

SUPPORTING STATEMENT

Part A

**Home Assessments for Patients and Families with Special Health Care Needs: Developing Tools,
Communication Strategies, and Standards**

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A. Justification

1. Circumstances Making the Collection of Information Necessary

Children and youth with special health care needs (CYSHCN), such as those with access and mobility challenges, chronic illness and medical technology dependence, intellectual and developmental disabilities, and other communication difficulties, require significant preparation and planning by their caregiver before a potential disaster, well beyond that of families with typically developing children and/or youth to ensure their safety. Disaster preparedness checklists are available for the general population, and limited research on disaster preparedness home visits and related checklists are emerging for elderly, frail adults. However, for the most vulnerable population of children, CYSHCN, research related to disaster preparedness tools and the utility of home visits in preparation for such an event is largely absent. Although research shows that families and individuals are more likely to prepare for emergencies or follow health-related emergency directives when the information comes from a health care professional, pediatric health care professionals, in particular, are poorly equipped with tools designed to assist caregivers, specifically, in preparing for a disaster with their CYSHCN. Moreover, a scoping review by the Drexel team found that additional research is required to better understand the needs generated by particular disabilities and contexts so that targeted interventions for CYSHCN can be developed to help caregivers prepare and plan for different disaster situations across all phases of the disaster lifecycle.¹

In response to the above knowledge gaps, Drexel University Dornsife School of Public Health (<https://drexel.edu/dornsife>), under contract with the CDC (sponsoring and coordinating Federal agency) seeks to gain a deeper understanding of the preparedness needs of caregivers of CYSHCN. This project will deploy a multidisciplinary home assessment team which includes a social worker, bilingual community health worker, medical equipment provider, and an American Red Cross-trained responder (as available) to administer a comprehensive disaster preparedness home assessment tool tailored to the specific needs of CYSHCN. This home assessment may occur in-person, in the caregiver's home, or virtually via Zoom /telephonic. This adjustment to the research protocol allows for virtual visits via a HIPAA compliant Zoom platform/telephone, a response to the COVID-19 pandemic. A virtual/telephonic visit means that the caregiver will be on a videoconference in their home, and the study team will be on the same videoconference call from a separate location. The study team will be engaged with the caregiver via the video/phone which allows the caregiver to "show" (via video) certain items in their home as they arise when asking questions from the home assessment tool. For example, the caregiver could show the study team pieces of medical equipment in question, or where they keep their child's oxygen tank, etc.). In person visits will occur when deemed safe and allowable by the Commonwealth of Pennsylvania. This formative research project aims to:

- 1) develop a home-based emergency and disaster preparedness assessment tool for families of children and youth with special health care needs (CYSHCN);
- 2) pilot the tool during an initial home visit and follow up home visit 3-6 months after the first visit (visit may occur virtually via Zoom/telephonic or in-person);

- 3) conduct qualitative semi-structured interviews with caregivers, and children, as applicable, to assess participant experience on the study process; and
- 4) enhance understanding of preparedness needs of caregivers of CYSHCN and determine the utility of the assessment tool, developed as part of this project, to identify preparedness needs of families with CYSHCN.

The data resulting from this study will be used to prepare future disaster preparedness assessment tools targeting families of CYSHCN. In keeping with the purpose of the Formative Research GenIC, this information collection will be beneficial for a) understanding a population at great risk for specific health issues (CYSHCN in the context of disasters), b) creating programs specific to the needs of this population, c) ensuring that programs are acceptable and feasible to this population, and d) improving the relationship between the population and providers of needed services. This formative research is specific to CYSHCN and their families, and resulting data is not intended to be generalizable to broader populations.

