Queensland Government
Children's Health Services

THE UNIVERSITY of ADELAIDE

Parent/Guardian Information Sheet
The Australian Cerebral Palsy Biobank

Investigators:

Dr Lisa Copeland, Queensland Paediatric Rehabilitation Service, Lady Cilento Children's Hospital

Professor Alastair MacLennan, Professor Eric Haan and Professor David Adelson
The Australian Cerebral Palsy Research Group, The University of Adelaide

The Queensland Paediatric Rehabilitation Service at the Lady Cilento Children's Hospital is working with the Australian Cerebral Palsy Research Group at the University of Adelaide to recruit participants and their families to help build a biobank for cerebral palsy.

Background

In Australia, there are around 34,000 people living with cerebral palsy. Approximately one in 400 children born in Australia has cerebral palsy – the most common motor disability of childhood. It is now recognised that most cases of cerebral palsy are associated with factors present before labour begins, and not as a result of events occurring during labour and delivery. Research in the field of cerebral palsy is vast and rapidly changing as new technologies emerge. Our research team wishes to build a biobank of DNA from consenting families with a child who has cerebral palsy for continuing international research collaborations. Our objective is to understand how cerebral palsy develops, and how we can ultimately prevent it.

How will my samples and personal information be used?

By participating in the biobank, families consent to the DNA and medical information they provide being stored indefinitely and used in ongoing and future cerebral palsy research. We will use modern genetic testing to look for changes in the DNA from all participants that may explain the causes of cerebral palsy in participating families. The investigators responsible for this biobank (the custodians) will ensure that each research project will be assessed for its scientific merit, has appropriate funding and has approval from a human research ethics committee.

The field of cerebral palsy research is large and genetic technologies are rapidly changing, so it is impossible for us to predict what research ideas will develop in the future. Examples of our recent research collaborations include: using the latest genetic technologies to further understand possible genetic causes of cerebral palsy, patterns of inheritance of cerebral palsy within families and studies to better understand the interactions between genetic and clinical characteristics, to name a few. Projects currently underway can be seen at our website (see below).

What is a biobank, and what is its purpose?

A biobank is a collection (repository) of biological samples that can be linked to other medical information for research purposes, while appropriately maintaining the privacy of participants.

By collecting and storing genetic material (DNA from biological samples such as blood) from children with cerebral palsy and their families, and linking characteristics of this DNA to clinical information about their health, we hope to create a powerful and ongoing research tool that may contribute to important discoveries about the condition. The Australian Cerebral Palsy Biobank has been established to encourage collaborative genetic research in cerebral palsy around the world and into the future.

Who can participate in the study?

Children with cerebral palsy, their mother and father, and where available a sibling without cerebral palsy (aged 5-18 years) and with the same parents.

Most children recruited to this biobank will be aged 5 yrs and over. Participation will also be invited where cerebral palsy has been clinically confirmed at a younger age (2 upwards) and blood sampling is available. A sibling without cerebral palsy is an important genetic control and must be aged at least 5 yrs - if potential genes of relevance are discovered in the cerebral palsy affected child and are not present in the sibling, it may help to explain the cerebral palsy in your family.

If you agree to participate we will:

1. Collect a blood sample (11mL, approximately 1 tablespoon) from the child with cerebral palsy, and 9mL from each of their: mother, father, and where available, a sibling without cerebral palsy (aged 5-18 years) and with the same parents.

   Samples will be collected under anaesthetic or sedation for children who may be booked in for a procedure in hospital by prior arrangement. Samples can also be taken by an experienced and qualified research nurse for children who do not require anaesthetic and for parents. A topical local anaesthetic (EMLA) can be offered for these children to minimise discomfort. The entire blood sample will be collected with only one attempt for all children.

   The blood sample will also be used to provide a high quality sample of DNA required for many new genetic tests, and both blood and DNA will be stored in the biobank for future cerebral palsy research.

