

Global Angelman Syndrome Patient Registry Access Policy

The Foundation for Angelman Syndrome Therapeutics Australia (FAST Australia) has engaged researchers, clinicians, parent organisations and families in the Angelman Syndrome community in the development of the Global Angelman Syndrome Registry. For more information about the registry, please review the research protocol at <https://angelmanregistry.info/participants.html>

Overview and Background

The Global Angelman Syndrome Registry is the first online registry for Angelman Syndrome, and will become a powerful tool in advancing scientific understanding and therapeutics for Angelman Syndrome. This will be achieved via:

- Collating a repository of data on the natural history of Angelman Syndrome, and;
- Providing a resource for participant recruitment for clinical treatment trials and other studies.

To achieve this end and advance Angelman Syndrome therapeutics, it is vital to ensure that the registry is accessible to clinicians and researchers in a timely manner. The registry team has developed a two-step process to streamline the data access process:

1. Identify what level of access is required for your purpose, and
2. Complete an application form to access the registry.

The data curator will endeavour to action requests not requiring a committee review within 7 days. More complex requests requiring committee review will take 4-8 weeks to action.

Levels of Access to Registry Data

There are 3 levels of access to the Global Angelman Syndrome Patient Registry. These are outlined below. Please note that data cells with fewer than five (5) participants will be further aggregated or not provided in line with the *Guidelines for the Use and Disclosure of Health Data for Statistical Purposes*.

Level 1: Registration is required for this level of access.

Level 1 requests are for professionals, researchers, or students who wish to request de-identified data in an aggregate format. Individuals may submit a level 1 request to the data curator to generate information such as:

- Age at diagnosis by birth cohort
- Medical complications by age and sex

A level 1 request is also useful for researchers who wish to preview the registry content and data elements prior to making a higher level request. Please note that level 1 access does not enable users to view the raw data set or individual participant data.

Parents and families can also submit a question to the data curator via email such as, “What are the most common medications used by children with Angelman Syndrome aged up to 12 years?” These questions will be processed by the data curator and disseminated to the registry community via newsletter and social media.

Level 2: Registration and data curator review are required for this level of access.

Level 2 access requires approval from the data curator. This level of access is for professionals, researchers, or students who intend to undertake complex data searches or obtain a de-identified data set in .csv format for the purposes of statistical analysis, publication or presentation of data. Examples of level 2 data access queries may include:

- Detailed comparison of various medical outcomes by age, gender and phenotype
- Complex designs investigating links between adaptive behaviour measures and medication use

Approval from the Global Angelman Syndrome Registry Governance Committee may be required to ensure that the proposed analysis or research can be feasibly completed using the registry data.

Level 3: Registration and review by the data curator and Global Angelman Syndrome Registry Governance Committee are required for this level of access.

This level of access is for researchers who wish to recruit participants for a clinical treatment trial or other research study. Requestors will be required to provide more details of their proposed research in their application, and approval from the Global Angelman Syndrome Registry Governance Committee is mandatory. If you are granted level 3 access, the data curator will assist you in recruiting participants for your study or trial via the following methods:

- Contacting eligible participants parents/ caregivers via email to advise them of the study
- Providing details about the study on the registry website and newsletters

Researchers are requested to advise the data curator of relevant study updates including changes to participant recruitment criteria or termination of clinical trials.

Please also complete a level 3 access request if you wish to use the data for commercial purposes or would like to propose a new module or data collection instrument for use within the registry. For more information, please review the chart “What level of access do I need to apply for?” (see page 4 of this document)

Participant confidentiality and privacy

The research team is committed to protecting all participants’ personal information and data against breaches of security or loss in accordance with the Federal Privacy Act of Australia and the National Statement on Ethical Conduct in Human Research. Under the Federal Privacy Act, it is prohibited to distribute an individual’s personal information to a third party without their permission. All requests to access potentially identifiable information such as birth date, postal/ zip codes, or details of distinct clinical features will require requestors to complete a confidentiality and information use agreement (contained in the application process).

Publications

Researchers are required to notify the data curator when manuscripts using Global Angelman Syndrome Registry data are accepted for publication. Please provide a citation and a pdf copy to assist with the maintenance of a bibliography and repository. All publications utilising the Global Angelman Syndrome Patient Registry data must include an acknowledgement, suggested below:

The authors gratefully acknowledge the Global Angelman Syndrome Patient Registry team for the use of Patient Registry data to conduct this research. In addition, we would like to thank the patients, parents and caregivers, and clinicians for their involvement in the Global Angelman Syndrome Patient Registry.

It is requested that no individually identifiable information from the Global Angelman Syndrome Patient Registry be included in any publications, presentations or reports. Only aggregate data is to be presented. This is important to preserve the privacy and security of families who willingly share information with the registry. Furthermore, it is requested that data cells with fewer than five (5) participants be further aggregated or not published in line with the *Guidelines for the Use and Disclosure of Health Data for Statistical Purposes*.

Many periodicals request a statement on the availability of the data. The following wording is suggested:

Data is available for request via the Global Angelman Syndrome Patient Registry. You can view their data access policy at <https://angelmanregistry.info/> or contact the data curator at curator@angelmanregistry.info. Data access restrictions are required to ensure patient privacy and security of information for all families in the Global Angelman Syndrome Patient Registry.

Global Angelman Syndrome Patient Registry: What level of access do I need to apply for?