2. Purpose and Use of the Information Collection

The primary purpose of this formative research is the development and field testing of a disaster preparedness home assessment tool (**Attachment G- Drexel Tool**) for CYSHCN. The tool will be tested in two home visits with caregivers of CYSHCN; an initial home visit and a follow up home visit 3-6 months after the initial visit. This home assessment may occur in- person, in the caregiver's home, or virtually via Zoom/telephonic. This adjustment to the research setting is in response to the COVID-19 pandemic. This formative research is designed to assess the appropriateness, acceptability, reliability, and validity of the home assessment process using data collected during an initial visit and a follow up visit. Based on responses from the tool during the first home visit, resources or referrals may be provided to the caregiver by the home assessment team. Recommendations will include activities such as discussing an evacuation plan with household members and reviewing with caregivers an emergency information form template for their CYSHCN. In addition, by including questions addressing social determinants of health, the tool may identify basic needs such as food insecurity, transportation needs, or lack of health insurance among this population, that heighten risks of disaster-related morbidity and mortality particularly for vulnerable groups. In those cases, caregivers will be linked to resources in their community for follow up and assistance. At the second home visit, 3-6 months after the first home visit, the disaster preparedness home assessment tool will be administered again to assess instrument reliability and validity and better ascertain the knowledge gaps most relevant to the target population, to inform future intervention development.

During the second home visit, Drexel staff will administer a qualitative semi-structured interview (**Attachment H - Interview Guide**) to the caregiver to assess the caregiver's experience with the study process in its entirety. If willing and able, the CYSHCN themselves will be asked to participate in the semi-structured interview. Feedback from these interviews can be used in future programs to facilitate better linkage to care for families of CYSHCN, and open discussion with members of this vulnerable target population can yield input on project methods and instruments to assure feasibility and

successful implementation. These qualitative interviews will be an important step in this formative research to understand the effectiveness of the assessment tool and study process.

Findings from this study may be presented and shared in aggregate with other clinicians and health care professionals in the form of abstracts, conference presentations, briefs, webinars, and manuscripts. Information will also be shared with the disaster preparedness and emergency response community. Most importantly, findings based on the data gathered as part of the study will be shared in aggregate with the CDC to further refine disaster preparedness tools and resources for the pediatric special needs population and their families. Outcomes collected under this generic pathway are intended for internal CDC/ATSDR use only and will not be generalized beyond the scope of the study or to broader populations.

3. Use of Improved Information Technology and Burden Reduction

A variety of modes will be used as part of a data collection strategy, all of which employ some form of information technology (IT). Both instruments used in this study, the demographic intake form (**Attachment F** - Drexel Intake) and the disaster preparedness home assessment tool will be administered by study team members, who will directly enter data into a password-protected RedCap database (a secure web application for building and managing online surveys and databases). Participants will not be asked to enter any data directly. Rather, home assessment team members will read survey questions aloud and enter the caregiver's response directly into the database. The demographic intake form will be administered over the phone and the disaster preparedness home assessment tool will be administered in-person or virtually/telephonic during the COVID-19 social distancing period. For virtual home assessment visits, the research team and caregiver will use the HIPAA compliant version of Zoom. Zoom is the chosen platform for this project per the recommendation of Drexel's Institutional Review Board. Drexel staff have access to the Zoom HIPAA compliant platform through the Drexel license. Study staff are part of a HIPAA covered entity. If the caregiver does not have the technology at home to support a Zoom visit, the instruments will be administered over the phone with resource materials (i.e. food pantry list) dropped off at the caregiver's door or sent via traditional postal mailing service. Otherwise, referral materials will be emailed to the caregiver and a hard copy mailed, if requested. Under no circumstances will CDC sponsored websites (or any websites) be directed to children, CYSHCN, or adults as part of this information collection.

