

## Information Sheet

### Do Our Genetics Contribute to Cerebral Palsy? A Genomic Basis for Cerebral Palsy – Studies in a Large Australian Cohort

#### Background

Approximately one in every 500 children born in Australia has cerebral palsy. It is now recognised that most cases of cerebral palsy are associated with factors present before labour begins, and are not the result of events occurring during labour and delivery as previously thought. However, what actually causes cerebral palsy is still not clear, so it is important to conduct more research into possible basis of cerebral palsy.

#### What This Study Adds

Our team is interested to discover whether cerebral palsy is associated with hereditary (inherited) susceptibility to infection in the fetus or mother and/or in some cases clotting disorders (where blood clots too easily in the blood vessels). Our study looks for genetic markers (genes) linked with these by using a swab of skin cells taken from the inside of the cheek of the mother and the child. We will compare the results of these genetic markers from 2,500 children with cerebral palsy and their mothers with 2,500 children without cerebral palsy and their mothers. The results of our study may lead to prevention of cerebral palsy in the future.

#### Your Involvement

Cerebral palsy occurs in all ethnic groups, however for statistical and scientific reasons it is only feasible for us to study Caucasian families in this particular study. By Caucasian families, we mean where both parents of the child are of European origin. Please ignore this request if you do not think you are eligible.

We request permission:

1. For you to take a small sample of cheek cells from you and your child, using a buccal swab kit. This is a painless procedure which involves rubbing a special swab on the inside of your cheek in your mouth and then placing it back into a container to be posted back to the research team. This would be at no cost to you, as we will provide reply paid envelopes for you to post the samples back to us.
2. For the mother to complete a short questionnaire about her medical and pregnancy history. When answering the questionnaire provided, please note that each piece of information we ask for is not necessarily a cause of cerebral palsy. For example we may ask about you taking medicines during your pregnancy. This does not mean we expect these medicines to cause cerebral palsy, we are simply interested in identifying an association and this may or may not be causal.
3. If necessary, to review the case notes of mother and child to collect basic clinical information, of which you may not be certain, about the pregnancy and birth and again if your child requires re-admission to hospital. This information is confidential. When collected it will be linked only by a code number to our research results which does not reveal your identity.
4. For us to review data collected on the Supplementary Birth Record form, a form filled in by midwives after each birth. This form also contains basic clinical information about the pregnancy, birth and hospital stay. These records are kept by the State Perinatal Data Collection Unit, and are also confidential. When collected it will be linked only by a code number to our research results.
5. Every baby born in Australia has blood taken and screened for many disorders, such as cystic fibrosis. We are also seeking your permission to retrieve and sample your child's newborn screening card (Guthrie Card). This old heel prick blood spot taken after birth will be tested for evidence of exposure to viral infection, and these results linked with the buccal swab test results. Consent for this part of the study is independent of the buccal swab consent. You can consent for one or both parts of the study.
6. **For families with a child who has cerebral palsy only:** Lastly we request permission to access the clinical information collected by the Cerebral Palsy Register as part of your involvement in this register. This information is confidential, and will be linked only by a code number to our research results. At all times, the research results will not identify the families involved.

## Your Privacy and Access to Results

In accordance with the above guidelines:

- You are free to refuse consent for this research without giving any reasons. You may withdraw from the research project at any stage. Refusal to participate will not affect you or your child's medical care.
- Your information will remain confidential except in the case of a legal requirement to pass on personal information to authorised third parties. This requirement is standard and applies to information collected in both research and non-research situations. Such requests to access information are rare; however we have an obligation to inform you of this possibility.
- This research does not detect non-paternity (e.g. who is the father).
- There is an option for you to allow your samples to be retained and used in future research projects, provided these projects have the approval of the Children, Youth and Women's Health Service Research Ethics Committee. If you agree to this, your samples will be archived in a de-identified manner, and not linked back to you or your child. If you do not agree to this, any remaining samples will be destroyed in accordance with the hospital's guidelines for the safe disposal of biological specimens when the research is complete.
- Data arising from this research is required to be retained for 15 years, in a secure facility.
- You will not receive any payment for your participation in this research study. We have designed this study so that the impact on your time is minimal, and no hospital visits are required. No invasive tests will be performed. Our research is mostly directed to improving understanding of disease. Sometimes the research will lead to findings that result in the development of a commercial test or treatment that may be overseen by pharmaceutical companies. Australian law indicates that there is no financial reward or payment to you in such an event.
- Analysis of results and their possible future clinical relevance will take about 4 years. A few of the tests in a small minority of children may have potential relevance to that individual's future health e.g. if a hereditary tendency to thrombosis (clotting) is suspected. In such cases it is possible for you to state now that you would like to be notified if such a possible clinically relevant result is obtained. It would be necessary for any test result to be re-checked by your doctor or specialist. Specific counselling about the ramifications of being tested and acting on that result would be offered at the time of notification. Alternatively you can request that all results are permanently disconnected from you and your child's details (i.e. de-identified without connecting codes) and that you receive no further information about your family's results. Where you have asked for a coded identification link to remain so that potentially relevant results can be offered to you, this information will not be released for other use without consent, unless required by law.
- It should be clearly understood that individual results (other than where there is a risk of thrombosis) cannot be identified and returned to you as their clinical relevance is not yet known.
- You may request a lay summary of the overall study findings.

Please feel free to discuss the research in detail with the investigating team who have approached you. Where possible the consent of both of you and your partner is requested and we encourage you to discuss participation with your child. This research is conducted with the permission of the Adelaide Children, Youth and Women's Health Service Research Ethics Committee. If you have any concern, complaint or wish to discuss this committee's approval process please phone the secretary of the Ethic's committee, Ms Brenda Penny, 8161 6521. The research is conducted within the guidelines of the National Health and Medical Research Statement on the Ethical Conduct in Research involving Humans (1999).

We thank you for considering participation in this research project which may help determine the causes of cerebral palsy. This knowledge may lead to the prevention of these problems.

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