to stay-at-home orders, social distancing, and other mitigation efforts. Additionally, therapeutic, supportive, and mental health challenges faced by individuals with DDs and their caretakers may have worsened during the COVID-19 response. Families of young children with autism spectrum disorder (ASD) may be particularly vulnerable to pandemic response efforts due to traits specific to ASD, including insistence on sameness and adherence to routines and rituals. Characterizing the associations of COVID-19 mitigation efforts on children with ASD and other DDs and their families may inform preparedness guidance and reveal effective coping strategies now and in future public health emergencies.

Attachments:

1. ITEM #1 Appendix A_COV-IMP_Surveys with prior COVID content
2. ITEM #2 Appendix B_COV-IMP_Power Calculations
3. ITEM #3 Appendix C.1_COV-IMP_CBCL_1-5yrs
4. ITEM #4 Appendix C.2_COV-IMP_CBCL_school age
5. ITEM #5 Appendix C.3_COV-IMP Survey_FINAL
6. ITEM #6 Appendix C.4_COV-IMP_Vineland Scoresheet
7. ITEM #7 Appendix A.1_COV-IMP_Invitation letter

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.

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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.
- 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:

For the SEED 3 Supplemental COVID-19 Impact Assessment, we are intentionally collecting data on outcomes that have been collected in other studies (See **Appendix A_COV-IMP**). This will allow us to compare our results from a special population (children with ASD and other developmental disabilities) with the results from other studies. The unique features of our proposed data collection were confirmed through an environmental scan of existing related studies (**Appendix A_COV-IMP**), and through the extensive networks and ongoing knowledge of autism research among the collaborating institutions participating in SEED 3 data collection (John Hopkins University; University of Colorado, Denver; University of North Carolina at Chapel Hill; University of Wisconsin, Madison; Washington University at Saint Louis). These unique features include:

1. The ability to compare the impact of COVID-19 and mitigation efforts on children with ASD to children carefully matched from an existing case-control study who have other developmental disabilities (DDs), or are from the general population (POP).
2. The ability to re-administer standardized assessments that measure behavior problems related to internalizing and externalizing behaviors (anxiety and aggression, and every-day living skills) to assess changes related to COVID-19 and mitigation efforts, among children with ASD and in comparison to children with other DDs and from the general population.

Estimated Burden hours:

The following Information Collection Instruments will be implemented for the SEED3 Supplemental COVID-19 Impact Assessments

Although power calculations were conducted anticipating a 60% response rate to ensure a sufficient sample size, burden hours and cost are calculated based on a 70% response rate to ensure adequate accounting for time and burden. Estimates are thus based on the calculation that of the approximately 1,900 participants who completed SEED 3 prior to the end of March 2020 and received a final class of ASD, DD or POP, 1,330 participants will be successfully reach and will agree to participate in the survey.

The total burden is estimated at **1552** hours.

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Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hrs.)	Total Burden Hours
Caregivers of children who completed the SEED 3 protocol prior to the end of March 2020	Child Behavior Checklist (Appendix C.1_COV-IMP ; or C.2_COV-IMP , depending on age of child)	1,330	1	20/60	443
Caregivers of children who completed the SEED 3 protocol prior to the end of March 2020	COVID-19 survey (Appendix C.3_COV-IMP)	1,330	1	25/60	554
Caregivers of children who completed the SEED 3 protocol prior to the end of March 2020	Vineland Adaptive Behavior Scales (Appendix C.4_COV-IMP)	1,330	1	15/60	333
Caregivers of children who completed the SEED 3 protocol prior to the end of March 2020	Review of invitation letter and call script	1,330	1	10/60	222
Total					1552

Estimated Costs to Participants

There will be no anticipated costs to respondents other than time.

Annualized burden costs are summarized in the table below. The hourly wage estimates are based on the Bureau of Labor Statistics National Occupational Employment and Wage Estimates (available at http://www.bls.gov/oes/current/oes_nat.htm). The mean hourly wage rate for all occupations (\$25.72) was used.

Given that each individual participant is anticipated to take 70 minutes to review and complete all study materials, \$30 will be provided as a token of appreciation for their time.

Type of Information Collection	Form Name	Number of Respondents	Total Burden Hours	Average Hourly Wage Rate	Total Respondent Costs
Caregivers of children who completed the SEED 3 protocol prior to the end of March 2020	Child Behavior Checklist (Appendix C.1_COV-IMP ; or C.2_COV-IMP , depending on age of child)	1,330	443	\$25.72	\$ 11,394
Caregivers of children who completed the SEED	COVID-19 survey (Appendix C.3_COV-	1,330	554	\$25.72	\$14,253

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3 protocol prior to the end of March 2020	IMP)				
Caregivers of children who completed the SEED 3 protocol prior to the end of March 2020	Vineland Adaptive Behavior Scales (Appendix C.4_COV-IMP)	1,330	333	\$25.72	\$8,552
Caregivers of children who completed the SEED 3 protocol prior to the end of March 2020	Review of invitation letter and call script	1,330	222	\$25.72	\$5,701
Total					\$ 39,900