



## Informed Consent and HIPAA Authorization Form

**Study Title:** Locomotor learning in infants at high risk for cerebral palsy

**Version Date:** December 19, 2019

**Principal Investigator:** Laura A. Prosser

**Telephone:** (215) 590-2495

Your child may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits to your child of participating.

In the sections that follow, the word “we” means the study doctor and other research staff.

### Study Overview

Your child is being asked to take part in this research study because your child has experienced a brain injury early in life, and is at risk for having cerebral palsy because of this brain injury. Cerebral palsy is a condition that makes it hard for infants to learn how to move and control their balance.

The purpose of this study is to find out how infants who are at risk for cerebral palsy learn to move. We will provide many investigational motor training therapy sessions designed to help infants learn to move. We want to understand how infants who have this study training learn to move.

If you agree to take part, your child’s participation will last for a year and a half and will involve up to 178 study visits (168 study therapy sessions of motor training, and 10 testing visits). Your child will still receive all other medical care as planned and whenever needed. If your child is no longer at risk for cerebral palsy by 3 or 4 months of age, study participation will end before starting the study therapy sessions.

As a participant in the research your child will:

- Have 1 developmental assessment per month for the first 5 months. These visits will include tests of infant movement, and measurement of leg movements using small sensors worn on the ankles. Two of the developmental assessments (at age 3 months and 4 months) will help us to determine if your child is still at risk for cerebral palsy.
- If your child is still at risk for cerebral palsy by 4 months of age (the neonatology team will talk with you about this when the determination is made):
  - Have crawling therapy visits 3 times per week from age 5 to 9 months old. These study therapy visits focus on teaching your infant to crawl using a skateboard-type device.

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- Have walking therapy visits 3 times per week from age 9 to 18 months old. These study therapy visits focus on teaching your infant to crawl using a harness device that supports them.
- Have 6 other developmental assessments during and after the year of study therapy. These visits will include tests of motor function and thinking skills.

The risks of this study are not greater than the risks in daily life. Your child could get bumps or bruises from the study therapy, as during play time. They might get tired from the therapy or the testing.

Your child may benefit if the motor training study therapy is helpful in teaching infants at risk for cerebral palsy how to move.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time. If you do not choose to take part in this study, you can discuss other treatment options with your doctor.

Please see below for additional details about the study.

### **How many people will take part?**

About 60 infants will take part in this study. We expect at least half of them to continue into the study therapy phase.

### **What is the current standard of treatment for this disease?**

For infants who are at risk for cerebral palsy, the current standard is to have some physical or occupational therapy, usually weekly or monthly. This is the standard here at CHOP. Sometimes, the medical team just waits to see if the infant does have cerebral palsy. This is usually known by 1-2 years of age, but this is after the brain has tried to learn how to move the body.

### **What are the study procedures?**

Some of the procedures in this study will be repeated several times. Tests that are part of your child's regular, routine medical care will continue to be performed. The study involves the following tests and procedures.

Medical record review: We will review your infant's medical record to determine if he/she is eligible for the study. We will also review your child's medical records to get information about your child's birth history and medical history.

Developmental Assessments: We will do different types of developmental assessments at different ages. These include tests of infant movement, motor function, and thinking skills, and a neurological exam. These can happen in the hospital, in your home, or at outpatient locations at CHOP.

Leg movement recordings: Once a month for the first 4 months, we will record how your child's legs move using a small sensors on each ankle. Your child will wear leg warmers that hold the sensor in a pouch. These will be worn for two whole days

each month. These can happen in the hospital, in your home, or at outpatient locations at CHOP.

Study therapy sessions: (If your child is still at risk for cerebral palsy by 4 months of age) Study therapy sessions will be 3 times per week, starting at 5 months old. From age 5 to 9 months, study therapy will focus on crawling. We will place your child on a skateboard-type device which may help them learn to crawl. From age 9 to 18 months, study therapy will focus on walking. We will support your child in a harness-type device which may help them learn to walk. The crawling and walking devices measure how your child moves when using them. A pediatric physical therapist will be with your child one-on-one during all study therapy time. Crawling therapy sessions can happen in the hospital, in your home or child care facility, or at outpatient locations at CHOP. Walking therapy sessions will happen at an outpatient location at CHOP.

Videotaping: For one of the infant movement tests, we will video your child laying on his/her back for several minutes. We will also video two study therapy sessions per month so that we can understand how your child moved during the therapy. The cameras on the skateboard device will also capture your child’s efforts during crawling.

### Visit Schedule

The table below provides a brief description of the purpose and duration of each study visit.

