

**Request for GenIC Approval**  
**CDC/ATSDR Formative Research and Tool Development**  
**0920-1154**

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**CIO:** Mary Leinhos, Senior Health Scientist, Office of Applied Research, Center for Preparedness and Response

**PROJECT TITLE:**

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

**PURPOSE AND USE OF COLLECTION:**

Drexel University Dornsife School of Public Health, under contract with CDC (sponsoring and coordinating Federal agency) seeks to develop and pilot a home-based (virtual via Zoom/telephonic or in-person) emergency and disaster preparedness assessment tool for families of children and youth with special health care needs (CYSHCN). 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 assessment tools and checklists are available for the general population, and limited research on disaster preparedness home visits and related assessment tools are emerging for elderly, frail adults. However, for the most vulnerable population of children, CYSHCN, evidence regarding the utility of disaster preparedness tools, and the utility of home visits in particular, 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 are poorly equipped with tools, particularly tools designed to assist caregivers of CYSHCN in preparing for a disaster with their CYSHCN.

This formative research project aims to: 1) develop a home-based disaster preparedness assessment tool for families of CYSHCN; 2) pilot the tool during an initial home visit and follow up home visit 3-6 months after the first visit (home visit to be conducted either virtually via Zoom/telephonic, or in-person); 3) conduct semi-structured qualitative interviews to assess the participant's experience with the study process; and 4) enhance understanding of preparedness needs of families of CYSHCN and determine the utility of the assessment tool, developed as part of this project, to identify preparedness needs of families with CYSHCN. This is a pilot study specific to CYSHCN, and resulting data is not intended to be generalizable to broader populations.

Of note, the study protocol has changed to include virtual home visits via Zoom/telephonic during 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 videophone 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 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.).

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.

In-person home visits will only occur when deemed safe and allowable by the Commonwealth of Pennsylvania following the COVID 19 Pandemic and guidance from state and government officials.

**DESCRIPTION OF RESPONDENTS:**

Project staff from Drexel University Dornsife School of Public Health will recruit and enroll up to 200 caregivers of CYSHCN across the Commonwealth of Pennsylvania (PA), with a goal of obtaining complete data from 100 caregivers at two data collection points. CYSHCN themselves may also be asked to participate in the second data collection interview, as appropriate based on their age and ability to participate, and with proper consent from a legal guardian. Interviews with children will only occur if an in-person interview is safe and allowable by the state of Pennsylvania. Caregiver respondents will be recruited from primary care practices affiliated with the PA chapter of the American Academy of Pediatrics (PA AAP) Medical Home Initiative. Caregivers will be representative of both rural and urban geographic areas across PA, and include both English and Spanish speaking caregivers, and represent patients and families with diverse levels of socioeconomic status.

**CERTIFICATION:**

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. Information gathered will not be used to substantially inform influential policy decisions.
5. The study is not intended to produce results that can be generalized beyond its scope.

Name: \_\_\_\_\_ Renee Turchi \_\_\_\_\_

To assist review, please answer the following questions:

**Personally Identifiable Information:**

1. Is personally identifiable information (PII) collected? [ **X** ] **Yes** [ ] **No**
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [ ] **Yes** [ **X** ] **No**
3. If Applicable, has a System or Records Notice been published? [ ] **Yes** [ ] **No** **Not Applicable**

**Gifts or Payments:**

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants?  **Yes**  No

Respondents will be asked to participate in two home visits (virtual via Zoom/telephonic or in-person) to pilot and test the disaster preparedness home assessment tool developed for this project. Eligibility criteria for respondents is very specific. Respondents must be caregivers of CYSHCN, and the CYSHCN must receive primary health care with a practice affiliated with the PA AAP Medical Home Initiative. Caregivers must be willing to allow the study team to enter and assess their home using the home assessment tool. For participation, respondents will receive a gift card incentive of \$50 per visit to Wal-Mart (or a comparable retail store in their community) after completion of each home visit as a token of appreciation.

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.<sup>1,2,3</sup> 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.<sup>4</sup> A study investigating varied survey methods and modes of incentives found a direct relationship between in-person data collection and promised monetary incentives.<sup>5</sup> 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.<sup>6,7,8</sup>

### BURDEN HOURS

<b>Category of Respondent (Individuals or Households)</b>	<b>Form Name</b>	<b>No. of Respondents</b>	<b>Participation Time (minutes)</b>	<b>Burden in Hours</b>
Caregiver of CYSHCN	Phone Screening Form	200	5/60	17
Caregiver of CYSHCN	Informed Consent	200	10/60	33
Child or Youth with Special Health Care Needs (as able)	Assent Form	100	2/60	3
Caregiver of CYSHCN	Demographic Intake Form	200	10/60	33
Caregiver of CYSHCN	Disaster Preparedness Home Assessment Tool (Initial home visit)	200	180/60	600
Caregiver of CYSHCN	Disaster Preparedness Home Assessment Tool (Follow up home visit)	100	90/60	150
Caregiver of CYSHCN	Semi-structured Interview Guide	100	15/60	25
Child or Youth with Special Health Care Needs (as able)	Semi-structured Interview Guide	100	10/60	17
Totals	--			878

**FEDERAL COST:** No additional cost is incurred by the federal government. This cost is incurred by Drexel University Dornsife School of Public Health 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.

**If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:**

**The selection of your targeted respondents**

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?  Yes  **No**

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

Using a convenience sampling strategy, caregivers of CYSHCN will be identified by staff within the child's primary care practice. Only medical practices affiliated with the PA Medical Home Initiative will participate in identifying potential caregivers of CYSHCN for recruitment. Efforts will be made to recruit approximately 75% of caregivers from urban regions of PA and approximately 25% of caregivers from rural and non-urban communities across PA.

**Administration of the Instrument**

1. How will you collect the information? (Check all that apply)  
 Web-based or other forms of Social Media  
 **Telephone**  
 **In-person**  
 Mail  
 Other, Explain HIPAA compliant Zoom application through a Drexel University license.
2. Will interviewers or facilitators be used?  **Yes**  No

Interviewers will be either staff from Drexel University Dornsife School of Public Health or consultants trained by the Drexel team (in conducting interviews and home assessments).

## References:

1. 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](https://journals.lww.com/ccmjournal/Citation/2018/01001/405__A_COMPARISON_OF_PROVIDERS_AND_FAMILIES_.371.aspx)
2. 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>
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5. 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>
6. 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/>
7. 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>
8. 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.