



Consent to Take Part in Human Research Study
Consent to Take Part
In a Research Study
At St. Christopher's Hospital for Children

If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may be required. When we say “you” in this consent form, we mean you or your child; when we say “we” in this consent form, we mean Drexel University.

1. Title of research study: Home Assessments for Patients and Families with Special Health Care Needs: Developing Tools, Communication Strategies, and Standards

2. Researcher: Dr. Renee Turchi

3. Concise Summary of Key Information:

We want to understand what caregivers of children and youth with special health care needs (CYSHCN) need, to be prepared in an emergency or natural disaster. We would like to test an emergency preparedness checklist and resources we developed to see if it meets your needs. Participation in this project is voluntary, and your child/youth's medical care will not be affected if you choose not to participate in this project.

If you would like to participate, we would set up two different times to either come to your house in-person, or schedule a virtual/telephonic home visit. The second visit (in-person or virtual) would happen 3-6 months after the first visit. The project team members (who would come to your home in-person or virtually) are a social worker, a community health worker, and a medical equipment provider. If a first responder from your community is available for the visits, they may also come to your home in-person or virtually. The home assessment team would use a checklist developed for this project and ask you some questions to see the things you have done to prepare for an emergency, try to understand your ideas about emergencies and disasters, and help you look at things you could do in the future to prepare for an emergency with your child. This may include things like making sure you always have your child's back-up medical equipment available if the power goes out, or making sure there is an exit in your home that everyone can easily use if you need to get out of your house quickly. The team would walk through your entire house (in-person or virtually) using the checklist. You (or another family member) would be with the project team the entire time. The project team members will ask permission before entering each room, but it will be important for them to see your whole house before they leave to best help you be prepared with your child with special health care needs. Before the home assessment team leaves, they will talk with you about an emergency plan that would be specific to your family, give you some resources, discuss your child's medical needs and recommendations for you to be prepared in your house. If the visit is being conducted virtually, we will email or mail you resources that we think may be helpful. The team may also refer you to some community resources if certain things are identified in the visit that they can help with such as help with food or utilities. We expect this visit to be about 2.5 to 3 hours long.

About 3-6 months after the first visit the home assessment team would like to come back (either in-person to your home, or virtually). The goal of this follow up visit is to see if you were able to do some of the

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suggestions from the emergency plan discussed at the first visit. The team will use the same checklist to see if any items have changed and where else we can help provide support for you. The team will also ask you a few questions in brief interview at the end of the visit to see how you felt about taking part in this project, if you feel like it was helpful to you and your family, and what we could do better/differently to make this work. This brief interview will be tape recorded. We expect this second visit to be shorter, about 1-1.5 hours long.

You may benefit from this project by identifying and understanding things you can do to better prepare your family for an emergency and receive resources including, but not limited to a customized emergency preparedness plan specific to your families' and your child's needs. You may also be connected with community resources as part of this project that may be helpful to you and your family on a more regular basis. The risks to participation are discomfort from having strangers in your home and walking through your home. There is no cost to participate in this project.

4. Why you are being invited to take part in a research study

We invite you to take part in a research study because you have a child/youth with special needs that may require extra attention or planning if an emergency or disaster were to happen and we would like to better understand how to help you and your family.

5. What you should know about a research study

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part now and change your mind later.
- If you decide to not be a part of this research no one will hold it against you and it will not affect your child's care.
- Feel free to ask all the questions you want before you decide.

6. Who can you talk to about this research study?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at St. Christopher's Hospital for Children. You can call 215-427-8363 and ask to speak with Renee Turchi (the Principal Investigator) or Katie Feehan (the Project Coordinator).

This research has been reviewed and approved by an Institutional Review Board (IRB). An IRB reviews research projects so that steps are taken to protect the rights and welfare of human subjects taking part in research. You may talk to them at (215) 762-3944 or email HRPP@drexel.edu for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.



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7. Why are we doing this research?

We want to understand what caregivers of children and youth with special health care needs (CYSHCN) need, to be prepared to an emergency or natural disaster. We would like to test out an emergency preparedness checklist we developed to see if it meets your needs. Participation in this project is voluntary, and your child's medical care will not be affected if you choose not to participate.