2. Provide some of the blood collected from your child with cerebral to a research facility called 'Genetic Repositories Australia' (GRA). GRA has the expertise to extract and store high quality DNA for us. They will do this by taking white blood cells from the original blood sample provided and keeping these growing in a special medium to provide an ongoing supply of DNA for our cerebral palsy research - this is called a lymphocyte cell line. This means that we shouldn't need to come back and ask you for more blood later.

   GRA processes samples for a whole range of diseases to improve outcomes, and is supported by the National Health and Medical Research Council of Australia. *See extra information sheet and consent form for this - we apologise for the large amount of reading.* As explained in the GRA information statement, the stored DNA from the cell line is anonymous i.e. not linked to your personal details, and may be provided in a completely non-identifiable way by GRA to other researchers (with ethics committee approval) for research in any medical disorder, not only cerebral palsy. This is a condition of our use of GRA services for our research, and is clearly explained in the GRA Participant Information Statement under 'How are GRA samples used?

   There is a rare possibility (around 1 in 500) that other researchers or our own research group may find a health condition or another clinically significant finding that may affect your or your child's health now or in the future. You will need to decide if you wish to be informed of such a finding. You will need to indicate your decision on both the GRA and Biobank consent forms provided.

3. Ask the mother to complete a short questionnaire (approximately 10 minutes) about her medical and pregnancy history connected to the child with cerebral palsy that includes basic demographic, family and obstetric history data in addition to that available from the pregnancy outcome records and cerebral palsy register. Information sought will include health and education in your child's family, diagnosis of CP, other health conditions (e.g. epilepsy, intellectual disability, vision and hearing impairment), along with information about pregnancy, labour and birth (e.g. gestational age, birth weight, Apgar scores).

4. Access and store the following clinical and medical information:

   - Supplementary Birth Record Forms for both the child with cerebral palsy and their sibling. This is 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.

- Clinical information collected by the relevant Cerebral Palsy Register about the type of cerebral palsy and details of diagnosis, if appropriate.
- Blood spots from your child's newborn screening (Guthrie) card, if necessary.
- Any other clinical/medical information that may be relevant to cerebral palsy research, which may include as yet unspecified data linkages.

You can consent to any or all of these extra clinical information requests. All data obtained through these data linkages 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 individuals or families involved.

Are there any benefits for my child participating in the study?

There are no known benefits for your child in participating in this study of for other family members. By providing a blood sample from which we can extract the participant's DNA, and linking this with other medical information, we hope to discover links that provide more information about the origins and development of cerebral palsy.

Are there any side-effects and risk associated with this study?

Collection of a blood sample from a vein in the arm can be painful and bruising can occur. Samples will be mainly collected from children with cerebral palsy under anaesthesia or sedation. Samples can also be taken by an experienced and qualified research nurse for children who do not require anaesthetic and for parents. A topical local anaesthetic (EMLA) can be offered for these children to minimise discomfort.

Your Privacy and Confidentiality

- The biobank is located at the University of Adelaide, Discipline of Obstetrics and Gynaecology research facilities and will store: blood samples, DNA samples, dried blood spots from Guthrie Cards and clinical data (collected from you and your child/children's medical records, perinatal records and cerebral palsy register) that are stored in a completely confidential manner. This means that any information that reveals your personal identity will be removed from the samples/data, and replaced with a study code.
- You are free to refuse consent for this biobank without giving any reasons, and this will not affect you or your child/children's medical care.
- You may withdraw from the biobank at any stage. If you wish to do so, you will need to download the 'Withdrawal Form' from the website (see below) and post it back to the Biobank Team. There are a number of levels of withdrawal from the Australian Collaborative Cerebral Palsy Biobank you can choose from:
    - *No further contact*: The biobank will no longer contact you directly, but still has your permission to retain and use information and samples previously provided, and to obtain and use further information from your health records or other sources.
    - *No further access*: The biobank will no longer contact you or obtain further information from your health records or other sources, but still has your permission to use previously provided information and samples.
    - *No further use*: The biobank will no longer contact you, or obtain any further information about you. In addition, the biobank will destroy your samples (although it may not be possible to trace all distributed sample remnants). Your signed consent and withdrawal will be kept as a record of your wishes. Such withdrawal will prevent information about you from contributing to further analyses. However, it is not possible to remove your data from analyses that have already been complete, or to withdraw your de-identified DNA samples or data from use or publication where they have already been passed

