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| ID: STUDY00011386 | Early Powered Mobility for Toddlers With Cerebral Palsy Using the Permobil® Explorer Mini and a Modified Ride-On Car | NCT04684576 |

Informed Consent Document- All Site
Approval Date: 12/1/2020

# CONSENT FORM FOR RESEARCH PARTICIPANTS AND FOR PARENTAL PERMISSION

**Project Title:** Early Powered Mobility for Toddlers with Cerebral Palsy: A Comparative Case Series of the Permobil® Explorer Mini and a Modified Ride-On Car

**Research Site Information:** **[insert institution information and primary investigator contact information here]**

**You and your child are being asked to volunteer in a research study.**

## Purpose

The purpose of this study is to understand parent perspectives, use patterns, and child development patterns after trial use of two devices designed to support mobility and socialization for toddlers with disabilities.

## Study Materials and Procedures

Two devices will be used during this study. The first is a battery powered toy ride-on car. This car is widely used by young children for fun and mobility. It is often adapted for children with disabilities. The top picture shows one style of this car. The second is the Permobil® Explorer Mini. This is a new commercial powered mobility device. It can be driven in either sitting or standing. The bottom picture shows the Explorer Mini. This research will provide a better understanding of the role of these devices in rehabilitation for children with CP.

Child using one style of an adapted ride-on toy

The study will involve approximately 15-20 hours of your time across a 16-week study period. These procedures will take place three times across the study period.The timeline for the study is broken down into two, 8-week periods. Your child will use a modified ride-on car for 8 weeks. Your child will also use the Explorer Mini for 8 weeks. The device you use first will be randomly assigned. At the end of each 8-week period, the devices will be removed by the research team. There will be a 5-day grace period within each 8-week period. This will help schedule study activities and account for scheduling issues.

Child using an Explorer Mini.

**Device delivery, training, and safety check-off**: (time is variable) Research staff will deliver each device and train you to use it. Research staff will complete a safety check-off document with you. Research staff will conduct a home safety assessment to determine safe driving areas of your home. This will occur at the beginning and middle of the study.

**Developmental Assessment:** (30-70 minutes) The research team will perform or instruct you to perform activities with your child. This will assess their development. These activities will be video-taped and scored by research staff at a later time.

**Participation and Engagement Surveys:** (30 minutes) The research team will provide you with two surveys to complete. These will describe your child's current participation in daily life activities.

**Brief Interview:** (30-45 minutes) The research team will lead you through an interview. This will help us understand what you think about each device. It will also help us understand how you think about your child's mobility. This interview will be audio recorded and transcribed.

**Mobility Observation:** (10 minutes) The research team will observe your child using each device. This observation will take place at the beginning and end of each 8-week device trial. This observation will be video-recorded and scored by research staff at a later time.

**Daily Driving Log:** (less than 5 minutes) You will document daily/weekly use for each powered mobility device. You will log the driving time, the environment, and your child's reaction to using the device. The research team will also collect automated data about the use of each device. For the ride-on car, we will install a data logger that records location, frequency, and duration of device use. For the Explorer Mini, the same information is logged by the operating system and will be collected through the manufacturer's secure mobile app. This automated data collection will not require any additional action from you.

**Device Acceptability Survey:** (less than 5 minutes) The research team will provide you with an additional survey. This survey asks you to rate how likely you would be to continue using each device. This survey will be conducted at the end of each 8-week device trial.

**Remote Check-In periods:** (10 minutes) The research team will conduct two check-ins during each 8-week period of device use. We will contact you using your preferred contact method (email, text, phone call, or video chat). We will offer support and ideas for device use. We will also answer questions or provide technical assistance. If you prefer to contact the research team more frequently, you are able to do so using your preferred method of contact.

**Covid-19 statement**

The safety and health of our participants and research team is our first priority. The research team has developed research protocols that minimize in-person contact and maximize infection control precautions. These involve:

1. Only some interactions will occur in-person. The majority of the study research procedures are able to take place remotely. In-person interaction will only be required for brief periods (approximately 90 minutes), three times during a 4-month study period and will proceed using infection control precautions.