During the home visit, each question in the disaster preparedness home assessment tool requiring self-report from the caregiver will be read aloud to the caregiver and immediately recorded electronically by study team members. For Spanish speaking caregivers, questions will be administered by a bilingual community health worker, thus reducing the time burden required for translation. This electronic form makes extensive use of skip logic to decrease the time burden to the caregiver by omitting non-applicable questions based on each prior response. Some items within this tool do not require a self-reported answer from the caregiver, but rather an objective observation by a home assessment team member (i.e. Are smoke alarms present in the home?). Virtual home visits will utilize the caregiver's smart phone, tablet, or laptop camera to show the study team equipment, spaces, etc. We anticipate

there may be isolated circumstances where a subject does not have such a camera, and thus this data may not be collected during the social distancing period. The electronic interface is designed to allow multiple home assessment team members to collect data from the same instrument on the same subject simultaneously. In some cases (in-person visits), up to three home assessment team members could collect data from the disaster preparedness tool at the same time (medical equipment provider, ARC-trained responder, social worker and/or community health worker). This technological ability greatly reduces the time burden to the caregiver, while allowing the project team to collect robust data (e.g., enabling cross-validation of observations by different study team members).

Lastly, the qualitative interviews will be recorded with a digital voice recorder and later transcribed verbatim in preparation for analysis. Spanish interviews will be transcribed into English with a bilingual transcriber. The use of the digital recorder allows respondents to speak freely without interruption to maximize their ability to provide feedback on the project experience with minimal time burden.

The approach to embed technology throughout the entire data collection process is intentional and ensures data quality. Electronic survey responses will directly populate the password-protected study database which in turn minimizes the burden of staff time required for data entry and cleaning.

4. Efforts to Identify Duplication and Use of Similar Information

There are no similar data available for use in this study based on literature search, conference attendance, and communications with other CDC staff. While there are guidelines and recommendations for individuals with functional needs and for children related to emergency preparedness, these recommendations do not focus on CYSHCN. To our knowledge, this formative research will be the first to focus on the development and field testing of a disaster preparedness home assessment tool specific to the vulnerable target population of caregivers of CYSHCN. No consultation was done outside CDC.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

Data will be collected for this ICR twice, once during the initial visit, and a second time during the follow-up home visit. Not collecting this information will limit our understanding of disaster preparedness needs of caregivers with CYSHCN and the ability to create such a tool to effectively assess disaster preparedness needs and gaps in the target population. This study was designed to collect information at the first home visit, and then assess for change at the 3-6 month follow up home visit using the disaster preparedness home assessment tool at both times to collect data. Assessing change in responses over time will allow the research team to determine if the process of the home assessment visit, using the home assessment screening tool (virtual or in-person) and related follow up as part of

this process (providing additional education, resources, etc.) has a made difference (change in responses to the tool) at the 3-6 month follow up visit. There are no legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Relevant portions of the Guidelines of 5 CFR 1320.5 are met through the submission of the formative research GenIC package.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

Not Applicable

9. Explanation of Any Payment or Gift to Respondents

Respondents will be asked to participate in home visits (virtual via Zoom/telephonic or in-person) to test the disaster preparedness home assessment tool developed for this project. Households will receive a gift card worth \$50 (to Wal-Mart or a comparable retail store in their community) after completion of the initial home visit and another gift card worth \$50 after completion of the follow up home visit. Per the approved indication of the Formative Research GenIC, these incentives do not exceed \$40 per hour, because each initial home visit will require an average of up to 2.6 hours, and each follow-up visit will require 1.5 hours. This incentive is an acknowledgment and appreciation of respondents' time, and willingness to open their home to the project team. This incentive is appropriate as the target population required for this study is extremely narrow (caregivers who have CYSHCN, belonging to a medical practice associated with the PA AAP Medical Home Program) and data collection requires consent (**Attachment E** – Consent) to be in the caregiver's home. Although every effort has been made to minimize time burden to respondents, data collection will still require significant time and thoughtful, honest responses on the part of the caregiver.

