**DATA SHARING AGREEMENT FOR PATIENT REGISTRIES SUPPORTED BY THE OFFICE FOR RARE CONDITIONS, GLASGOW**

**1. Purpose of this document**

* 1. This document describes the minimum arrangements for sharing of information for all condition-specific registries (‘Registries’) supported by the Office For Rare Conditions, Glasgow ‘the Office’) with agencies external to the University of Glasgow. It is to be used as the basis of agreements made about specific services with these agencies. The sections in boxes are to be composed to suit the specific information sharing agreement.

1.2 **Parties to the agreement**

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| Party A  Office For Rare Conditions  School of Medicine, Dentistry & Nursing  College of Medicine, Veterinary & Life Sciences  University of Glasgow | Party B - Applicant |

**2. Exclusions**

* 1. Some bodies have rights in law in certain circumstances to be given certain patient identifiable information without an information sharing agreement being needed. Examples include the UK Audit Commission or other statutory auditor when undertaking an audit that requires such information, but there are many others. This subject is not covered in this protocol.
  2. Information sharing with external agencies is governed by the Office’s patient confidentiality policy for the Registries. This policy is founded on the Caldicott principles which are based on the Data Protection Act 1998 (c 29) which is a UK Act of Parliament designed to protect personal data stored on computers or in an organised paper filing system. It follows the EU Data Protection Directive 1995 on protection, processing and movement of data.
  3. The Registries supported by the Office do not contain person identifiable information including name, address and identifiable images.
  4. Information exchanged as part of research is covered by research governance.

**3. Definitions**

3.1 Person identifiable information/data

This means information that can lead to the identification of an individual living person or client. It includes above all:

name (including initials)

address

photographs or videos.

Other details may, especially in combination, enable an individual to be identified, such as:

full postcode

date of birth

telephone number

e-mail address.

3.2 Information sharing

This means the Registry and third parties sending in either direction information using any physical (including handwritten notes or completed forms) or encrypted electronic medium. **Data sent externally must be encrypted.**

**4. Principles**

* 1. Information sharing between organisations must always be consistent with the Caldicott principles. These are:

1. Justify the purpose(s) for using confidential information.
2. Use it only when absolutely necessary.
3. Use the minimum that is required.
4. Access should be on a strict ‘need to know’ basis.
5. Everyone must understand their responsibilities.
6. Understand and comply with the law.
   1. The Office staff must always abide by the information governance policies and guidance available on [http://www.gla.ac.uk/schools/medicine/research/childhealth/ researchinterests/i-dsdproject/thei-dsdregistry/securityandconfidentiality/](http://www.gla.ac.uk/schools/medicine/research/childhealth/%20researchinterests/i-dsdproject/thei-dsdregistry/securityandconfidentiality/)

**5. Details of the agreement**

* 1. Purpose/s for sharing information

*Why is the information being shared?(to be completed by Party B)*

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* 1. Information to be shared

*Specifically what information is being shared? (to be completed by Party B)*

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| *(Use I-DSD CAH metadata file for large datasets)* |

* 1. When and how often is the information to be shared? *(to be completed by Party B)*

*e.g. on an ad hoc basis, at the beginning of every quarter etc.*

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* 1. What media is used for transferring the data (format *and* method)? *(to be completed by Party B after discussion with Party A)*

*How will the information be transferred and in what format? (e.g. documents by fax, post, courier, messages by answer machine, encrypted CD by special delivery, etc.).*

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* 1. How is the information to be stored? *(to be completed by Party B)*

*What format is it in? e.g. secure server database, encrypted CD etc.*

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* 1. Who will handle the data? Please state the authorised users *(to be completed by Party B)*

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5.7 How long will the data be held by Party B, i.e. retention period?

*The Registry will keep a record of all data that are supplied to the investigator. However, it is advised that Party B should keep the data supplied as well as any analysed data for a minimum period of 5 years from date of supply or from date of publication (whichever is latest). If the data are not used in a publication within 5 years of date of supply, the retention period should not extend beyond these 5 years.*

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* 1. What is the destruction process? (*(to be completed by Party B*)

*How will the information be destroyed when no longer required? (e.g. shredding) Please give details.*

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5.9 Responsibilities

The applicant(s) must treat the patient information received from the Registry with a level of confidentiality that is at least equivalent to all the Caldicott principles (Section 4.1).

