



**U.S. Department of  
Health and Human Services**  
Centers for Disease  
Control and Prevention

*Print Date: 7/4/22*

**Title:** COVID-19 and Emergency Preparedness Home Assessments for Families of Children and Youth with Special Healthcare Needs

**Project Id:** 0900f3eb81f19fd4

**Accession #:** CPR-OAR-5/6/22-19fd4

**Project Contact:** Mary R Leinhos

**Organization:** CPR/OSPHP/OAR

**Status:** **Project In Progress : Amendment**

**Intended Use:** **Project Determination**

**Estimated Start Date:** 06/15/2022

**Estimated Completion Date:** 09/30/2022

**CDC/ATSDR HRPO/IRB Protocol #:**

**OMB Control #:** No OMB Control Number issued

## Determinations

Determination	Justification	Completed	Entered By & Role
HSC: Does NOT Require HRPO Review	Not Research / Other  <i>45 CFR 46.102(l)</i>  Program Evaluation Quality Assurance / Improvement	6/22/22	Garcia_Albert D. (asg9) CIO HSC

**Qualifies for a statutory waiver:**

21st Century Cures Act - Sec. 3087 (Public Health Emergency)

*Justification:* Description of Activity The objectives of the tabletop exercise are to:

- a. assess the preparedness and efficacy of families CYSHCN to respond to emergency scenarios that may impact their health and safety in their home, reflecting on their experience during COVID-19 and the home assessment process
- b. promote interdisciplinary collaboration and coordination with families and key service providers (e.g., emergency response agencies including EMS organizations, medical practices and other healthcare organizations; public health, and emergency management agencies,) to facilitate emergency preparedness and improve implementation of health protective behaviors during emergencies of families with CYSHCN
- c. identify things that families can do to improve their preparedness for emergencies
- d. identify things that public safety agencies, pediatric practices, other service providers can promote to improve preparedness of families with special health challenges

Data will be collected throughout the event in several ways: # The exercise facilitator or moderator will pose questions to participants at two points during the exercise (phase 1 and phase 2 of the simulated disaster). They will work together in small groups and report out (verbally) to the larger group. Observers/evaluators will record answers and key discussion points. # At the end of exercise, the moderator will lead a debrief discussion in which participants reflect on what they learned during the event and identify next steps for planning and education. # Participants will be asked to complete a written evaluation at the end of exercise. Activity#s relationship to COVID-19 - The Home Assessment project took place during COVID-19 pandemic, and the assessment itself identified key preparedness issues that families with CYSHCN were experiencing during and because of the pandemic. The exercise scenario, particularly the first phase, contains disaster elements (sheltering at home, loss of home health aides and

PRA:  
PRA Applies

6/22/22

Garcia\_Albert D. (asg9) OMB / PRA

	<p>other supports, need for medical input) that many experienced during the pandemic. Efforts to assess and minimize duplication of effort - To our knowledge, there are no studies that assess the impact of an in-home assessment on the preparedness of families with CYSHCN and couple that assessment with an exercise in which parents and caregivers work collaboratively with healthcare providers and emergency response professionals to improve the preparedness of families with CYSHCN and to promote better response and coordination during emergencies. Steps to ensure quality of project, activity methods - Most of the data collected to ascertain the outcome of this activity are qualitative and the research team includes several investigators who have extensive experience in both the conduct of tabletop emergency preparedness exercises as well as in the collection and analysis of qualitative data. The written evaluation tool also contains several questions with Likert-scale answers, which will be analyzed with simple statistics (e.g., frequency distributions, median and mean responses) using SPSS or SAS. The research team includes several statisticians who will assist with the analysis of these quantitative questions. Minimizing burden on respondents - The estimated burden hours are 90 during the exercise. (30 respondent for 3 hours). Evaluation form. (10 minutes x 30 participants = 5 burden hours. TOTAL Estimated Burden hours = 95</p>		
ICRO: PRA Applies	OMB Approval date: 6/23/22 OMB Expiration date: 12/31/99	6/23/22	Zirger_Jeffrey (wtj5) ICRO Reviewer