Visit	Purpose	Main Procedures	Duration
Visit 1	Screening visit	Medical record review, physical exam	1 hour
Months 1-4 (monthly)	Observe early movement behaviors	Leg movement recordings, 3 developmental assessments	30 minutes – 1 hour
Months 5-9 (3 times per week)	Crawling therapy	Study therapy sessions, 3 developmental assessments, and videotaping	30 minutes (therapy sessions) 1 hour (developmental assessments)
Months 9-18 (3 times per week)	Walking therapy	Study therapy sessions, 3 developmental assessments, and videotaping	30 minutes (therapy sessions) 1 hour (developmental assessments)

### What will be done with my child’s data during this study?

The information we collect about your child’s medical history, movement patterns, study therapy sessions, and development will be stored on secure computer systems or on paper in locked cabinets. We will share the information, including videos, with our research partners at two others institutions. Our research partners at Oklahoma University are

experts in the crawling study therapy and device. Our research partners at University of Southern California are experts in the leg movement recordings.

If you are interested in the results of any of the developmental assessments that we do, we will share them with you. They will not be used for decision making about your child's clinical care at CHOP.

## **What are the risks of this study?**

Taking part in a research study involves inconveniences and risks. The main risks of taking part in this study are discussed below.

### **Risk of bumps, bruises or falls during study therapy**

It is possible that infants could get bumps or bruises, or bang into toys during study therapy. They could also lose their balance and fall during the walking therapy. We will not prevent your child from making mistakes or losing his/her balance, because this might be an important part of learning to move, but we will protect your child from getting hurt. Your child will be supervised at all times by a licensed pediatric physical therapist during study therapy sessions, and by a physical therapist or trained study team member during all developmental assessments. The environment will also be prepared such that only items safe for infants will be in the testing and play areas.

### **Risk of frustration during study therapy or developmental assessments**

If your child becomes frustrated while attempting movements or activities that are hard for them, you and the therapist can attempt to calm them. We use positive reinforcement to encourage the infants, and you will always be able to talk to and touch your child. If he or she continues to be uncomfortable or upset, you can pick up your child, feed him/her, or we can end the session and try again on another day.

### **Risk of discomfort from leg movement sensors, crawling device, or walking device**

If your child is uncomfortable with any of the technology (such as the leg sensors, the crawling device or the walking harness), we will reposition them on your child until comfortable. The leg sensors are held in place by special leg warmers that have a pocket to secure them. There will be fabric between the sensor and your child's skin. The skateboard like device for crawling supports the infants, including their head, while they lay on their belly. We will allow time for your child to get used to lying on the skateboard. The harness device for walking has several different straps that we can adjust for comfort. Infants wear clothing under the harness. We have used all of these devices in the past with many infants, and generally infants are comfortable using them.

### **Risk of a breach in medical support**

If your child relies on life-sustaining medical equipment, such as an oxygen mask or ventilator, there is the risk of a breach in the medical support during the study, similar to any risk during therapy sessions, nursing care or floor play time. A trained caregiver will be required to accompany your child at all times during the study.

### **Risk of loss of privacy or confidentiality**

As with any research study, there is the possibility of a loss of privacy or confidentiality. Every precaution will be taken to secure your child's personal information to ensure confidentiality. Your child will be assigned a study identification number. This number will be used on all research data instead of their name or other private information. All data and videos will be stored on secure systems designed to protect privacy.

### **Risk of identifying an unrelated concern for a child's safety**

If we visit your home for the study therapy sessions, and have any concerns about your or another child's safety, we may raise this concern with a CHOP or Penn social worker or with state or local agencies that could intervene on behalf of the child. If you ever have any concerns about your or your child's safety, please tell us and we will try to help you.

### **Are there any benefits to taking part in this study?**

Your child might benefit from the study therapy sessions by learning how to crawl and walk better than without the study therapy. However, we cannot guarantee or promise that your child will receive any direct benefit by participating in this study. There is no direct benefit to you, the caregiver. The knowledge gained from this research may help doctors and therapists understand how best to help infants at risk for cerebral palsy learn to move.

### **Do you need to give your consent in order to participate?**

If you decide to have your child participate in this study, you must sign this form. A copy will be given to you to keep as a record.

### **What are your responsibilities?**

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study. You will need to try your best to keep the study appointments.

### **What happens if you decide not to take part in this study?**

Participation in this study is voluntary. Your child does not have to take part in order to receive care at CHOP.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

### **Can you stop your participation in the study early?**

Your child can stop being in the study at any time. You do not have to give a reason.

### **Can the study doctor take your child out of the study early?**

The study doctor may take your child out of the study if your child does not tolerate any of the testing procedures or if they cannot complete the testing visits.

