

Parent / Guardian Information Sheet

Study Title	NeuroCONNECT: The SCHN Registry for Neurological Disorders
Principal Investigator/s	<p>Prof. Russell Dale & Dr Richard Webster The Children’s Hospital at Westmead Ph: 02 9845 2006 E: Russell.dale@health.nsw.gov.au ; Richard.webster@health.nsw.gov.au</p> <p>A/Prof Michelle Farrar & Dr Hugo Sampaio Sydney Children’s Hospital Ph: 02 9382 1549 E: m.farrar@unsw.edu.au ; Hugo.Sampaio@health.nsw.gov.au</p>
NeuroCONNECT Team	This registry was established on behalf of all neurologists of the Sydney Children’s Hospital Network, who will be the part of the collaborative NeuroCONNECT Team.
Main Study Contact Person	<p>Kristine Concepcion The Big Brain Project, Kid’s Neuroscience Centre Sydney Children’s Hospital Network E: Kristine.Concepcion@health.nsw.gov.au</p>

This Participant Information Sheet is 4 pages long. Please make sure you have all the pages.

1. Invitation to Participate

Your child is invited to participate in the project, **NeuroCONNECT: The Sydney Children’s Hospital Network (SCHN) Registry for Neurological Disorders**.

This information sheet tells you about the study. It explains the processes involved in participating in a registry. Knowing what is involved will help you decide if you want your child to take part in the study. Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about.

Once you understand what the project is about and if you agree to take part in it, you will be asked to provide your consent electronically. Through the online consent, you indicate that you understand the information given and that you consent on behalf of your child to participate in the research project.

If you would like a hard copy of this document, we can provide one for you.

2. What is the registry about?

A registry is a collection of information about individuals who have a specific diagnosis, condition or procedure.

This project aims to establish a database of pediatric neurological disorders. The data obtained from the registry will be used in studies that aim to improve the quality of care, diagnosis and treatment outcomes in a large paediatric population with neurological disorders. This will also serve as a resource for investigating pediatric neurological disorders and promote collaborative research across SCHN and possible international research groups.

Your child's demographic and medical data will be assigned with a unique NeuroCONNECT ID. There will be no personal or identifying information kept in the registry. The collected data relating to your child will be used for medical and/or scientific research, including publications in scientific journals. Coded data (data from which you cannot be identified) will be transmitted to the registry and may be passed on to other investigators for statistical analyses and further investigation.

Participation in the registry does not require you to take part in any extra activities. The information collected about your child will be collected from your hospital medical record, including scans, laboratory results and genetic testing (if done).

You may be contacted in future to update your child's medical information which will be checked by your treating clinician for accuracy. You may also be contacted for future research studies, if you allow it.

3. Who is running the project?

This registry is run by The Children's Hospital at Westmead, led by Prof. Russell Dale and The Sydney Children's Hospital by A/Prof Michelle Farrar. This is funded by The Ainsworth Foundation, which has the agreement of clinicians at SCHN looking after children with neurological disorders.

Oversight for this database will be provided by an advisory panel and maintained by the registry custodian.

This registry has been reviewed and approved by the SCH Research Ethics Committee (2020/ETH3064).

4. Why is my child being asked to take part?

We are inviting your child to take part because they have a neurological condition. Your child's medical information is valuable and will help contribute to improving the diagnosis and treatment of children with similar conditions. It will also contribute to the incidence and prevalence rate of their specific medical illness.

Participation is completely voluntary. If you do not wish for your child to take part, they do not have to. If you decide that they can take part and later change your mind, you are free to withdraw your child from the database at any time.

Your decision that your child can or cannot take part, will not affect their routine care, relationship with professional staff or relationship with **The Children's Hospital at Westmead and/or Sydney Children's Hospital.**

5. What do I need to do for my child to be part of the registry?

If you would like your child to be included in the registry, you will be given a web link to provide your consent. A confirmation email will also be sent to you indicating you have provided consent for your child's inclusion in the registry, along with a copy of this information sheet for you to keep. By providing consent, your child's medical records will then be de-identified, and entered into the registry.

This will be an ongoing registry. Once your child reaches the legal age of consent (18 years), they have a right to withdraw or provide their own consent for participation.

6. Can I withdraw my child from the registry?

You and your child can stop taking part in the registry at any time. You just need to email your treating clinician or the registry custodian at Kristine.concepcion@health.nsw.gov.au. You will not be asked to provide a reason for withdrawing nor will it affect the care provided to your child.

If your child leaves the registry, the information obtained from your child's records will no longer be active nor will it be included in any further study or analysis. De-identified data that has already been used in research projects cannot be unshared nor withdrawn.

7. What are the possible risks and disadvantages of taking part?

There is neither immediate risk nor disadvantage to you or your child for taking part in the registry. There is the possible risk to privacy, in the form of unintended release of your child's personal and health information. Safeguards have been put in place to maintain your child's privacy.

8. What are the possible benefits of taking part?

We cannot promise that your child will receive any benefits from this research; however, possible benefits may include:

- You and your child will contribute to the scientific knowledge about paediatric neurological disorders
- You and your child will help clinicians and researchers analyse large-scale information about paediatric neurological disorders
- We may be able to improve the diagnostic and treatment outcomes for children with similar neurological disorders

9. What will happen to information about my child?

By providing online consent, you consent to the registry team collecting health information about your child for the registry. Their personal information will only be disclosed with your permission,

except as required by law. For example, researchers are required to report if a participant is believed to be at risk of harm.

In order to protect your child's privacy, the registry custodian will remove any information that may be used to identify them from any study documents, and instead of their name appearing on the documents, they will be identified by a NeuroCONNECT identification number. Only this registry ID number will be used on any research-related information collected about your child for this study, safeguarding your child's privacy. Only the registry custodian, Kristine Concepcion, will have the ability to link this code number with your child's personal information, and the linking information will be kept in secure computer drive, at Kid's Neuroscience Centre, SCHN. Your child's data will be stored in the registry on a continuing basis. The registry will be stored in REDCap, a data platform hosted by the University of Sydney. Storage and maintenance of data will be in accordance with data policies of the University of Sydney and the Sydney Children's Hospital Network. Registry data cannot be accessed without any approval from the lead researchers.

If you withdraw your child from the study, we will not collect any more information about your child, and their registry ID number will be deemed inactive.

10. How will the registry data be utilised?

It is anticipated that the registry data will be utilised in future Australian or international studies on improving diagnosis and treatment outcomes. These will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that your child cannot be identified, except with your explicit permission.

Anonymised data may also be shared to other Australian or international research projects, as approved by the NeuroCONNECT Advisory Panel.

11. Who should I contact if I have any questions?

If you have any questions or want more information about this study before or during participation, you can contact **Kristine Concepcion** on Kristine.concepcion@health.nsw.gov.au.

12. Who do I contact if I have concerns about the registry?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This study has been approved by the Sydney Children's Hospitals Network (SCHN) HREC 2020/ETH3064 .

If you have any concerns or complaints about any aspect of the project or the way it is being conducted, you may contact the Executive Officer of the SCHN HREC on (02) 9845 1253 or SCHN-Ethics@health.nsw.gov.au.

A copy of this information sheet will be emailed to you for you to keep. We will also send you a confirmation email that online consent has been provided for your child to join the registry.