Application for Caldicott Guardian Approval

NOTE: You must address the 6 Caldicott principles (Appendix A) when submitting this application.

1. Study / Project Title

The I-DSD & I-CAH Registries

2. Please tick the type of study/project you are undertaking

Audit X Research X Service Improvement X Other ☐
If other, please provide further details:

3. Who is providing clinical support for the study / project

Name: Dr M Guftar Shaikh
Designation: Lead for Paediatric Endocrinology
Email Address or Telephone Number:
Guftar.shaikh@ggc.scot.nhs.uk

4. Details of individual / organisation requesting data

Name: S. Faisal Ahmed
Designation: Professor of Child Health
Work/University Address: RHC & QEUH campus, Govan Road, Glasgow

Contact Number: 0141 451 5249

5. Purpose for which data are to be used (Principle 1)

The I-DSD & I-CAH Registries have now been in existence for over a decade and its clinical users are spread across all continents. The two registries have separate websites (www.i-dsd.org) and (www.i-cah.org) but use the same registry platform which is managed at the University of Glasgow. The project is managed by a Steering Committee & its Project Management Group https://home.i-dsd.org/governance/. The only identifiable data that are collected includes the date of birth. The reason for collecting this includes the collection of age-dependent clinical indicators as well as matching the data fields to core data elements that are collected in European rare disease registries. It is expected that the Registry will mainly perform Secondary Research on the data that shall be collected during routine clinical care and this form of research is approved under its current ethics approval and has also been described in the participant information sheet. It is anticipated that, in time, these data will be used for the following purposes by a wide range of stakeholders.

a. Provide a source population for the conduct of clinical trials
b. Provide the patient with details of their condition
c. Provide information on specific interventions related to defined patient groups
d. Provide for the follow-up of small patient populations.
e. Life-cycle assessment of the effectiveness and safety of interventions and medicinal products
f. Provide robust data on disease epidemiology, patients' characteristics and current standard of care
g. Provide source population data that can be linked to other datasets on specific outcomes
h. Provide data to industry, regulators and other trialists to facilitate the design of pragmatic trials for rare conditions as well as for conducting post-authorisation studies
i. Enable linkages to other rare disease registries approved by the Data Access Committee.

6. Which identifiable data items are required? Please detail why these are required. (Principles 2 and 3)

PID Required	√	**Justification**
CHI Number	NA	
Forename	NA	
Surname	NA	
DOB	√	The date of birth is necessary for two purposes. Firstly, it will be used to calculate several clinical indicators such as age at presentation, age at diagnosis, age at death, etc. Secondly, it will also allow data to be matched to other registries that collect the same field
Age	NA	
Gender	√	Knowledge of initial and current gender are important for this registry as alterations may be due to the underlying condition
Address	NA	
Post code (full)	NA	
Post code (partial)	NA	
Clinical data	√	Clinical features including diagnosis, investigation, treatment and outcome details are necessary for this detailed disease registry
Other (please specify)	NA	

7. Who will have access to this information? (Principle 4)

Internal: The clinician entering the case data shall hold the NHS, CHI or Hospital ID number separately at local centre. On notification of the case, the clinician shall be provided with a a unique case ID. The clinician shall store this ID and the link to local case details (NHS,CHI number) in their local institution and physically separate from the database.

External: The database shall be held at the University of Glasgow. The MVLS IT Services at the University of Glasgow have a body of projects associated with high-level security. In restricting access to the registry and its contents, roles based access control (RBAC) and identity based access control (IBAC) mechanisms are applied. The X509-based digitally signed roles (attribute certificates) shall be maintained in a secure attribute server. Authentication to the portal and delivery of attribute certificates for local authorisation at the portal level is made through the UK Access Management Federation and a dedicated Identity Provider. No personal data except those mentioned above shall be stored on the Registry. All those involved in the running and development of the Registry will have to be up to date with Data Protection Regulations and will complete the University of Glasgow online course (http://www.gla.ac.uk/services/dpfoioffice/ dataprotectiononlinetrainingmodule/) and attend the University's course on DP (http://www.gla.ac.uk/services/humanresources/employeeandorganisationaldevelopment/learningcoursesandres

8. Storage and use of personal data during the audit/project (Principle 5)

Will you be undertaking any of the following activities at any stage (including the identification of potential participants)? Please tick as appropriate.