### **What choices do you have other than this study?**

There are options for your child other than this study including:

- Receiving just routine therapy services outside of this study.

- Not participating in this study.
- You may discuss other options available to you with your doctor.

### **What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?**

As part of this research, health information about your child will be collected. This will include information from medical records, physical exams, leg movement recordings, study therapy sessions, and videos. Some information related to the physical exams and study therapy sessions will go in your child's medical record. Medical records are available to CHOP staff. Staff will view your child's records only when required as part of their job. Staff are required to keep your child's information private. Information that could identify your child will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We will do our best to keep your child's personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your child's personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your child's identity private in any publication or presentation. We will only show videos of your infant if you give us your consent to use them for education or scientific purposes.

Several people and organizations may review or receive your child's identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP;
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.
- The National Institutes of Health who is sponsoring this research;
- Your child's data/videos will be shared with our research partners at Oklahoma University and University of Southern California, who will help us analyze the results of this research. Your child's data/videos will be labeled with a unique study number and the visit date. We will not share any private information (such as full name or medical record number) with our research partners that they do not need to know to help analyze the research data. However, they will be able to see your child's face in the videos, they will know your child's age, and they may know your child's first name if the therapists use it when talking to your child during the study therapy sessions.
- If you agree, your child's data will be shared through databases that may be publicly available to anyone. The data will not include identifiers like your child's name, medical record number, date of birth or videos. To use your child's data, researchers must promise not to try to re-identify your child. You can tell us at the end of this form whether you will allow us to share your child's data in this way.

By law, CHOP is required to protect your child's health information. The research staff will only allow access to your child's health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your child's health information for this research. Some of the organizations listed above may not be required to protect your child's information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

### **Certificate of Confidentiality (CoC)**

A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your child's identifiable information. A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies your child will not be shared outside this research.

- No one can be forced to share your child's identifiable information for a lawsuit.
- Your child's information can't be used as evidence even if there is a court subpoena.

If you consent, your child's data could be shared for other scientific research.

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The National Institutes of Health may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

### **Can you change your mind about the use of personal information?**

You may change your mind and withdraw your permission to use and disclose your child's health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Laura A. Prosser  
The Children's Hospital of Philadelphia  
Division of Rehabilitation Medicine  
34<sup>th</sup> Street and Civic Center Blvd.  
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your child's health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your child's personal health information, your child will be withdrawn from the study.

## **Financial Information**

While you are in this study, the cost of your child's usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

### **Will there be any additional costs?**

There will be no additional costs to you by taking part in this study, except for the cost of travel to CHOP for the outpatient study visits.

The National Institutes of Health is providing financial support and material for all experimental procedures, as listed above, for this study. The following research procedures and study visits will be paid by the National Institutes of Health:

- Developmental assessments done just for the study
- Leg movement recordings
- Crawling and walking study therapy sessions

### **Will you be paid for taking part in this study?**

- Caregivers will be paid for their time and effort. They will be paid \$25 for the completion of each developmental assessment (maximum of 10, \$250). For the study therapy sessions, caregivers will be paid \$50 per month when attendance exceeds 50% of planned training sessions, and \$25 per month when attendance is less than or equal to 50% (maximum of \$650 for 13 months).
- Children/participants will occasionally receive small tokens of appreciation for their time and effort (i.e. stickers, small toys).

You will receive payment using a bankcard, and the bank will have access to identifiable information. The bank will not have access to any medical information. If payment to you exceeds \$600 in a calendar year, you will receive a W9 form and may have tax implications.

### **Who is funding this research study?**

The National Institutes of Health is providing funding for this study.

## **What if you have questions about the study?**

If you have questions about this study or how your child's data are going to be used, call the study doctor, Dr. Laura Prosser at 215-590-2495. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

A description of this clinical trial will be available on <http://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.

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## **What will be done with my child's data when this study is over?**

We will use and may share data for future research. This includes sharing data in databases supported by the National Institutes of Health for future research. They may be shared with researchers/institutions outside of CHOP. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from all of your child's data except for the videos, which means that nobody who works with the data for future research will know who your child is. Therefore, you will not receive any results or financial benefit from future research done with your child's data.

However, we will not be able to remove images of your child's face from the videos, which could be used to identify them. Therefore, we will ask for your consent separately to be able to share your child's videos with anyone outside of the study team.

