

## The I-DSD Registry

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

### What is I-DSD?

I-DSD stands for the International (network) of Disorders of Sex Development. This network consists of health care workers across the world who have a particular interest in the care of children and young adults who have concerns about their general development. The local hospital doctor looking after you or your child and who is highlighted at the end of this leaflet is approved by I-DSD and has provided this information to you.

### What is the purpose of the I-DSD Registry?

Development of the sex organs is a very complicated process and sometimes it does not occur as planned. Health care workers call this a disorder of sex development (DSD). To understand these rare conditions better and to improve and maintain the best standard of practice we want to keep a brief and secure record of some of the affected person's details. You can ask your hospital doctor to show you the kind of information that is generally stored. The Registry will also help doctors and scientists from across the world to pool their knowledge and experience and improve the care of children and adults with these rare conditions.

### Why have I been chosen?

The I-DSD Registry is looking for all children or adults who are born with a concern about their sex organs and who may require medical or surgical attention at the hospital. If the affected person is under 14 years old we provide this leaflet to the parents. The affected young person will be approached for their approval after turning 16 years.

### Do I have to take part?

No. If you do not return the attached sheet then your hospital doctor will assume that you are not happy for the information to be stored and shared on the registry. Please remember, even if you do approve, these doctors and scientists will still not be able to contact you directly as they will not have any of your contact details.

### What will happen after inclusion on the Registry?

There will be no personal contact with the affected person and 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 your 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 some data about hormone or genetic tests that may have been performed. Your 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. These studies will be explained in detail 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 unless approved separately by a Research Ethics Committee.

### What do I have to do?

Nothing but do talk to your hospital doctor. You can always change your mind later and ask your hospital doctor to remove the information from the Registry. You can also ask your hospital doctor to look at the information that is stored in the Registry.

### 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 doctors to improve their care and understanding of affected children and adults.

### What if something goes wrong?

We do not expect any problems. However 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 network through the address at the end of this information sheet.



### **Will the information be kept confidential?**

You and/or your child's participation will be kept strictly confidential and all information will be handled in exactly the same way hospitals handle all other information on patients. 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. If you are reading this information on behalf of your child, please remember your child will receive this information at the age of 16 years.

### **What will happen to the information collected on the Registry?**

The information may be published in medical journals so that other professionals and patients around the world can also benefit. The Registry does not have any names so nobody will be named in any publication, so it will be impossible to identify any individual person directly through the Registry. We will also send our results to the EU and the Governments of our own countries and use it to improve the care of people with these conditions. We will also use the data to develop new studies. Some of these studies will require contacting you in the future to find out whether you would like to take part. You will only be contacted through your hospital doctor who first notified the Registry with your details.

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

In Scotland, NHS Quality Improvement Scotland, National Services Division, NHS Scotland, National Information Systems Group, NHS Scotland and the Director of Health Information & Technology, GGCHB have reviewed the clinical activity of the Scottish Genital Anomaly Network ([www.sgan.nhsscotland.com](http://www.sgan.nhsscotland.com)). The I-DSD Registry is based on similar principles to the SGAN 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 and the AIS Support Group have also been consulted and have approved the use of this Registry.

### **Who is overseeing and funding the I-DSD Registry?**

The Registry is currently funded by the MRC as the I-DSD programme of research. (new website url to be added)

### **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 general information about the Registry please contact:**

Jillian Bryce  
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0044-141 201 6939, [Jillian.Bryce@glasgow.ac.uk](mailto: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 doctors approved by I-DSD panel
- 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

### Please let your Hospital Doctor know if:-

- 1. You approve of the information to be stored on the Registry and shared with other doctors in the EU.
- 2. You approve of the information to be stored on the Registry and shared with other doctors beyond the EU.

### If Any Of The Following Apply To You Please Place Initial In Box

- ☐ 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 on the Registry to be stored on the Registry and shared with other health professionals in the EU
- ☐ I approve of the information on the Registry to be stored on the Registry and shared with other health professionals beyond the EU

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

The I-DSD Registry is maintained by:  
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