



The I-DSD Registry

(Information for Adults & Young People Over 14 Years Old)

What is I-DSD?

I-DSD stands for the International Registry of Disorders of Sex Development. Sex development is a very complicated process and variations and differences in this development can lead to a group of rare conditions that have been brought together under the umbrella term 'DSD'. Sometimes the same condition may lead to concerns in one sex but not the other. For instance, congenital adrenal hyperplasia in boys and men is not usually associated with concerns about sex development. The local hospital doctor looking after you or your child and who is highlighted at the end of this leaflet is a registered user of the I-DSD registry and has provided this information to you. A registry is similar to a medical database containing a range of medical records. Registries are used very often these days by doctors and scientists to perform research into rare conditions such as DSD.

What is the purpose of the I-DSD Registry?

The Registry will keep secure information of some of the affected person's details. You can ask your hospital doctor to show you the kind of information that is stored. The purpose of the Registry is to share this information with other registered users of the Registry. This will allow doctors and scientists from across the world to pool their knowledge and experiences and perform research in these rare conditions. This will lead to improvements in our understanding of these conditions and improve the care of affected children and adults.

Why have I been approached?

The hospital doctor looking after you or your child and who is highlighted at the end of this leaflet is a registered user of the I-DSD registry and has provided this information to you. The I-DSD Registry is open to all children or adults who are born with a condition which affects sex development and requires medical or surgical attention. In addition, it is also open to all children and adults without any concerns about physical sex development but who are born with a condition which may affect sex hormones. If the affected person is under 14 years, old we provide this leaflet to the parents. In addition, we provide a less detailed leaflet to those who are under 14 years old. When the young person turns 16 years, we will approach them again to check whether they are keen to stay on the Registry.

My affected child is still very young – how do I know this is what my child will want?

Sometimes it can be difficult to decide on your child's behalf. Please remember that all the information can be removed from the Registry at anytime by you or by your child. Your child does not need to wait until they turn 16 years old and you can discuss the Registry at an earlier age.

Do I have to take part?

No. If you do not return the attached sheet then your hospital doctor will assume that you do not want the information to be stored and shared on the Registry. The management of your condition/your child's condition will not be affected by your decision.

If I take part, what will happen when the data are included on the Registry?

The Registry users will not be able to make contact with you because the name, address, date of birth and hospital number will not be recorded. Only your hospital doctor will be able to link the data in the Registry to the hospital records. Nobody else will be able to identify people in the Registry, not even the people who have set up the Registry. Your hospital doctor will enter data describing any examination they have performed. They can also enter details of any tests they have performed. Remember, you can ask your hospital doctor to show you the kind of information that is stored. If you choose to be included in the Registry, you can view your own details as they are entered in the Registry.

The data shall be stored for a period of thirty years and in the future, your hospital doctor may contact you about possible studies that have been approved by a Research Ethics Committee. Some of these studies may involve extra tests or face to face interviews. These studies will be explained in detail to you by your hospital doctor and you or your child will be under no obligation to take part in them. If any samples have previously been collected and stored they will not be used for a study unless approved separately by a Research Ethics Committee.



What will happen to the information collected on the Registry?

- The data collected on the Registry might be used to perform research or develop new research studies
- The results of the studies will be published in medical journals so that other professionals and patients around the world can also benefit.
- The data will allow specialists around the world to contact other specialists looking after people with similar conditions

Will the information be kept confidential?

You and/or your child's participation will be kept strictly confidential and all information will be handled through very secure electronic systems. As the Registry involves collecting information from different hospitals, the system will be password protected and only those who are directly involved with the Registry will have access. Please remember, the Registry does not collect any information about names, addresses, dates of birth and local hospital numbers. In that way it is even more secure than the data systems used in hospitals.

What are the possible disadvantages and risks of the Registry?

There are no disadvantages to being included on the Registry that we can see. As previously stated, agreeing to be included on the registry does not commit you to take part in any studies.

What are the possible benefits of the Registry?

The Registry is designed to help scientists and doctors to improve their understanding of DSD and provide best care to affected children and adults.

Can I access my own record?

Yes. You can arrange access for yourself through the local doctor who has entered the data and you can view some of the information in the Registry. If you would like to change any of this information or would like to find out more, please ask your local doctor.

If I change my mind, have a complaint or want to provide feedback, who do I turn to?

If you wish to remove your details from the Registry, you can contact the I-DSD Registry through the address at the end of this information sheet. If you are unhappy about any aspect of the way you have been approached or treated, you can complain through your local health service complaints procedure. Your hospital doctor or your family doctor shall be able to advise you about this. In addition, you can also contact the I-DSD Registry directly through the address at the end of this information sheet. The I-DSD Registry is very keen to hear from you so please feel free to contact them with any comments.

Who has reviewed the activity of DSD networks and the Registry?

In the UK, the British Society of Paediatric Endocrinology & Diabetes (BSPED) and the Society for Endocrinology have reviewed the Registry. In the UK, the National Research Ethics Service has also reviewed and approved the Registry. The European Society of Paediatric Endocrinology (ESPE) and the European Union Framework Project 7 have also approved this Registry. In the UK, patient groups including the CLIMB CAH support group, the AIS Support Group and dsdfamilies.org have also been consulted. Further details of these groups are on www.i-dsd.org.

Who is funding the I-DSD Registry?

The Registry was previously funded by the EU and is currently funded by the UK Medical Research Council.

What do I have to do?

Simply talk to your doctor to decide if it suits your circumstances to put the information on the Registry, and complete the attached form. You can always change your mind later and ask your hospital doctor to remove the information from the Registry.



For further information and discussion about your entry on the Registry, please contact your local hospital doctor as follows

{Local clinician}

{Local Hospital Address}

For further information about the Registry please contact:

Jillian Bryce PhD,
I-DSD Registry Project Manager
University of Glasgow,
Royal Hospital For Sick Children
Glasgow G3 8SJ, United Kingdom
Tel: 0044-141 201 0509
E-mail: Jillian.Bryce@glasgow.ac.uk

I-DSD Registry Consent Form

We would like to enter some information about the person named below on the I-DSD Registry

This information will allow us to:-

- a. Share information about the person with other registered users of the I-DSD Registry
- b. To plan services
- c. To help our understanding of these rare conditions

You can ask your Hospital Doctor (details below) to find out more about the information that is in the Registry

If any of the following apply to you please place initials in box and let your hospital doctor know

- I have read the information sheet about the I-DSD Registry
- I have discussed the information sheet about the I-DSD Registry with the hospital doctor who is looking after the care of the person below.
- I approve of the information to be stored on the Registry and shared with other health professionals in the EU
- I approve of the information to be stored on the Registry and shared with other health professionals beyond the EU
- I approve of the information to be stored on the Registry and shared with approved researchers
- I require on-line access to the registry to view the record of the person named below

e-mail address: _____

Name of the person to be registered:

Name of parent if person to be registered is less than 16 years old:

Address of person to be registered:

Signature of person to be registered:

Signature of parent of person to be registered (if less than 16 yrs old):

Date

The person's information shall be provided to the register by the following Hospital Doctor:-

{Local clinician}

{Local Hospital Address}

Please keep one copy of this sheet in case records and hand one copy to the person who has signed this form