

# Guidelines for researchers - how to access data from the South Australian Birth Defects Register

## (Incorporating the South Australian Cerebral Palsy Register)

The SA Birth Defects Register is a valuable resource for a wide variety of research projects, and is happy to provide data to all bona fide researchers. In order to facilitate this process and to avoid delays when seeking access to data, it is important that researchers appreciate the constraints under which the SA Birth Defects Register operates, and that they follow the necessary preliminary steps before any data can be released for their use.

### Ethics

Researchers must obtain approval from the appropriate Human Research Ethics Committee(s) (HREC) and also complete the relevant Site Specific Assessment forms (SSA) for the work they propose to undertake.

All projects seeking data from the SA Birth Defects Register or the SA Cerebral Palsy Register require approval from the SA Health HREC or the Women's and Children's Health Network (WCHN) HREC, depending on the type of project, and data requested. SSA forms are also required. Further information about specific ethics requirements is available online at:

[www.sahealth.sa.gov.au/researchethics](http://www.sahealth.sa.gov.au/researchethics)

The SSA forms require details about the data being requested from the SA Birth Defects Register and must be signed by the Head, SA Birth Defects Register prior to submission.

- Signatures from the SA Birth Defects Register will only be provided if researchers adhere to the following guidelines:
  - All researchers who wish to use data from the SA Birth Defects Register or the SA Cerebral Palsy Register must provide a brief synopsis of the proposed research project to the Register Managers at least 2 weeks prior to the ethics submission date, to enable sufficient time to review and comment on the submission.
  - The ethics application must clearly state which data fields are needed, how the data will be used and whether the data are required to be identified or deidentified.
  - The ethics application must be reviewed by the Register Manager before being submitted.
  - At least one staff member from either the SA Birth Defects Register or the SA Cerebral Palsy Register must be named on the ethics application.
  - Copies of both the final ethics application and the acceptance letter must be lodged with the Register.
- Projects that entail the reviewing of hospital medical records must also obtain ethics approval from each hospital involved. This process will often be facilitated by first obtaining approval from the SA Health HREC.

## **Funding**

- Staff in the SA Birth Defects Register are funded to collect and verify birth defect data, and to maintain the SA Birth Defects and SA Cerebral Palsy Registers. They can perform small individual data linkages at no cost to the user, but anything more will require an appropriate level of funding. It is the responsibility of researchers to ensure that adequate resources are available for large projects.
- The Register Management Group is the final arbiter of what qualifies as 'small' or 'large'. To assist researchers we have provided a guide:
  - Small projects are those which require less than a total of 3 hours of work from register staff per research project.
  - Large projects are those which are ongoing, or require more than a total of 3 hours of work from register staff per research project. The first 3 hours of work will be provided free of charge, with the remaining hours charged at a fee of \$100 per hour.

As this is a guide only, Register staff are happy to discuss individual projects with researchers, and provide a detailed estimate of the total time and costs involved.

- Register staff may also be able to provide advice on organisations that could be approached to fund your project.

## **Authorship**

Authorship of any paper prepared for publication which uses Register data should be discussed with Register staff at the initial meeting. Appropriate acknowledgement and/or authorship should be given for work/expertise contributed.

An electronic copy of any publications or published abstracts that use Register data must be provided to the SA Birth Defects Register as soon as they become available.

## **Confidentiality Agreement**

All researchers working with either the SA Birth Defects Register or the SA Cerebral Palsy Register are required to read and abide by our Confidentiality Guidelines. A Confidentiality Agreement must be signed by all researchers before any data will be provided.