The study's primary investigators and other colleagues at Drexel University Dornsife School of Public Health have completed research using in-depth interviews of individuals and families with CYSHCN, adolescents, and related populations, with the same geographic and socioeconomic population, and used incentives to successfully facilitate recruitment and participation.^{2,3,4} A CDC funded study by Windle et al., provided incentives (\$70 in total) to children and caregivers in a successful effort to examine adolescent health behaviors over time.⁵ A study investigating varied survey methods and modes of incentives found a direct relationship between in-person data collection and promised monetary incentives.⁶ Other studies outside of the institution have found the use of incentives to be commonly used, and yield success in recruitment and retention, especially for disadvantaged populations such as the target population for this GenIC request.^{7,8,9}

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

Respondents are informed during the active consent process that their responses will be secure and only used by the study team for research purposes. Although personally identifiable information (PII) is collected as part of the project, all data will be stored in RedCap, a password-protected, encrypted database designed for academic research. Any data transmitted to the CDC will be in aggregate, de-linked from identifiers and with PHI removed.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Drexel has received IRB approval (**Attachment A** – Drexel IRB) to conduct human research for this project through their institution’s IRB (see attachments to Supporting Statement B). This formative research will not produce generalizable data. The CDC Center for Preparedness and Response made a determination that this project is human subjects research in which CDC is not engaged, documented by an Agreement to Prohibit CDC from Receiving Identifying Key signed by collaborating Drexel and CDC investigators (see Attachment B to Supporting Statement B).

This GenIC request involves questions that may be considered sensitive, such as questions related to poverty, mental health concerns, or concerns of intimate partner violence. Questions in the social determinants of health section of the survey are important to ask as we know caregivers living with food insecurity, untreated mental health concerns, or concerns related to their physical safety, as examples, likely do not have the capacity to think about issues related to disaster preparedness for themselves or their CYSHCN. Likewise, it is well documented that there is a strong association between poor outcomes in disasters with poverty and other SES challenges. Moreover, CYSHCN are reported to have higher exposure to adverse childhood experiences (ACEs).¹⁰ Examples of ACEs include child abuse or exposure to domestic violence. It has also been shown that linking CYSHCN and their caregivers to supportive school and community environments can improve psychological well-being.¹⁰ During the COVID-19 pandemic, we have seen public health officials place purposeful emphasis on mental health and the promotion of mental health resources, for example. The pediatric medical community in Philadelphia has anecdotally seen an increase in child abuse cases since the start of COVID-19 mitigation efforts as well as an increase in the volume of calls to the child abuse hotline. Proactively identifying such challenges in the home assessment allows the team to quickly refer caregivers to relevant resources in the community. Lastly, these questions were shared with our target audience for feedback and they found them important to ask. These questions will be useful in making associations between SDOH risk factors (i.e. screening positive for depression) and level of disaster preparedness.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1: Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Caregiver of CYSHCN	Phone Screening Form	200	1	5/60	17
Caregiver of CYSHCN	Informed Consent Form	200	1	10/60	33
CYSHCN	Assent Form	100	1	2/60	3
Caregiver of CYSHCN	Demographic Intake Form	200	1	10/60	33
Caregiver of CYSHCN	Disaster Preparedness Home Assessment Tool (Initial Visit)	200	1	120/60	400
Caregiver of CYSHCN	Disaster Preparedness Home Assessment Tool (Follow Up Visit)	100	1	90/60	150
Caregiver of CYSHCN	Semi-structured Interview Guide	100	1	15/60	25
CYSHCN (as able)	Semi-structured Interview Guide	100	1	10/60	17
Total Burden = 678					

The annualized response burden is estimated at 678 hours. See Exhibit 1 above for breakdown of time estimates for each type of data collection. Data collection will occur one time for all items except the disaster preparedness home assessment tool, detailed as initial visit and follow up visit in distinct rows above.