*Party B should provide assurance that it has confidentiality policies and that their employees are trained in confidentiality, including citation of the relevant policies*

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5.10 How often will you report back to the Registry on the use the data has been put to?

*This may vary depending on the level of support you have requested from the Registry, but will generally involve a brief progress report on output from the analysis once every 6 months and a full list of outputs at the end of the project. (to be completed by Party B)*

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**6. Conditions on release of data**

6.1. Secondary release of data

Data are released for specific projects to specific people. Registry data cannot be used for other research projects by the same researchers or used by other researchers for any purpose. The release of Registry data to other people or research projects is not permitted without prior approval from the Office.

6.2. Acknowledgement and attribution of publications

If data from the Registry are used for a report or publication without any intellectual, statistical or clinical input from Registry employees in design, analysis or interpretation of data, the use of Registry data must be acknowledged along with a disclaimer (see disclaimer below).

*‘We thank the Office for Rare Conditions, Glasgow and all the contributing centres for providing data to the [name of the registry]. The [name of the registry] is supported by funding from [details of funders].’*

Registry employees must be included as co-authors in any publication or report when intellectual, statistical or clinical input and analysis has been required. Any document to be distributed or published must be made available to the Registry for review well in advance of the distribution or publication date.

A copy of published research based on Registry data, must be sent to the Registry.

6.3. Disclaimer

The disclaimer to be included in publications and reports based on Registry data that have not, with prior agreement, involved any Registry statistician or clinical input is:

*‘The views and opinions expressed in this article are those of the authors and do not reflect the* views of the Office for Rare Conditions, Glasgow.’

The source and data handling methods should be made clear in the ‘Methods’ section. The abstract should also include ‘[*name of the registry*]’ which would allow for searching Registry publications. Logos for inclusion in publications and reports are available on the Registry website.

Data published in any Annual Reports for the condition-specific registry are expected to be in the public domain, but the Office should be acknowledged as the source of the data and the disclaimer used.

**7. Agreement formalities**

Agreement to be signed by the responsible lead or deputising officer for the Office for Rare Conditions, Glasgow and by the equivalent office holder of the partner organisation.

**Office For Rare Conditions Glasgow reference number:**

**DSA/[Registry Name]/……**

**Period of agreement**

* **Data shared and available for analysis: dd/mm/yy to dd/mm/yy**
* **Data shared for storage only: dd/mm/yy to dd/mm/yy**

**Review date: dd/mm/yy**

Signed on behalf of the Office for Rare Conditions, Glasgow by

Name (print) Jillian Bryce

Role Project Manager

Signature

Date

Signed on behalf of by

Name (print)

Role

Signature

Date

**Copy of agreement to be stored for provision to information governance officer for the Office for Rare Conditions, Glasgow for inclusion on the information sharing register**.

**Once the end date of the agreement has been reached then Party B will confirm, using the form below, to the Office that:**

1. **The data have been used in accordance with this agreement.**
2. **The data have not been shared with other parties not mentioned in this agreement.**
3. **The data have only been used for the purposes outlined in this agreement.**
4. **The data have been destroyed in accordance with the criteria set out in this agreement**

**End of Agreement Sign off**

**Office For Rare Conditions Glasgow reference number:**

**DSA/[Registry Name]/…….**

**Party B** …………………...…………………...…………………...…………………...

Confirms that:

1. **The data have been used in accordance with this agreement.**
2. **The data have not been shared with other parties not mentioned in this agreement.**
3. **The data have only been used for the purposes outlined in this agreement.**
4. **The data have been destroyed in accordance with the criteria set out in this agreement and were destroyed on dd/mm/yy**

Signed on behalf of *……………………………………………*by

Name (print)……………………………………………………….

Role………………………………………………………………...

Signature…………………………………………………………..

Date / /