

## **PARENT/GUARDIAN INFORMATION STATEMENT** **AND CONSENT FORM**

**HREC Project Number:** 0830424 (University of Melbourne), 28148 (Royal Children's Hospital)

**Research Project Title:** Patient-specific Computational Tools for Diagnosing and Treating Gait Disorders in Children with Cerebral Palsy

Thank you for taking the time to read this Information Statement. This Information Statement and Consent Form is 5 pages long. Please make sure you have all the pages, as well as the Information Sheet for Kids.

Your child is invited to participate in a research project that is explained below.

### **What is an Information Statement?**

These pages tell you about the research project. It explains to you clearly and openly all the steps and procedures of the project. The information is to help you to decide whether or not you would like your child to take part in the research.

Please read this Information Statement carefully. You can ask us questions about anything in it. You may want to talk about the project with your family, friends or health care worker.

Participation in this research project is voluntary. If you don't want your child to take part, you don't have to. You can withdraw your child from the project at any time without explanation and this will not affect their access to the best available treatment options and care from The Royal Children's Hospital.

Once you have understood what the project is about, if you would like your child to take part please sign the consent form at the end of this information statement. You will be given a copy of this information and consent form to keep.

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### **1. What is the research project about?**

Walking uses several key muscles. Children who have cerebral palsy (CP, a condition that results from brain damage around the time of birth) have difficulties using their leg muscles. They don't walk like children who don't have CP. They often need surgery or other treatments. The doctors need to know which muscles are causing problems. We want to know more about how and why the muscles are making walking tough for these children. We need to compare children with CP with children who don't have CP, which is where your child can help us.

Thirty children will be taking part in this project, twenty with diplegic CP, and ten children who don't have CP. All the children will be between 7 and 12 years old. The information will help us understand why children with CP walk the way they do, and may lead to better treatment for children with CP.

### **2. Who are the researchers?**

- Professor H. **Kerr Graham**, Orthopaedic Surgeon at the Royal Children's Hospital (ph:9345 5399)
- Professor **Marcus Pandy**, Chair of Mechanical and Biomedical Engineering at the University of Melbourne, , and supervisor for Tomas Correa's PhD (ph: 8344 4054)
- Associate Professor **Richard Baker**, Gait Analysis Service Manager at the Royal Children's Hospital (ph: 9345 5354)
- **Tomas Correa**, Graduate Research Student, Department of Mechanical Engineering at the University of Melbourne (ph: 8344 3910)

### **3. Who is funding this research project?**

This project has been fully funded by an Australian Research Council Discovery Grant.

### **4. Why is my child being asked to be in this research project?**

We are asking your child to be involved because he/she walks normally and is between 7 and 12 years old. In this project we will compare data from children who don't have CP against data from children with CP. Your child can be in the project if he/she does not suffer from claustrophobia (fear of being in small places).

### **5. What does my child need to do to be in this research project?**

You and your child will come to the Royal Children's Hospital (RCH) for one visit, and will be there for up to four (4) hours. You and one of the researchers will be with your child at all times.

#### *Gait Analysis*

We will carry out a 3D gait analysis of your child's walking at the Hugh Williamson Gait Analysis Laboratory. It will take up to three (3) hours. Your child will wear shorts and a singlet. We will stick about 30 small reflective markers onto their skin, mostly on their legs and hips, using adhesive tape. We may attach several small electrodes to their skin to record the activity of leg muscles. Your child will do several simple movement tasks, including walking. They will be video recorded during several trials. Your child may take as long as they like, and will be provided drinking water between trials.

We will also measure your child's height, weight, leg lengths and alignments, and how flexible their joints are.

#### *MRI Scan*

We will take an MRI scan of your child's lower body at the Department of Medical Imaging. It will take up to one (1) hour.

MRI stands for magnetic resonance imaging. A MRI scanner is a machine that uses electromagnetic radiation (radio waves) in a strong magnetic field to take clear pictures of the inside of the body. Electromagnetic radiation is not the same as ionising radiation used, for example, in X-rays. The pictures taken by the machine are called MRI scans. The data is used for modelling the position of muscles and bones relative to each other, and therefore plays an important role in this study.

