

IUPUI and CLARIAN INFORMED CONSENT STATEMENT FOR

*Safe Escape:
Analysis of a Model Program's Delivery of Products and Education on
Emergency Evacuation of Children with Special Health Care Needs or Disabilities.
Study # 0707-57*

You are invited to participate in a research study that will help us to better understand the needs of families receiving products and education from Safe Escape. You were selected as a possible subject because you showed an interest in receiving free adapted evacuation products by scheduling a Safe Escape appointment (assessment). We ask that you read this form and ask any questions you may have before agreeing to be in the study.

The study is being conducted by Karen Bruner Stroup and Emily S. McQuade, Department of Pediatrics, Community Education and Child Advocacy. Safe Escape is funded by the US Department of Homeland Security.

STUDY PURPOSE

The purpose of this study is to assist the Safe Escape project team in making informed decisions regarding future Safe Escape product and education offerings, and to increase the body of knowledge available regarding safe evacuation of children with special health care needs or disabilities.

NUMBER OF PEOPLE TAKING PART IN THE STUDY

If you agree to participate, you will be one of approximately 400 subjects who will be participating in this research.

PROCEDURES FOR THE STUDY

If you agree to be in the study, you will do the following things:

Come to the Riley Safety Store and participate in a one-hour needs assessment.

1. You will be asked to complete paperwork that asks you to tell the Safe Escape team:
 - a. About your home and home life
 - b. Your emergency evacuation concerns
 - c. Which type of products would be helpful in evacuating your child
 - d. Which types of emergencies concern you when evacuating your child
2. You will be asked to provide information concerning your child's special health care needs or disabilities and how this may impact the ability to safely evacuate during an emergency situation
3. You will be offered free adapted evacuation products that may help you to evacuate your child safely during an emergency; you are not obligated to take any of the products offered
4. You will be given instruction on the proper use and installation of each product you receive
5. You will be given appropriate education and resources to create your own emergency preparedness plan at home
6. You may be contacted in the future for follow up on this study or for future research studies

RISKS OF TAKING PART IN THE STUDY

1. The risk of completing the assessment process is being uncomfortable answering the questions. You will be asked to talk about your child's special health care needs or disability. You will be asked how these affect your exit during an emergency. At any time during your appointment, you can tell the researcher that you feel uncomfortable with or do not want to answer a question.
2. The risk of participating in the Safe Escape program is a possible loss of confidentiality or loss of privacy. It is highly likely that individuals not related to Safe Escape may enter the Riley Safety Store to purchase merchandise during your assessment. You can ask the researcher to close the door a little to discourage others from entering. You may also reschedule your appointment at a time when a private conference room is available.

BENEFITS OF TAKING PART IN THE STUDY

The potential benefits are:

- Learning how to get your child out during an emergency
- A lower chance of injury during an emergency
- A lower chance of death during an emergency

ALTERNATIVES TO TAKING PART IN THE STUDY

The alternative to taking part in the study is to request that your responses not be included in the research study. You are still able to receive free products and education from Safe Escape. You will still be asked to complete the questionnaires as this is necessary to determine the correct products

and education to meet your individual needs. The Safe Escape staff member will indicate on each questionnaire your desire to opt out of the research study, if you so decide.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published and databases in which results may be stored.

At times, the Safe Escape program sponsors interns from several universities. As such, it is possible that your assessment will be recorded, either video or audio, with your prior consent and completion of a media release form. Your identity will remain confidential. This recording is for educational purposes only and will remain the property of Indiana University. The original recording will be kept with the Indiana University Department of Pediatrics, Community Education and Child Advocacy, or destroyed.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the IUPUI/Clarian Institutional Review Board or its designees, study sponsor, and (as allowed by law) state or federal agencies (specifically the Office for Human Research Protections (OHRP) may need to access your medical and/or research records.

COSTS

The costs associated with this program are your time and possible parking fees. You will not be reimbursed for parking or any related expenses.

PAYMENT

You will receive free safety products and education, when available, for taking part in this study. The total value of products received will vary depending on your unique responses to the assessment questions. Products are determined during the assessment process; you may not receive the same products as other individuals with the same or similar diagnosis. Products cannot be reserved in advance or mailed to you, and are only available while quantities last.

COMPENSATION FOR INJURY

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact the researchers, Karen Bruner Stroup or Emily McQuade, at 1-888-365-2022 toll free. If you cannot reach the researcher during regular business hours (i.e. 8:00AM-4:00PM), please call the IUPUI/Clarian Research Compliance Administration office at 317/278-3458 or 800/696-2949.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IUPUI/Clarian Research Compliance Administration office at 317/278-3458 or 800/696-2949.

VOLUNTARY NATURE OF STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with the Riley Safety Store.

Your participation may be terminated by the investigator without regard to your consent in the following circumstances: Inability to provide adequate information to assess your family's needs and identify appropriate products or education resources.

SUBJECT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent statement to keep for my records.

SUBJECTS SIGNATURE: _____ Date: _____
(must be dated by the subject)

SIGNATURE OF PERSON
OBTAINING CONSENT: _____ Date: _____