## **Optional Consent for Use of Identifiable Videos for Future Research, Scientific and Educational Purposes**

### **Future Research**

As part of the study, we will collect videos as described above. The videos will help us understand how your child moves and how he/she is learning to move his body. We will store these videos in a database called Databrary, which is a video library funded by the National Science Foundation and the National Institutes of Health for sharing videos on developmental and behavioral research. We will store the videos from this study in Databrary because it has room to store large videos and so that our research partners can view them. They will be private and only accessible to our study team for this research. At the end of the study, and if you agree, we can choose to make the videos available to other researchers who use Databrary. Other researchers outside of CHOP may be interested in learning information from the videos we take of your child during study therapy. Databrary access is limited to Authorized users. Users must sign the Databrary Investigator Agreement and have their agreement co-signed by their Institution or Sponsor to become authorized. Data are only visible if they have been: (a) released by the participants for sharing in Databrary and (b) released for sharing by the contributing researcher. If you do not want us to share your child's videos with other researchers at the end of the study, we will keep them private. You do not have to agree to have your child's videos shared to participate in this study.

### **Scientific and Educational Purposes**

The videos (or photos from a single frame of video) we take during the study may be useful to show other health care workers about our research and the therapy we do. If you agree, we might show your child's videos during educational lectures, medical conferences, or research publications. We will not use your child's name or any other private information if we show the videos, but they might include images of your child's face which could be used to identify them. You do not have to agree to let us use your child's videos or images in this way to participate in the study.

A number of different groups of people could see these images or video recordings, including members of the general public, scientists and medical researchers. Although

these images/video recordings will be used without your child's name, it is possible that someone might recognize your child.

If images/recordings are shared with or released to other individuals or organizations, the recipients could use, distribute, broadcast and/or publish them in ways that do not protect your child's privacy and that CHOP cannot control. If you change your mind about taking part in this study after recording or filming is done, images/recordings that were released outside of CHOP may continue to be used. You will not be paid for the use or release of the images/recordings.

If you leave the study, you can ask to have the data collected about your child removed or destroyed. You can also ask us to remove information that identifies your child from the data. This may not be possible if your child's data have already been shared.

Please indicate whether you will allow identifiable videos to be used for **future research** by putting your initials next to one of the following choices:

\_\_\_\_\_ (initials) NO, my child's identifiable videos may not be used for future research.  
They may be used for this study only.

\_\_\_\_\_ (initials) YES, my child's identifiable videos may be used for other future research studies.

Please indicate whether you will allow identifiable videos to be used for **scientific and educational purposes** by putting your initials next to one of the following choices:

\_\_\_\_\_ (initials) I agree to allow videos and photos of my child to be used for scientific and educational purposes.

\_\_\_\_\_ (initials) I do not agree to allow videos and photos of my child to be used for scientific and educational purposes. They can be used for the research only.

## Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

\_\_\_\_\_  
Person Obtaining Consent

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your child's participation. You are also authorizing the use of your/your child's health information as discussed above. If you don't agree to the collection, use and sharing of health information, you cannot participate in this study. **NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

\_\_\_\_\_  
Name of Subject

\_\_\_\_\_  
Name of Authorized Representative

\_\_\_\_\_  
Relation to subject:

Parent  Legal Guardian

\_\_\_\_\_  
Signature of Authorized Representative

\_\_\_\_\_  
Date

**STUDY SUMMARY SIGNATURE PAGES**  
**For Subjects with Limited English Proficiency**

**Consent to Take Part in this Research Study and Authorization to Disclose Health Information**

\_\_\_\_\_  
Name of Subject

\_\_\_\_\_  
Name of Authorized Representative  
(if different than subject)

\_\_\_\_\_  
Relation to subject:  
 Parent       Legal Guardian

The research study and consent form have been explained to the subject or parent/legal guardian. By signing this form, you are indicating that you have answered the subject's or parent's/legal guardian's questions, they have agreed to take part in this research study and they are legally authorized to consent to their or their child's participation. They have also agreed to let CHOP use and share their or their child's health information as explained above. If they don't agree to the collection, use and sharing of their or their child's health information, they cannot participate in this study.

\_\_\_\_\_  
Person Obtaining Consent

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date:

**Witness/Interpreter**

By signing this form, you are indicating that

- The information in the Summary Document as well as any additional information conveyed by the person obtaining consent was presented to the subject in a language preferred by and understandable to the subject; and
- The subject's questions were interpreted and the responses of the person obtaining consent were presented in a language preferred by and understandable to the subject.
- At the conclusion of the consent conference, the subject was asked in a language preferred by and understandable to the subject if s/he understood the information in the Summary Document as well as any additional information conveyed by the person obtaining consent (including responses to the subject's questions) and responded affirmatively.

\_\_\_\_\_  
Name of Witness/Interpreter

\_\_\_\_\_  
Signature of Witness/Interpreter

\_\_\_\_\_  
Date: