

ICR Non-Substantive CHANGE REQUEST MEMO

Study to Explore Early Development Phase 3 (SEED3)

OMB NO. 0920-1171

Expiration Date 12/31/2021

Spanish Translation of the SEED COVID-19 Impact Study Instruments

Summary:

For this change request, we are seeking approval of the Spanish translation of the instruments for the COVID-19 Impact Study that was developed for the Study to Explore Early Development (SEED). This project was previously approved by OMB on 12/10/2020. The Spanish translation of the instruments will allow families for whom English is not their primary language to participate in this important component of the study.

Attachments:

Attachment 1: Appendix C.1s_COV-IMP_Spanish CBCL_1-5yrs

Attachment 2: Appendix C.2s_COV-IMP_Spanish CBCL_School Age

Attachment 3: Appendix C.3s_COV-IMP_Spanish COVID-19 Impact Study Survey

Attachment 4: Appendix C.3s_COV-IMP_Spanish Cover Sheet for Survey

Attachment 5: Appendix C.4s_COV-IMP_Spanish VABS (pages 1-16)

Background & Justification:

The project uses existing resources from a study (SEED 3; OMB NO. 0920-1171; expiration Date 12/31/2021) to understand the impact of COVID-19 on children aged 3-6 years and their families. 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.

The English version of the COVID-19 Impact Survey was previously approved by OMB on 12/10/2020. For this change request, we are seeking approval of the Spanish translation of the survey. This will allow families for whom English is not their primary language to participate in this important component of the study.

Effect of Proposed Changes on Current Approved Instruments:

This request only adds Spanish translations of the already approved instruments: Child Behavioral Checklist (CBCL, two versions: 1-5 years, school age), COVID-19 Impact Survey (and cover sheet), and Vineland Adaptive Behavior Scales (VABS). This will allow for families for whom English is not their primary language to participate in this important component of the study.

Form	Current/Question Item	Requested Change
Appendix C.1s_COV-IMP_Spanish CBCL_1-5yrs	All	English to Spanish Translation
Appendix C.2s_COV-IMP_Spanish CBCL_School Age	All	English to Spanish Translation
Appendix C.3s_COV-IMP_Spanish COVID-19 Impact Study Survey	All	English to Spanish Translation

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Appendix C.3s_COV-IMP_Spanish Cover Sheet for Survey	All	English to Spanish Translation
Appendix C.4s_COV-IMP_Spanish VABS (pages 1-16)	All	English to Spanish Translation

Effect on Burden Estimate:

There will be no burden change.

Form	Approved Burden	Requested Burden
Appendix C.1s_COV-IMP_Spanish CBCL_1-5yrs	20 minutes	No change
Appendix C.2s_COV-IMP_Spanish CBCL_School Age	20 minutes	No change
Appendix C.3s_COV-IMP_Spanish COVID-19 Impact Study Survey	25 minutes	No change
Appendix C.3s_COV-IMP_Spanish Cover Sheet for Survey	10 minutes	No change
Appendix C.4s_COV-IMP_Spanish VABS (pages 1-16)	15 minutes	No change
Total		No change