PART A Consent Form

Parent Permission for a Minor to Participate in a Research Study

TITLE: Development and Pilot Testing of Smart Pediatric Belt and Mobile App for Toddlers

PROTOCOL NO.: SMIDE2
WCG IRB Protocol #20224920

SPONSOR: Soterix Medical Inc.

INVESTIGATOR: Abhishek Datta, PhD
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STUDY-RELATED PHONE NUMBER(S): 845-244-6600
888-990-8327 (24 hours)

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

Key Information

- This is a voluntary research study on the ability of the investigational smart pediatric belt (SPB) manufactured by Soterix Medical to track child motion data.
- This study involves a Part A: collecting motion data by having the child wear a smart belt or smart pediatric belt cane during mutually agreed upon sessions lasting no longer than 2 hours and a Part B: a 6-week evaluation period to validate smart technology developed in Part A, and a mobile application.
- Each parent/legal guardian will receive $50 dollars per hour.
- Each participant who is visually impaired will receive a smart pediatric belt cane to keep after completing the study.
- There are no foreseeable risks involved with this study as an adult will be present at all times during data collection and training.
- There is no expected direct benefit to participating, however, information learned from this research may help future pediatric patients who are visually impaired.
- This is not a treatment study and your child does not need to participate.

Description of the Study

This study has two parts. The purpose of Part A of the study is to collect motion data using a smart belt with a motion sensor consisting of a belt with a motion sensor. The collected motion data will be used to create a computer algorithm capable of measuring mobility skill in children who are blind or mobility visually impaired. In Part B, we will evaluate the SPB's ability to

determine mobility impairment in blind and mobility visually impaired children with new technology developed from the data collected in Part A, and a mobile app designed to help professionals and parents engage children in educational activities wearing the SPB. We hope this will provide parents and educators with information that can improve the child's mobility skills.

You are being asked to allow your child to participate in Part A of this study, which involves collecting motion data only. If you agree to allow the child to be in this study, you and/or the child will be asked to do the following things: Review, sign and date this informed consent. Complete a pre-screening questionnaire to determine if your child is eligible to participate in the study. Sighted participants will wear a pediatric belt with a motion sensor, and blind or mobility visually impaired participants will wear the smart pediatric belt cane with a motion sensor attached during up to two hours. Study sessions will be conducted at a location that offers the essential test condition of a smooth walking surface at least 80 feet in length. The motion test will be videotaped. In return, Soterix Medical will pay participants $50 per hour. All visually impaired participants will also retain the pediatric belt cane at the end of the study. We plan to enroll 100 sighted children and 100 mobility visually impaired children in this part of the study.

Duration of Participation
Your child's participation is expected to be completed within one hour.

Risks and Benefits
The study has no foreseeable physical risks to the participant as an adult will be present during the entire data collection procedure. There is the risk of a loss of confidentiality of your child's research-related information. However, participation in this research may result in harming your child in unknown ways.

There is no intended direct benefit to your child from participating in this study. The blind or mobility visually impaired participant will be given a smart pediatric belt cane that may improve their mobility skills. Blind or mobility visually impaired children may benefit in the future from information learned in this study.

Alternatives to Participation
Your alternative is to not allow your child to participate in the study.

Confidentiality
• This study is confidential. We will be collecting personal information of the participant and a code will be assigned to each participant to minimize the possibility of compromising any information collected. After the data collection is completed, the research team will keep the codes while deleting any proper nouns so the research team will not retain any information about your child's identity.

• The records of this study will be kept strictly confidential, however, complete privacy cannot be guaranteed. Research records will be both electronic and paper-based. Paper-based records will be kept in a locked cabinet only accessible by the research staff. All electronic records will be coded and secured using a password protected file. All data will remain extant for the researchers for a period of time not to exceed three years from the duration of the study they will be destroyed or erased. We will not include any information in any report we may publish that would make it possible to identify your child.

Information about a Certificate of Confidentiality for this research:

Dr. Datta and the institution have received a Certificate of Confidentiality from the government which will help protect the privacy of research subjects. The certificate protects against the involuntary release of information about subjects collected during the course of this research. The researchers involved in this study cannot be forced to disclose any information collected in this study in any legal proceedings.

However, the subject may choose to voluntarily disclose the protected information and this certificate does not prohibit such voluntary disclosure. Furthermore, the parties listed in the Confidentiality / Authorization section of this consent form may review our records under limited circumstances and this certificate does not prohibit such disclosure.

What happens to the information collected for this research?
Your child's private information and medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration (FDA)
- The Institutional Review Board (IRB) that reviewed this research

You may withdraw or take away your permission to use and disclose your child's health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, your child will not be able to stay in this study.

When you withdraw your permission, no new health information identifying your child will be gathered after that date. Information that has already been gathered may still be used and given to others.

• Your child's identity will not be made known in written materials resulting from the study.

Costs and Compensation
There are no costs to you for your child's participation in this research. Potential costs will be for transportation. The sponsor will not provide compensation for transportation or possible costs associated with parking.

You will receive the following compensation for your child's time:

You will receive $50 dollars per hour. Each participant who is blind or mobility visually impaired will receive a SPB at no cost to the participant, parent/legal guardian (LG).

Financial Conflict of Interest
Abhishek Datta, Phd, and Dr. Grace Ambrose-Zaken, investigators in this study, have received payment from the sponsor in the past 12 months. Please feel free to ask any further questions you might have about this matter.

Your Rights

The decision to allow your child to participate in this study is entirely up to you. You may refuse to have your child take part in the study at any time. Your decision will not result in any loss of benefits to which you are otherwise entitled. Your child has the right to skip any question or research activity, as well as to withdraw completely from participation at any point during the process. You have the right to ask questions about this research study and to have those questions answered before, during, or after the research. If you have any further questions about the study, at any time feel free to contact the researcher, Dr. Grace Ambrose-Zaken, at 845-244-6600 or 888-990-8327 (24 hours) or by email to contact@soterixmedical.com. If you have any questions about your child's rights as a research participant that have not been answered by the investigators or if you have any problems or questions, concerns or complaints about the research you may contact the overseeing Institutional Review Board at 855-818-2289 or by email toresearchquestions@wcgirb.com. Our policy does not offer medical treatment or compensation for treatment of injuries that may occur as a result of participation in research activities. The preceding information shall not be construed as a waiver of any legal rights or redress which the participants may have.

Future Use of the Research Data

After removing all identifying information from your child's data, the information could be used for future research studies or distributed to another investigator for future research studies without additional permission from you.

Your signature below indicates that you have agreed to allow your child to participate in this study, and that you have read and understood the information provided above. You will be given a signed and dated copy of this form to keep, along with any other printed materials deemed necessary by the study investigators.

- Assent of children is not required

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

_____	_____
Signature of child subject's parent, or individual authorized under state or local law to consent to the child subject's general medical care	Date
_____	_____
Printed name of child subject's parent or individual authorized under state or local law to consent to the child subject's general medical care	Date