8. How long will the research last?

We expect that you will be in this research study from the time of the first home assessment until the follow up home visit has been completed. Each home visit is expected to last a minimum of 1 hour but not to exceed 3 hours. A follow up visit will be scheduled approximately 3-6 months after your first home visit. In rare cases when the follow up visit is hard to schedule, this may take up to 7 or 9 months in total.

9. How many people will be studied?

We expect at least 100 caregivers of CYSHCN will be in this research study out of 614,000 CYSHCN in the entire state of Pennsylvania.

10. What happens if I say yes, I want to be in this research?

You will receive the initial and follow up home visit- as described in #3 above including 2 home visits (in-person or virtually) to collect information about you, your child and your home environment.

11. What are my responsibilities if I take part in this research?

If you take part in this research, it is very important that you:

Follow your physician's or researcher's instructions.

- Tell your study physician or researcher right away if you have a complication or injury.
- Allow the project team to walk through your entire home.
- Help us answer questions related to your knowledge and experience in a disaster.

12. What happens if I do not want to be in this research?

You may decide not to take part in the research and it will not be held against you.

13. What happens if I say yes, but I change my mind later?

You can agree to take part in the research now and stop at any time it will not be held against you.

If you stop being in the research, already collected data may not be removed from the study database.

14. Is there any way being in this study could be bad for me?

The risks of participation is discomfort from having the home assessment team in your home. In rare cases, the project team may see something in your home that they need to report to another agency such as the Department of Human Services or help you if you or your child is in imminent danger. This would only be in the case that



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your child is in immediate danger or at risk of serious harm. The project team would tell you if they were planning to make such a report.

15. Do I have to pay for anything while I am on this study?

There is no cost to you for participating in this study.

16. Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include receiving advise, specific to your family and household, that can help make your family safer and more prepared for an emergency or natural disaster. You may also receive referrals to community resources that can help you and family with more regular, daily living needs and to help you be better prepared in the event of an emergency or a disaster.

17. What happens to the information we collect?

Efforts will be made to limit your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. The Centers for Disease Control and Prevention (CDC) will also be reviewing only summary data from the project, but your name and your child's name will be anonymous.

18. What else do I need to know?

The sponsor, the Centers for Disease Control and Prevention (CDC) is paying Drexel University and St. Christopher's Hospital (SCHC) for Children for the contract related to this project.

This research study is being done by Drexel University and conducted by the Drexel University College of Medicine teaching faculty, who are based at St. Christopher's Hospital for Children.

It is important for you to follow your physician's instructions including notifying your study physician as soon as you are able of any complication or injuries that you experienced.

You will not be paid for any other injury or illness-related costs, such as lost wages. You are not waiving any legal rights by participating in this research study.

If you agree to take part in this research study, you will receive a \$50 gift card at the completion of each home visit (for a total of \$100) for the time you spend completing the home assessments and answering our questions related to your knowledge and experience.

Permission to Take Part in a Human Research Study

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject

Date

Printed name of subject

Signature of person obtaining consent

Date

Printed name of person obtaining consent

Signature Block for Children

Your signature documents your permission for the named child to take part in this research.

Printed name of child

Signature of parent or individual legally authorized to consent to the child's general medical care

Date

- Parent
- Individual legally authorized to consent to the child's general medical care (See note below)

Printed name of parent or individual legally authorized to consent to the child's general medical care

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Signature of parent

Date

Printed name of parent

If signature of second parent not obtained, indicate why: (select one)

- | | |
|--|---|
| <input type="checkbox"/> The IRB determined that the permission of one parent is sufficient. | <input type="checkbox"/> Second parent is incompetent |
| <input type="checkbox"/> Second parent is deceased | <input type="checkbox"/> Second parent is not reasonably available |
| <input type="checkbox"/> Second parent is unknown | <input type="checkbox"/> Only one parent has legal responsibility for the care and custody of the child |

- Assent
- Obtained
 - Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

Signature of person obtaining consent and assent

Date

Printed name of person obtaining consent

Form Date