onto another (third party) researcher for use in an ethically approved project or already been published.

- Your information will remain confidential, however it is important to note, as with all health information kept about you, that there may be circumstances where disclosure of your health information as kept for this study may be required by law, for example, as a result of a court order. 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.
- You will not receive any payment for your participation in this biobank. No hospital visits are required outside the blood sample collection, so that the impact on your time is minimal.

Will you or your child be provided with any results?

Since the results generated from you and your child's samples are primarily for research purposes, we will not be providing results from research conducted using biobank samples where the clinical significance is not well established.

However, there may be rare instances where information of clinical significance (i.e. information which has a significant probability of impacting on the health of you, your child or that of your family) is identified by researchers using samples from the biobank, and we will make every effort to contact you and facilitate the provision of these results using the assistance of appropriate medical channels and/or genetic counselling provided by a general practitioner (GP), clinical specialist and/or State Clinical Genetics Services.

Furthermore, there may be instances where mutations (changes in the genetic code or blue print) are discovered in biobank samples that can help provide an explanation for the cerebral palsy in the individual. In these instances it would be important to share these findings with the family.

Please indicate your wish to be made aware of such findings on the consent form provided. Information about specific research projects being undertaken using the biobank data will be available on our website (see below).

Incidental findings that might affect future health

Very rarely, incidental and known genetic changes (mutations) may be found that might affect the future health of you or your family members. We are specifically looking for mutations that might cause or contribute to cerebral palsy, but it is possible (about a 1 in 500 chance) that we could find a mutation that increases the risk of a cancer or other diseases. You can choose not to be told of this or to be told. If you choose to be told we shall inform you, your GP and a genetic counsellor of your choice. We recommend that the genetic test is repeated and verified. Then depending on your circumstances and the disorder you can be counselled about your future options. Very rarely this result may affect the long-term health of your child and that child could have the option at the age of adulthood (18 years) of knowing or not knowing the result in conjunction with genetic counselling. If you would like to take part in this biobank, please read and sign the consent forms provided. We encourage you as parents to talk about participation with your child/children and to encourage assent from your children aged 7-17 yrs. If your child/children are to take part in this biobank we seek the consent of both parents (where possible).

If you would like any more information about this study please contact your local study co-ordinator on (07) 3086 2950 or a member of the Biobank Team in Adelaide. They will be happy to answer any of your questions:

Chief Investigators Prof Alastair MacLennan, Prof Eric Haan and Prof David Adelson
The Australian Cerebral Palsy Research Group, The University of Adelaide
Phone: (08) 8313 1404

Principle Investigator Dr Lisa Copeland
Queensland Paediatric Rehabilitation Service
Lady Cilento Children's Hospital
Phone: (07) 3068 2950

The Biobank Team Kelly Harper and Jessica Broadbent
Phone: (08) 8313 1404
Email: cerebralpalsy@adelaide.edu.au
Website: www.adelaide.edu.au/cerebralpalsy

This project has been approved by The QLD Children's Health Services (RCH) Human Research Ethics Committee (HREC). If you have any worries or questions about the study or your rights as a participant, or if you wish to make a confidential complaint, at any time, please call the Co-ordinator of the Ethics Committee on (07) 3636 9167. If this phone is unattended, please leave a message and your call will be answered as soon as possible.

This information is for you to keep. We will also give you a copy of the signed consent form.