We will ask your child to lie on a table inside the MRI scanner. The scanner will record information about your child's hips and legs. The MRI scan does not hurt. It is very important that your child keeps very still during the scanning. When your child lies on the table we will make sure he/she is in a comfortable position so they can keep still. The scanner is very noisy and we can give your child some earphones to reduce the noise.

Your child can watch a favourite video or listen to a CD during the scanning process.

We will also ask for your consent for your child's information (gait data and MR images) to be used by one other researcher, a post-doctoral fellow working with us on a similar project at the Department of Mechanical Engineering at the University of Melbourne, with Ethics approval from the same institutions.

### **6. What are my child's alternatives to taking part in this project?**

Your child does not have to be in this project. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. Any care or treatment that your child might be having now, or might need in the future, at the Royal Children's Hospital will not be affected by your decision. You may also withdraw any data that has been collected from your child at any time.

### **7. What are the possible benefits for my child?**

There is no direct benefit to your child. You and your child may feel a sense of satisfaction from taking part in and contributing to medical research. You will be provided with a copy of the MRI images if you want.

## **8. What are the benefits for other people in the future?**

The information that your child provides us will help us understand the reasons why children with cerebral palsy walk the way they do. This will hopefully lead to better treatment for children with CP.

## **9. What are the possible risks, side-effects and/or discomforts?**

### *MRI Scans*

There are no proven long-term risks related with MRI scans, as used at The Royal Children's Hospital in this project. MRI is considered a safe procedure when performed at a centre with appropriate guidelines. However, the magnetic attraction for some metal objects can pose a safety risk, so it is important that metal objects are not taken into the scanner room.

We will thoroughly examine your child to make sure there is no reason for your child not to have the scan. You or your child must tell us if your child has metal implanted in their body, such as a pacemaker, or metal pins after being involved in an accident.

If your child has not had a previous MRI scan done, it is possible that your child may be a little anxious about the procedure for the first time. In order to make your child more comfortable with the MRI procedure, your child can practice in a pretend scanner to begin with. A staff member from the hospital will contact you and your child to ask a few questions about your child to determine whether or not this needs to be done. The purpose of the pretend scan is so your child can become used to the position they will be required to maintain when in the real scanner and so your child can hear the typical noises of the real scanner. Both yourself and a staff member at the hospital involved in this project will be present at all times during this process.

### *What happens if something unusual is found in my child's scans?*

The scans we are taking are for research purposes. They are not intended to be used like scans taken for a full clinical examination. The scans will not be used to help diagnose, treat or manage a particular condition. A specialist will look at your child's MRI scans for features relevant to the research project. On rare occasions, the specialist may find an unusual feature that could have a significant risk to your child's health. If this happens, we will contact you to talk about the findings.

In the unlikely event that we find an unusual feature, it could have consequences for your child. It might affect your child's ability to work in certain professions, or get life or health insurance. However, if we do find an unusual feature and tell you about it, your child may be able to get treatment that might be of benefit.

We cannot guarantee that we will find any/all unusual features.

Please take time to consider the advantages and disadvantages of discovery of a health risk before deciding to take part in this research project.

### *Gait Analysis*

Whilst very unlikely, it is possible that your child's skin may be slightly irritated by the special tape used to hold the reflective markers onto the skin. If this does happen, it will settle quickly. Skin cream will be available if required, and your child can see a doctor if necessary.

If electrodes are used in your child's gait analysis session, they may cause some skin irritation, resulting in a slight stinging sensation. If required, antiseptic gel will be applied to reduce the stinging sensation. We will stop testing if your child is upset by discomfort or pain experienced.

### *New Information / Unknown Risks*

During the research project, we may learn new information about the risks and benefits of this project. If this happens, we will tell you about this new information. This new information may mean that you can no longer participate in this research. If this occurs, the person(s) supervising the research will stop your participation. In all cases, we will offer you all available care to suit your needs and medical condition.

There may be unforeseen or unknown risks. In the unlikely event that you (your child) suffer(s) an injury because of participating in this project, the public health service will provide hospital care and treatment at no cost to you.

