The Australian Paediatric Surveillance Unit
at Kids Research

kids research
The Sydney children's Hospitals Network

Participant Information Sheet – Parent/Carer

Title	Fetal Alcohol Spectrum Disorder Australian Registry
Short Title	FASDAR
Protocol Numbers	HREC/17/SCHN/209 EO144-10092019
Project Funder	Australian Government Department of Health
Coordinating Principal Investigator	Professor Elizabeth Elliott
Associate Investigators	Dr Melissa Cheung Dr Anne Morris
Location	Australian Paediatric Surveillance Unit, Kids Research, the Children's Hospital Westmead
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As a parent/caregiver of a child with Fetal Alcohol Spectrum Disorder (FASD), you are invited to take part in the FASD Australian Registry (FASDAR). Before you accept or decline the invitation, it is important for you to understand why this Registry has been established and what will be involved if you choose to participate. Please read this information sheet carefully, and feel free to discuss it with relatives, friends and clinicians caring for your child with FASD. If you have any questions, please contact a member of the FASDAR team whose contact details are detailed below.

What is the FASDAR?

The FASDAR is a national database that collects health information about children aged less than 15 years in Australia that have been diagnosed with FASD.

Why do we collect information in the FASDAR?

The FASDAR aims to improve the diagnosis, treatment and prevention of FASD in Australian children. There are many gaps in knowledge about FASD, including understanding about the long-term outcomes, how the condition progresses and which programmes improve outcomes. The information from the FASDAR will inform clinical, diagnostic and treatment guidelines, policies and programmes to improve outcomes for children with FASD and their families. The FASDAR will also support future research studies and clinical trials.

Who manages the FASD Australian Registry (FASDAR)?

The FASDAR is co-ordinated by staff from the Australian Paediatric Surveillance Unit (APSU), under the oversight of the FASDAR National Steering Group and the FASDAR Data Custodian Committee who ensure that data in the FASDAR remains private and secure.

What data is already collected about children with FASD in Australia?

The APSU has been collecting national de-identified health data about children with FASD since December 2014 through its network of ~1500 paediatricians across Australia. This APSU surveillance study has obtained ethics approval (HREC Reference: LNR/14/SCHN/441). The child's initials and date of birth is collected by the APSU to identify duplicate cases. Once duplicate cases have been detected, the initials are removed.

Enrolling in the FASDAR

The FASDAR builds on the existing de-identified health data collected through the APSU. If you would like to enrol your child in the FASDAR (opt-in), all you have to do is agree for your FASD treating doctor to pass on your name and contact details to the FASDAR Manager, who will then contact you to provide more information. Alternatively, if you wish to take some time to consider enrolling your child in FASDAR, you can contact the FASDAR team whose contact details are above.

The FASDAR will contain your child's name, address, date of birth, and your name, email address and contact telephone numbers, as well as the treating doctor's name and contact information. The relevant health information about your child's FASD condition, diagnosis and treatment will be obtained from your treating doctor and securely stored in the FASDAR database. The FASDAR is expected to function long-term in order to achieve clinical significance and utility, therefore the timeframe of this project may extend to or beyond 5 years (i.e. to 2024 or beyond).

Will FASDAR contact me after I enrol my child?

Yes, the FASDAR team will contact you by email or by telephone at least once a year to check whether your details are still correct and to ask whether you want to continue enrolment in the FASDAR. You may also be contacted by the FASDAR team if an opportunity arises for your child to participate in research studies or clinical trials. Before we contact you about such studies, they will have received approval from the FASDAR Data Custodian Committee, appropriate Ethics Committee(s) and Research Governance Office(s). You will have the chance to review information about these research studies and clinical trials and then decide whether or not you want to participate.

How will FASDAR keep information about my child and about me confidential?

Your information is protected by law and the FASDAR will not reveal your identity to any third party. The information in the FASDAR will be stored on a secure computer server at the University of Sydney. Your child's health information will be held in a separate file to your child's name and contact details. A unique FASDAR identification number will be assigned to each child to enable linking of the health data and the names and contact details when needed, for example when inviting participants to research studies. Your child's name or your name will never be used in reports or publications, and only summary data on groups of participants will be reported. Health data describing individuals will never be published in reports, newsletters, publications or conference presentations. The data will be kept indefinitely as the design of the FASDAR depends largely on the ability to monitor participants and families long-term.