Exhibit 2: Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Caregiver of CYSHCN	678	\$24.05	\$16,305.90

Exhibit 2 shows the estimated annualized burden costs of the data collection activities described above. From Exhibit 2 the total estimated annualized burden cost of data collection for this study is \$16,305.90. The hourly rates were based on data from the U.S. Bureau of Labor Statistics from May of 2018. The wage of \$24.05 is the average hourly wage across all occupations.¹¹ This table assumes that CYSHCN associated with this study will not be employed.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other cost burdens to respondents and record keepers for this data collection

14. Annualized Cost to the Federal Government

No additional cost is incurred by the federal government. This cost is incurred by Drexel University and subcontract staff as recipients of the Broad Agency Announcement 2018-N-67817—Public Health Emergency Preparedness and Response Applied Research (PHEPRAR) contract and hence, will be solely responsible for the execution of the data collection.

15. Explanation for Program Changes or Adjustments

This is a new generic information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Exhibit 3 illustrates the timeline for activities related to this collection, including recruitment of participants, data collection, data analysis, and publication.

Exhibit 3. Project Timeline

Activity	Time Schedule
Recruitment and ongoing enrollment	September 1, 2020
Data Collection	
a. Home Assessment - initial visit	September 1, 2020- March 1, 2021
b. Home Assessment - follow up visit	December 1, 2020- August 31, 2021

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References:

1. Hipper et al. The Disaster Information Needs of Families of Children with Special Healthcare Needs: A Scoping Review. *Health Security* 2018, 16(3) 178-192.
2. Ness-Cochinwalla M, et al. A comparison of providers' and families' viewpoints on discharge tracheostomy education. *Critical Care Medicine*. 2018; 41(1). Available from: https://journals.lww.com/ccmjournal/Citation/2018/01001/405_A_COMPARISON_OF_PROVIDERS_AND_FAMILIES.371.aspx
3. Massey P, Michael P, Calimlim B, Quiter ES, Glik DC. Contextualizing an expanded definition of health literacy among adolescents in a health care setting. *Health Education Research*. 2012; 27(6): 961-974. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC349860>
4. Turchi R & Massey P. Understanding and addressing the impact of low health literacy on the interaction of adolescents with the health information environment Presented at Society of Adolescent Health Medicine, 2016, Washington, DC.
5. Windle, et al. Healthy passages: a multilevel, multimethod longitudinal study of adolescent health. *American Journal of Preventative Medicine*. 2004; 27(2): 164-172. <https://doi.org/10.1016/j.amepre.2004.04.007>
6. Mercer A, Caporaso A, Cantor D, Townsend R. How much gets you how much? Monetary incentives and response rates in household surveys. *Public Opinion Quarterly*. 2015; 79(1): 105-129. <https://doi.org/10.1093/poq/nfu059>
7. Yu S, et al. The effectiveness of a monetary incentive offer on survey response rates and response completeness in a longitudinal study. *BMC Medical Research Methodology*. 2017; 17: 77. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5406995/>
8. Asire AM. A meta-analysis of the effects of incentives on response rate in online survey studies. [master's thesis]. Denver, CO: University of Denver; 2017. <https://digitalcommons.du.edu/cgi/viewcontent.cgi?article=2317&context=etd>
9. Bonevski, et al. Reaching the hard-to-reach: a systematic review of strategies for improving health and medical research with socially disadvantaged groups. *BMC Medical Research Methodology*. 2014; 14(42).1-29.
10. Mattson G, Kuo DZ, AAP COMMITTEE ON PSYCHOSOCIAL ASPECTS OF CHILD AND FAMILY HEALTH, AAP COUNCIL ON CHILDREN WITH DISABILITIES. Psychosocial Factors in Children and Youth With Special Health Care Needs and Their Families. *Pediatrics*. 2019;143(1):e20183171 Available from: <https://pediatrics.aappublications.org/content/pediatrics/143/1/e20183171.full.pdf>
11. U.S. Bureau of Labor Statistics. May 2017 State Occupational Employment and Wage Estimates Pennsylvania. Available from: https://www.bls.gov/oes/2017/may/oes_pa.htm#00-0000