## Description & Funding

### Description

Priority: Standard

Determination Start Date: 06/16/22

<b>Description:</b>	<p>Investigators at the Dornsife School of Public Health and St. Christopher's Hospital for Children developed a home assessment tool which they used during the COVID-19 pandemic to assist families with CYSHCN prepare for emergencies. The home assessment tool was used to get information about the health and medical, social service, and home-based emergency preparedness needs of families with CYSHCN, and provide counseling and tools to improve their preparedness for emergencies. Another home assessment was completed 3-6 months after the first visit to ascertain its impact on family preparedness. The aforementioned activities have been reviewed and approved by Drexel IRB and CDC human subjects and PRA review processes. In addition to this follow-up visit assessment, the investigators have planned to conduct two tabletop exercises with parents and caregivers. The exercises will simulate an emergency scenario and invite parents and caregivers of CYSHCN to work with representatives from emergency response agencies, medical practices, and other healthcare organizations to work together to improve family preparedness for emergencies and the knowledge and capacity of professionals to help these families before and during disasters. The first exercise will occur in June 2022 with participating personnel in the Philadelphia metropolitan area, and the second exercise will occur in September 2022 with participating personnel from rural jurisdictions in PA. THE exercises will be the same except for the location of the participating jurisdictions (i.e., metropolitan vs rural). The tabletop exercises will each take place virtually, over a 3-hour period. There will be approximately 30 participants for each exercise, including parents and caregivers, representatives from emergency response agencies, medical practices, and other health service organizations. Participants will work in small groups of approximately 5-6 people from across sectors to work through problems posed in fictitious emergency scenarios and engage in collaborative problem solving to improve the outcomes of families with CYSHCN during those situations. The exercises will be facilitated by a public health and medical professional who is experienced in both emergency preparedness and in exercise facilitation. Exercise observers and evaluators will take notes and record answers to questions, and major themes that emerge during the exercises. *Activity's relationship to COVID-19 (for request to use PHE PRA Waiver): The Home Assessment project took place during COVID-19 pandemic, and the assessment itself identified key preparedness issues that families with CYCHSN were experiencing during and because of the pandemic. The exercise scenario, particularly the first phase, contains disaster elements (sheltering at home, loss of home health aides and other supports, need for medical input) that were tested during the pandemic. The data collection items include questions about how the experience informed both caregiver and provider/emergency response professionals response to this type of event.</p>
<b>IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:</b>	No
<b>IMS Activation Name:</b>	Not selected
<b>Primary Priority of the Project:</b>	Not selected
<b>Secondary Priority(s) of the Project:</b>	Not selected
<b>Task Force Associated with the Response:</b>	Not selected
<b>CIO Emergency Response Name:</b>	Not selected
<b>Epi-Aid Name:</b>	Not selected
<b>Lab-Aid Name:</b>	Not selected
<b>Assessment of Chemical Exposure Name:</b>	Not selected
	<p>The exercises will simulate an emergency scenario and invite parents and caregivers of CYSHCN to work with representatives from emergency response agencies, medical practices, and other healthcare organizations to work together to improve family preparedness for emergencies and the knowledge and capacity of professionals to help these families before and during disasters. *COVID-19 related project requesting to use the PHE PRA Waiver: To CDC collaborating staff and investigators' knowledge, there are no studies that assess the impact of an in-home assessment on the preparedness of families with special needs children, and that couple such assessment with an exercise in which parents and caregivers work collaboratively with healthcare providers and</p>

<b>Goals/Purpose</b>	<p>emergency response professionals to improve the preparedness of families with CYSHCN and to promote better response and coordination during emergencies. A scoping literature review is under way for the project, and has turned up no similar activities to the tabletop exercise proposed. To our knowledge this is the first such exercise to include participation of families with special needs children; exercises are typically limited to participants representing emergency response organizations in the government, nonprofit, and health care sectors. The project officer will prepare and submit required paperwork to request use of the Formative Research Generic Information Collection mechanism for the second tabletop exercise, in case the PHE COVID PRA waiver is not extended to cover the timing of the second tabletop exercise.</p> <p>The objectives of the tabletop exercise are to: a. To assess the preparedness and efficacy of families with children with special health care challenges to respond to emergency scenarios that impact their health and safety in their home, reflecting on their experience during COVID-19 and recent home assessment intervention b. To promote interdisciplinary collaboration and coordination with families and key stakeholders (e.g., pediatric practices, EMS organizations, public health, and emergency management agencies, DME and home health providers) to facilitate emergency preparedness and improve implementation of health protective behaviors during emergencies of families with special health care challenges c. To identify measures that families can take to improve their preparedness for emergencies d. To identify measures that public safety agencies, pediatric practices, other stakeholders can promote to improve preparedness of families with special health challenges</p>
<b>Objective:</b>	
<b>Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and/or decreasing disparities?:</b>	Yes
<b>Project does not incorporate elements of health equity science:</b>	Not Selected
<b>Measuring Disparities:</b>	Not Selected
<b>Studying Social Determinants of Health (SDOH):</b>	Yes
<b>SDOH Economic Stability:</b>	Yes
<b>SDOH Education:</b>	Not Selected
<b>SDOH Health Care Access:</b>	Yes
<b>SDOH Neighborhood and Environment:</b>	Not Selected
<b>SDOH Social and Community Context:</b>	Not Selected
<b>SDOH Indices:</b>	Not Selected
<b>Other SDOH Topics:</b>	Disabilities; chronic health conditions; dependence on medical devices, medications, and therapies
<b>Assessing Impact:</b>	Yes
<b>Methods to Improve Health Equity Research and Practice:</b>	Yes
<b>Other:</b>	Formative research
<b>Activities or Tasks:</b>	New Collection of Information, Data, or Biospecimens
<b>Target Populations to be Included/Represented:</b>	Other - Families of children and youth with special healthcare needs; emergency responders who assist them