Risks and Benefits

While we intend this Registry to be used to improve medical knowledge and to improve treatment of FASD in the future, it may not be of direct benefit to your child or family. There are no risks to your child's health by having your child enrolled in the FASDAR. Please note that information about maternal alcohol consumption during pregnancy will be collected by the Registry; this may or may not cause psychological discomfort. Maternal alcohol use is acknowledged as a sensitive topic; the researchers and health professionals have experience with communicating about this topic using a non-judgemental and respectful approach.

We have developed the following distress protocol, detailing and defining a list of actions that the researchers will undertake if your child, you or your family becomes distressed due to the FASDAR or its content.

Step 1: Identification of distress
Your child, you or your family indicates that discomfort, stress and/or emotional distress is being experienced OR shows visible signs of distress (such as silence, anger, tears).

Step 2: Response
The consultation or discussion will be stopped, if applicable. One of the researchers (who is a health professional) will offer immediate support by initially asking several questions: Tell me what you are feeling right now? Tell me what thoughts you are having? Do you feel you are able to go on about your day? Do you feel safe?

Step 3: Review
If your child, you or your family feels able to carry on, your participation in the FASDAR will continue. If your child, you or your family feels unable to carry on, the researchers will proceed to Step 4.

Step 4: Response
The researchers will ask your child, you and your family to consider discontinuing your participation in the FASDAR by opting-out. The researchers will encourage your child, you and your family to speak with a member of the research team to discuss your concerns. If your child, you and your family prefers to speak with your health professional, the researchers will offer, with your explicit consent, to contact your preferred health professional to make an appointment on your behalf and this will be funded by the researchers.

Step 5: Follow-up
If you have consented to receiving a follow-up call, one of the researchers will contact you to check-in with how you are going. The researchers will encourage you to contact them through the below details if your child, you or your family experiences continued or increased discomfort, stress and/or emotional distress due to your participation:

Contacts and support
Contact details for the research team:

- Dr Melissa Cheung, Research Fellow & FASDAR Manager, 02 9845 2023, melissa.cheung@sydney.edu.au
- Professor Elizabeth Elliott, Paediatrician, 02 9845 3450, elizabeth.elliott@health.nsw.gov.au

The following external services are also available for support:

- NOFASD Australia (consumer advocate), free call 1800 860 613 or online via https://www.nofasd.org.au/contact-us
- FASD Hub Australia, where you can locate your local FASD service via https://www.fasdhub.org.au/services

Costs

Contributing to this Registry will not cost you anything, nor will you be paid.

Is enrolment voluntary and can I change my mind about being involved?

Yes, enrolment in the FASDAR is entirely voluntary. You can choose not to participate (opt-out) without giving a reason. Whatever your decision, please be assured that it will not affect your child’s medical treatment or your relationship with the health professionals, other staff who are caring for your child or the researchers.

If you decide to participate but later change your mind, you can withdraw at any time without having to give a reason. You may withdraw all of your child’s information (name, contact details and health data) or you may choose to withdraw only your child’s name and contact details, or only your child’s health data. You can withdraw (opt-out) by contacting the FASDAR Manager by phone, mail or email or by completing the Opt-Out Form included in the information pack and available on-line at the FASDAR website. The FASDAR Manager will delete all information as requested by you.

Ethics Approval and Complaints

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Sydney Children’s Hospitals Network Human Research Ethics Committee and the Australian Institute of Aboriginal and Torres Strait Islander Studies Research Ethics Committee.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

If you have any complaints about any aspect of the FASDAR or the way the FASDAR is being used, please contact:

- The Sydney Children’s Hospitals Network Human Research Ethics Office and quote: HREC/17/SCHN/209, by phone: (02) 9845 1253 or email: SCHN-Ethics@health.nsw.gov.au
- The Australian Institute of Aboriginal and Torres Strait Islander Studies Research Ethics Committee and quote (EO144-10092019), by mail: GPO Box 553, Canberra ACT 2601, phone: (02) 6246 1155 or email: ethics@aiatsis.gov.au

This information sheet is for you to keep. A copy of this information sheet is also publicly available on the FASDAR website (www.fasdregistry.org.au).