## 10. What are the possible inconveniences?

The MRI scan could be inconvenient because your child must remain very still while in the scanner. There is also a lot of machine noise during scanning. Other inconveniences might be the time taken for travel, the requirement to take time off school or work, and parking or public transport costs.

## 11. What will be done to make sure my child's information is confidential?

Any information we collect from your child will remain confidential. Only the researchers involved with this project, one other post-doctoral research fellow (working on a similar project at the Department of Mechanical Engineering at the University of Melbourne), the Royal Children's Hospital Ethics Committee, and the University of Melbourne Ethics Committee can have access to this information. We can disclose the information only with your permission, except as required by law.

You and your child have the right to look at, and ask correction of, your child's information in accordance with the Freedom of Information Act 1982 (Vic).

The information will be re-identifiable. This means that we will remove your child's name and give the information a special code number. Only the research team can match your child's name to his/her code number, if it is necessary to do so.

All information will be stored securely in a locked filing cabinet in the Department of Mechanical Engineering at the University of Melbourne and the Hugh Williamson Gait Laboratory at the Royal Children's Hospital. Your child's information will also be stored on a password-protected computer database.

We will keep your child's information until the youngest participant in this project turns 25 years old. After this time, we will destroy the information.

When we write or talk about the results of this project, we will report information about the whole group of participants. This means that no one will be able to identify your child or your family.

We do plan to present information from this project at conferences and in professional journals. This will be done in a way that does not identify your child.

## 12. Will we be informed of the results when the research project is finished?

At the end of the study, we will send you a summary of the results, without technical terms. This will not identify individuals.

If you would like more information about the project or if you need to speak to a member of the research team in an emergency please contact:

**Name:** Tom Correa

**Contact telephone:** 03 8344 3910 or [t.correa@pgrad.unimelb.edu.au](mailto:t.correa@pgrad.unimelb.edu.au)

Should you have any concerns about the conduct of the project, you are welcome to contact the Executive Officer, Human Research Ethics, University of Melbourne, on Ph: 8344 2073; or Fax: 9347 6739

If you have any concerns about the project or the way it is being conducted, and would like to speak to someone independent of the project, you are welcome to contact:

Head of Department  
Ethics and Research Department  
Human Research Ethics Committee  
The Royal Children's Hospital  
Telephone: (03) 9345 5044

OR

Executive Officer  
Human Research Ethics  
University of Melbourne  
Telephone: (03) 8344 2073  
Fax: (03) 9347 6739

**CONSENT FORM FOR PARENT/GUARDIAN TO GIVE INFORMED CONSENT  
FOR THEIR CHILD TO TAKE PART IN A RESEARCH PROJECT**

**HREC Project Number:** 0830424 (University of Melbourne), 28148 (Royal Children's Hospital)

**Research Project Title:** Patient-specific Computational Tools for Diagnosing and Treating Gait Disorders in Children with Cerebral Palsy

**Names of investigators:** Professor H. Kerr Graham, Professor Marcus Pandy, Associate Professor Richard Baker, Tomas Correa

I (Parent/Guardian name) \_\_\_\_\_

of (child's name) \_\_\_\_\_

voluntarily consent for my child/dependent to take part in the above research project

- I believe I understand the purpose, extent and possible effects of my child's involvement in this project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I consent to the use of my child's gait dataset (marker movement, force plate data, and perhaps EMG data) and MR images for this project by the named researchers and to the use by one other post-doctoral fellow.
- I acknowledge that my child will be videotaped during the 3D gait analysis procedure
- I understand that this project has been approved by The Royal Children's Hospital Human Research Ethics Committee and the University of Melbourne Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
- I understand I will receive a copy of this Parent/Guardian Information Statement and Consent Form.

**Parent/Guardian Signature** \_\_\_\_\_ **Date** \_\_\_\_\_

Print name of witness to parent/guardian's signature \_\_\_\_\_

**Witness Signature** \_\_\_\_\_ **Date** \_\_\_\_\_

I have explained the project to the parent/guardian who has signed above, and believe that they understand the purpose, extent and possible effects of their child's involvement in this project.

**Researcher Signature** \_\_\_\_\_ **Date** \_\_\_\_\_

Note: All parties signing the Consent Form must date their own signature.