- ☐ Access to Health Record (paper)
- ☐ Access to Health Record (electronic)
- ☐ Sharing of identifiable data with other organisations (provide further detail below)
- **X** Publication of data (if this could identify individuals provide further detail below)
- ☐ Use of audio/visual recording devices
- ☐ Storage of personal identifiable data on any of the following:
  - ☐ Manual files, including x-rays
  - **X** NHS Computers
  - ☐ Home or other personal computers
  - ☐ University computer
  - ☐ Private company computer
  - ☐ Laptop computer (or any other mobile device)
  - ☐ USB Flash Drive

Additional Information:

The data shall be published as non-personally identifiable metadata and provided as reports to steering committee and these data will be openly accessible on the I-DSD and I-CAH websites. Non-personally identifiable data shall also be supplied to investigators and registries approved by the Registry Scientific Panel/data Access Committee.

9. Destruction of Data

How long will the data be held?
The project has already been in operation for 11 years and it is likely that the non-identifable data that will collected will be stored for over 30 years in accordance with GDPR

How will the data be destroyed?
All electronic data will be erased from the servers.

10. Please provide your organisation's Data Protection Registration Number (if external to NHSGGC)

The University of Glasgow's current Notification Number is Z6723578.

Note:

- Copies of any other relevant supporting documentation (e.g. ethics approval, patient information leaflet etc.) should be attached to this application
- Appendix A details the Caldicott Principles

Person responsible for the requested data

Name ……S. Faisal Ahmed……

Designation ……Professor of Child Health, Project Lead for EuRRECa, ……

29/7/19

Signature: …….. Date:……..

The release of data as described above is: **approved**

Caldicott Guardian  **Date …31/07/2019…….**

Appendix A

Caldicott principles

Principle 1 - **Justify the purpose(s)**
Every proposed use or transfer of patient-identifiable information within or from an organisation should be clearly defined and scrutinised, with continuing uses regularly reviewed, by an appropriate guardian.

Principle 2 - **Don't use patient-identifiable information unless it is absolutely necessary**
Patient-identifiable information items should not be used unless there is no alternative.

Principle 3 - **Use the minimum necessary patient-identifiable information**
Where use of patient-identifiable information is considered to be essential, each individual item of information should be justified with the aim of reducing identifiability.

Principle 4 - Access to patient-identifiable information should be on a strict need-to-know basis
Only those individuals who need access to patient-identifiable information should have access to it, and they should only have access to the information items that they need to see.

Principle 5 - **Everyone should be aware of their responsibilities**
Action should be taken to ensure that those handling patient-identifiable information - both clinical and non-clinical staff - are made fully aware of their responsibilities and obligations to respect patient confidentiality.

Principle 6 - **Understand and comply with the law**
Every use of patient-identifiable information must be lawful. Someone in each organisation should be responsible for ensuring that the organisation complies with legal requirements.

Caldicott Guardian for NHS Greater Glasgow & Clyde

Emilia Crighton
Interim Public Health Director
Greater Glasgow & Clyde NHS Board
J B Russell House
Gartnavel Royal Hospital
Gt. Western Road
Glasgow

All queries in the first instance should be made to:

Isobel Brown, Information Governance Manager Tel 0141 201 4438 or Email:
Isobel.brown@ggc.scot.nhs.uk

Faisal Ahmed
Faisal.Ahmed@glasgow.ac.uk

Data Protection Officer
Information Governance Department
NHS Greater Glasgow & Clyde
2nd Floor, 1 Smithhills Street
Paisley
PA1 1EB

Date: 31 July 2019

Enquiries to: Isobel Brown
Tel: 0141 355 2020
Email: Isobel.Brown@ggc.scot.nhs.uk

Dear Faisal

Re: The I-DSD & I-CAH Registries

Thank you for your Caldicott application received on 29/07/2019 regarding your proposed Service Evaluation / Audit / Research Project.

I have reviewed this application and can confirm that I am happy to approve this application on behalf of the Caldicott Guardian.

Please note that this approval only covers access to NHSGGC patients.

Please find attached a signed copy of your application for your records.

Yours sincerely

IBrown

Isobel Brown
Data Protection Officer
Information Governance