



Children's Health Services

Investigators:

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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 Un

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 or 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 sh a 7424(be)14()-wes45 ou, ou, tP)-161- w1 -8(en)3(e)1tic-13(c

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:

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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.