Parent/Carer Information Sheet

Project Title: **Global Angelman Syndrome Registry**

Principal Investigators:

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You are being invited to take part in a global registry as the parent/ caregiver of a patient (either a child or adult) who has a diagnosis of Angelman Syndrome (AS). Before you accept or decline the invitation, it is important for you to understand why this registry is being built and what it will involve. Please read this information sheet and discuss it with relatives, friends and clinicians caring for your child/ adult with AS, if you wish. If you have any further questions, please contact a member of the research team above.

Participation in the registry is voluntary. Please take the time to decide whether you would like to take part, or not.

Project Overview

The Global Angelman Syndrome Registry is being initiated and funded by the Foundation for Angelman Syndrome Therapeutics (FAST) Australia with support from the Mater Medical Research Institute and Mater Children's Hospital in Brisbane, the Royal Children's Hospital in Melbourne, and the Centre for Comparative Genomics at Murdoch University in Perth.

The study is being coordinated in Queensland by the Mater Medical Research Institute, and is being supported by the Mater Children's Hospital in Brisbane, and the Royal Children's Hospital in Melbourne. The lead researcher in Queensland is Associate Professor Honey Heussler from the Mater Children's Hospital. Professor Katrina Williams heads the contribution of the Royal Children's Hospital in Melbourne.

The aim of the registry is to establish a database, which will be an electronic report containing information about your child/ adult with AS and his/ her disorder. Having an electronic database of patients with AS means that we can identify groups of patients from all over the world, who might be able to participate in clinical trials and other research to help develop new therapies for AS. The database will contain all the data that researchers will need, including each patient's diagnosis, symptoms and other important aspects of their disorder. In addition, registry data collected over time may help to enhance understanding of the long term clinical outcomes and natural history of AS, which may help to shape future research in treating this disorder.

Before you consider registering you child/ adult's details, it is important that you understand what is involved and what will be done with the information you provide. This form contains answers to some of the questions you might have on

the database. At the end of the form, and after you have had some time to think about it, we shall ask if you wish to register.

If you do, we shall ask you to submit an online consent form saying that you agree to join to start entering data into the registry. If you have any questions, please contact us before consenting to join the registry.

How will I benefit from registering?

This database aims to benefit patients living with your condition. We will make contact with you when we are able to offer new treatments for your condition or to ask you to help assess possible new treatments (clinical trials). By holding secure records of your clinical details we will be able to decide whether or not such trials would be suitable for you. You will not receive any payment or any other financial benefit as a result of joining the database. The results of research arising from the database may have business potential (if for example utilised by a pharmaceutical company to develop a new drug) but you will not receive financial benefits from such development.

Nevertheless, there may be other benefits to joining, including the following:

- We will inform you about suitable clinical trials that you might wish to join.
- The details collected will also provide information for doctors interested in the best standards of care for your disease.

I want to be involved in a clinical trial. If I register, is this guaranteed?

No. Although one of the main aims of this database is to make it easier for patients to be recruited for clinical trials, there is no guarantee that registering your details will mean you will be automatically approached to take part in a clinical trial. Doctors organizing a clinical trial will review the details you have given and if the trial appears to be suitable for you they will invite you to join.

All patients invited to join a particular trial will then be assessed in greater detail and at this stage it may be clear that other developments in your health or details not recorded on the database mean that the trial is not a suitable one for you.

Will information about me be kept confidential?

All information we receive from you will be treated confidentially. We make every effort to ensure your data is kept safe but we remind you to be vigilant when entering information online. Details of your specific diagnosis as well as personal information (name, age, address, gender) will be stored on the database. This information is all required to enable us to match you with the criteria, however only doctors and scientists involved in this project who are given specific permission will be allowed to look at this information. The information you provide can be made available to your treating doctor is you wish. If we publish any research or other documents based on information from the database, this will not identify you by name. Please note that non identifiable data must be stored for 15 years as required by government regulations (National Health & Medical Research Council Guidelines).

Do I have to join the database and can I withdraw if I change my mind?

Joining the database is voluntary. Should you wish to withdraw your information from the database you will be free to do so at any time without having to provide any explanation. If you wish to withdraw, you should get in touch with the staff in charge of the database. Contact details are provided above. Joining or leaving the database will in no way affect the care you receive for your condition.

How will my data be used?

The main aim of us asking you to be part of the registry is to help recruitment into clinical trials. However the data may also be used to learn more about people with your condition. The information you provide may be used to help researchers design future investigations. Any data released for research will not identify you by name.

How will my details be updated?

You will be able to update your details via the web page. We will also ask you for updated information at clinic visits. You can contact us at any time if you need to amend your details. We will also ask you at each clinical visit if you are still happy to have your details included on the database. You are free to have your information withdrawn from the database at any time. We will also ask you about the person in charge of your medical care so we can contact them for more specialist information.

Who is funding the research?

This study has been funded by the Foundation for Angelman Syndrome Therapeutics (FAST) Australia and Mater Children's Hospital Golden Casket grants and there is no conflict of interest on the part of any of the researchers.

Who has reviewed this project?

This project will be carried out according to the National Statement on Ethical Conduct in Research Involving Humans (May 2007) produced by the National Health and Medical Research Council of Australia. Additionally, this project has been approved by the Mater Health Services - Human Research Ethics Committee. Parents/guardians may contact Nicola Stepanov (ph +61 (0)7 3163 1585) who is the Research Ethics Coordinator at the Mater Research Ethics Department if they have any concerns or complaints about the conduct of the research.

What if I have any concerns?

If you have any concerns or other questions about this study or the way it has been carried out, you should contact one of the investigators on the telephone numbers or email addresses provided on page 1 of this document.

Thank you for taking the time to read this information sheet

CONSENT FORM FOR PATIENTS

Global Angelman Syndrome Registry

Name of Researcher:
Dr Megan Tones
Mater Research Institute, Brisbane

Please provide your informed consent by checking the boxes below. There is no need to sign or upload this form unless you are giving consent for the research team to contact your clinician on your behalf (see item 9 below).

1. I confirm that I have read and understand the information sheet (V3) dated 10th of February 2016, for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3. By entering data into the registry, I understand that I give consent for the storage of data on my child/ adult with Angelman Syndrome in the Global Angeman Syndrome Registry.	
4. I understand that the storing of data will allow contact to be made with me if a suitable clinical trial/ research study becomes available for my child/ adult with Angelman Syndrome.	
5. However, I accept that allowing my data to be stored on this database does not mean my child/ adult with Angelman Syndrome will automatically be entered into future clinical trials/ research studies.	
6. I understand that the data I provide may be used to inform and plan future research.	
7. I understand that the results from future research may not have any direct implications for me or my family.	
8. I am happy to consent to be included in this registry.	
9. I confirm I am happy for the specialist in charge of my medical care to be contacted to verify diagnostic information.	
10. I consent to being contacted to complete additional modules/ for longitudinal follow up.	
11. I consent to being contacted about clinical trials and research studies that my child/ adult with Angelman Syndrome may be eligible to participate in.	

Please sign here (parent/ caregiver):

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Name of Patient:

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Date Signature:

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