<b>Tags/Keywords:</b>	Disabled Children ; Emergency Responders ; Disaster Planning ; Community mitigation ; Infection control and prevention
<b>CDC's Role:</b>	CDC employees will provide substantial technical assistance or oversight ; CDC is NOT a recipient or provider of private data, specimens, materials or services ; CDC is providing funding
<b>Method Categories:</b>	Other - tabletop exercise with evaluators
<b>Methods:</b>	<p>The tabletop exercises will take place virtually, each during a 3-hour period. There will be approximately 30 participants per exercise, including parents and caregivers, representatives from emergency response agencies, medical practices, and other health service organizations from 1) the Philadelphia metropolitan area and Southeastern PA (June exercise), and from rural PA jurisdictions (September exercise). Parents/caregivers will be recruited from participants in the earlier home assessment portion of the study. Exercise planning committee members were recruited from the investigators' existing professional network and from other study activities they are conducting with first responders in PA (not funded by CDC). During the exercises, participants will work in small groups of approximately 5-6 people from across sectors to work through problems posed in fictitious emergency scenarios and engage in collaborative problem solving to improve the outcomes of families with CYSHCN during those situations. The exercises will be facilitated by a public health and medical professional who is experienced in both emergency preparedness and in exercise facilitation. Exercise observers and evaluators will take notes and record answers to questions, and major themes that emerge during the exercise. **Steps to ensure quality of project, activity methods (for request to use PHE PRA Waiver): A multidisciplinary planning team is leading this activity # developing the exercise scenario and questions. It is comprised of physicians, emergency management and public health professionals, EMS/first responders, and experts in emergency preparedness and applied research related to emergency preparedness. Most of the data collected to ascertain the outcome of this activity are qualitative and the research team includes several investigators who have extensive experience in both the conduct of tabletop emergency preparedness exercises as well as in the collection and analysis of qualitative data. The written evaluation tool also contains several questions with Likert-scale answers, which will be analyzed with simple statistics (e.g., frequency distributions, median and mean responses) using SPSS or SAS. The research team also includes several statisticians who will assist with the analysis of these quantitative questions. The exercises will be moderated by a public health preparedness professional with 20 years of experience developing and moderating tabletop and functional/field exercises for emergency preparedness. This individual leads the planning team and is also on the research team for the overall Home Assessment project. The moderator and research team will also prepare an after-action report using the HSEEP format, to ensure that the exercise findings are reported in a systematic fashion that contributes to the findings of the overall research project.</p>
<b>Collection of Info, Data or Biospecimen:</b>	<p>Data will be collected throughout the exercise events in several ways: # The exercise facilitator or moderator will pose questions to participants at two points during the exercises (phase 1 and phase 2 of the simulated disaster). They will work together in small groups and report out (verbally) to the larger group. Observers/evaluators will record answers, key discussion points. # At the end of each exercise, the moderator will lead a debrief discussion (e.g., #hotwash#) in which participants reflect on what they learned during the event and identify next steps for planning and education. # Participants will be asked to complete a written evaluation at the end of each exercise. See separate documents (Home Assessment Project Tabletop Exercise Questions) for data collection items and for exercise evaluation instrument.</p>
<b>Expected Use of Findings/Results and their impact:</b>	<p>Investigators will present findings in a summary report for families and agencies participating in the tabletop exercises, and use findings to develop a communication toolkit and message templates, and generate policy recommendations for response agencies. Estimated burden on respondents (for request to use PHE PRA Waiver): The estimated burden hours are 90 during each exercise, for a total of 180 hours. (30 respondent/participants participating for 3 hours each, per exercise). During each exercise, observers and evaluators (individuals who are tasked specifically to observe and evaluate the activity) will record respondent verbal answers to the questions that are posed throughout the scenario, and during the debrief period. Every respondent will be asked to complete written answers to a one-page set of questions at the end of each exercise. Respondents will email these forms to the exercise coordinators after their exercise has been completed. Respondents will spend no more than 10 minutes completing this form. (10 minutes x 30 participants x 2 exercises = 600 burden minutes or 10 burden hours. TOTAL Estimated Burden hours = 190</p>