2. When in-person interaction takes place, members of the research team will wear masks and eye protection. They will maintain 6 feet of social distance whenever possible. When social

distance cannot be maintained, we will limit the time spent in close contact to 15 minutes or less. All adult participants will be required to wear face coverings. All child participants must wear face coverings if possible. Other family members must also wear masks if they are in the area where research activities will take place. If you do not have your own face covering, a single-use, disposable face covering will be provided to you and each family member.

3. All members of the research team and all participants must complete a COVID-19 screening within 24 hours before each of the three scheduled in-person research visits.

**Risks, stress, or discomfort**

The risks of participating in this study are minimal. Ride-on cars are a common toy and many families with small children with and without mobility impairments use the cars. The Permobil® Explorer Mini is FDA cleared and is commonly used by children with mobility impairments. We have designed this study to reduce risks to you and your child.

Because your child will be using mobility devices for this research, the main risk to your child is fatigue or physical injury. To minimize these risks, we will train you in how to safely use the device and how to check your child for signs of fatigue while using the device. We also ask that you never allow your child to use the device without supervision. You are required to immediately report any issues with the device to our research staff. Qualified study staff will handle all repairs or replacements needed during the study.

There is a risk of loss of confidentiality if someone outside the study team got access to your family's information. We will use codes and false names to identify you and your child in our records to minimize this risk. The key linking your name and contact information with the codes will be stored in a separate, locked file cabinet in a locked office. We will store your digital information, including all recordings, on a password encrypted computer.

You may experience some distress during interviews that ask about disability or your child's medical history. You do not have to answer any questions that make you uncomfortable and you can stop your participation at any time.

**Benefits of the Study**

A direct benefit to you and your child will be to receive training, education, and trial use of two powered mobility devices. This research will also benefit other people by sharing knowledge about your family's experiences with the devices.

**Research Funding and Clinical Trial Status**

This research is funded by the National Pediatric Rehabilitation Research Center (C-PROGRESS). This research meets the definition of a clinical trial. A description of this clinical trial will be available on https://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**Privacy and Confidentiality**

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;
- authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the NIH funding for this study ends. Currently this is **December 31, 2021**. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

The researchers will do their best to keep the study information private and confidential. We will label your research information with a study number, and assign you a false name in written transcripts. We will keep any information that might identify you separate from the research information in a secure location. We will destroy any link between the study information and your identity 8 years after data collection has ended.

Audio recordings are included in this study to capture interview data. Your voice may be recognizable on the audio recording. Audio recordings will be transcribed and information that could identify you will be removed. The recordings will be deleted after data analysis.

Video recordings will also be included in this study to score the developmental activities. You and your child's image may be recognizable on the video recording. Video recordings will be deleted after scoring is completed.

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

**Leaving the Study**
You may leave the study at any time, for any reason. Nothing bad will happen if you choose to leave the study. All you have to do is tell the research team you do not wish to be in the study anymore. Research staff may tell you not to continue the study if the study activities are causing you stress. If you leave the study, the research team will keep and use data that has already been collected, unless you ask in writing to remove this data.

**Costs to You**
There are no costs to you to participate in this study other than your time.

**Compensation to You**
You may receive a total of $75.00 in electronic gift cards to your choice of several stores. A gift card for $25 will be emailed to you after each of the three scheduled research visits. Your child will also receive a toy upon completion of the study. In order to receive the gift card, you will need to provide some personal information to the research team.

**In case of Injury/harm**
If you think you have been harmed from being in this research, contact [insert site specific investigator or research coordinator contact information here]. They will refer you to resources for support or treatment.

**Participant Rights**
Being in this study is voluntary. You and your child do not have to be in this study if you do not want to.

- You have the right to change your mind and leave the study at any time without giving any reason. Nothing bad will happen if you leave the study.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will be given a copy of this consent and permission form to keep for your records.
- You do not lose any of your legal rights by giving your consent and permission to be in the study.

By telling us you consent and give permission for your child to be in this study, you agree that this study has been explained to you. You agree that you have had a chance to ask questions. If you have questions later about the research, you can contact the researchers listed on the first page of this form. If you have questions about your rights as a research subject, you can call the [insert institution specific Human Subjects Division contact information here].