Could Individuals potentially be identified based on Information Collected? No

## Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Contract	75D30118C03584	000HGCA7-2018-28566	2018	3	1619304.80

## HSC Review

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### HSC Attributes

Program Evaluation Yes

Quality Assurance / Improvement Yes

## Regulation and Policy

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Do you anticipate this project will be submitted to the IRB office No

Estimated number of study participants

Population - Children

Protocol Page #:

Population - Minors

Protocol Page #:

Population - Prisoners

Protocol Page #:

Population - Pregnant Women

Protocol Page #:

**Suggested level of risk to subjects**

Do you anticipate this project will be exempt  
research or non-exempt research

**Requested consent process wavers**

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection
Alteration of authorization under HIPPA Privacy Rule	No Selection

**Requested Waivers of Documentation of Informed Consent**

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

**Consent process shown in an understandable language**

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

**Clinical Trial**

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection



Evaluation of a health related biomedical or behavioral outcome No Selection

Registerable clinical trial No Selection

## Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus No Selection

Human genetic testing is planned now or in the future No Selection

Involves long-term storage of identifiable biological specimens No Selection

Involves a drug, biologic, or device No Selection

Conducted under an Investigational New Drug exemption or Investigational Device Exemption No Selection

## Institutions & Staff

### Institutions

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
Drexel University	FWA00005917	03/17/26	Drexel University IRB #3	03/08/24	000HGCA7-2018-28566

### Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Mary Leinhos	10/13/2023		09/11/2022		Project Officer		770-488-8619	OFFICE OF APPLIED RESEARCH

## Data

**DMP**

**Proposed Data Collection Start Date:** 6/15/22

Proposed Data Collection End Date: 9/30/22

**Proposed Public Access Level:** Restricted

*Restricted Details:*

**Data Use Type:** Data Sharing Agreement

**Data Use Type URL:** <https://www.cdc.gov/cpr/science/research.htm>

**Data Use Contact:** [CPROAR@cdc.gov](mailto:CPROAR@cdc.gov).

<b>Public Access Justification:</b>	Data collected may contain some sensitive information, requiring review and agreement by Drexel and CDC with possible redaction of some data.
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<b>How Access Will Be Provided for Data:</b>	Personal and jurisdictional identifiers will be removed to protect privacy and confidentiality of participants; data will be reviewed for any sensitive information (e.g., public safety/security concerns) that would be subject to redaction prior to data sharing.
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<b>Plans for Archival and Long Term Preservation:</b>	Contract investigators and participating agencies will retain data indefinitely.
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## Spatiality

Country	State/Province	County/Region
United States	Pennsylvania	

## Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									

## Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
	Zirger_Jeffrey (wtj5) ICRO Reviewer	06/23/2022	Activity previously approved under the PHE PRA Waiver.	Notice of Action	PHE PRA Waiver Approval.docx
	Leinhos_Mary R. (bfz4) Project Contact	06/16/2022	Zipped file containing updated activity description reflecting conduct of two tabletop exercises, along with the original data collection instruments to be used for both exercises.	Protocol	Amendment STARS project determination Home Assessment TTX v6.16.22.zip
	Zirger_Jeffrey (wtj5) ICRO Reviewer	05/26/2022	Activity conducted under the PHE PRA Waiver.	Notice of Action	PHE PRA Waiver Approval.docx
	Leinhos_Mary R. (bfz4) Branch Approver Projects	05/10/2022	Revised question bank, evaluation form, and activity summary for tabletop exercise.	Data Collection Form	Home Assessment TTX Revised pkg 05.10.22.zip
	Leinhos_Mary R. (bfz4) Project Contact	05/10/2022	Data collection instruments (question bank and evaluation forms) and activity description and methods for tabletop exercise, updated per reviewer comments and resubmitted 5/10/22.	Data Collection Form	Home Assessment TTX Revised pkg 05.10.22.zip
	Soler_Robin (dqx4) Branch Approver Projects	05/09/2022	Question bank	Other	Home Assessment TTX Question bank RES.docx
	Soler_Robin (dqx4) Branch Approver Projects	05/09/2022	Evaluation Form	Other	Home Assessmesnt TTX Evaluation Form_Final RES.docx
	Leinhos_Mary		Zipped file contains tabletop exercise project description,	Other-PHE PRA Waiver request	Home Assessment Special Needs Families TTX supporting

Current	R. (bfz4) Project Contact	05/06/2022	question bank, and evaluation form.	supporting materials	materials.zip
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