

Professor S. Faisal Ahmed
The University of Glasgow
Child Health
Royal Hospital For Sick Children
University of Glasgow
Glasgow
G3 8SJ

West of Scotland REC 1
Ground Floor - Tennent Building
Western Infirmary
38 Church Street
Glasgow
G11 6NT

Date 26 August 2014
Direct line 0141 211 6270
E-mail WoSREC1@ggc.scot.nhs.uk

Dear Professor Ahmed

Title of the Research Database: The I-DSD Registry v2.0
REC reference: 14/WS/1050
IRAS project ID: 153634

Thank you for your letter of 14 August 2014, responding to the Committee's request for further information on the above research database and submitting revised documentation.

The further information was considered at the meeting of the Sub-Committee of the REC held on 25 August 2014. A list of the members who were present at the meeting is attached.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC manager Miss Kirsty Sime, WosRec1@ggc.scot.nhs.uk.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion of the above research database on the basis described in the application form and supporting documentation as revised.

Duration of ethical opinion

The favourable opinion is given for a period of five years from the date of this letter and provided that you comply with the standard conditions of ethical approval for Research Databases set out in the attached document. You are advised to study the conditions carefully. The opinion may be renewed for a further period of up to five years on receipt of a fresh application. It is

suggested that the fresh application is made 3-6 months before the 5 years expires, to ensure continuous approval for the research database.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper		03 July 2014
Other [Caldicott Recommendation]		25 July 2014
Other [Confidentiality Policy]	3.0	01 June 2014
Other [Corporate information Security Policy]	1.0	05 May 2009
Other [Data Flow within I-DSD registry]	2.0	22 January 2012
Other [Data Protection Register]	n/a	04 June 2003
Other [I-DSD Steering Committee charter]	1.0	11 June 2012
Other [Original IRAS application of ESPE DSD Registry]	n/a	05 May 2009
Other [System Level Security Policy (SLSP)]	3.0	01 June 2014
Other [UK ethics approval for ESPE DSD Registry]	n/a	18 June 2009
Other [WoSRES letter approving name change to IDSD]	n/a	19 January 2012
Participant consent form [Adult]	3.0	14 August 2014
Participant information sheet (PIS) [Adult]	3.0	14 August 2014
Participant information sheet (PIS) [Child]	2.0	09 October 2012
Protocol for management of the database [SOP]	3.0	01 June 2014
REC Application Form		14 August 2014
Response to Request for Further Information		14 August 2014
Summary of research programme(s) [MRC grant application]		18 January 2011

Research governance

A copy of this letter is being sent to the R&D office responsible for University of Glasgow.

Under the Research Governance Framework (RGF), there is no requirement for NHS research permission for the establishment of research databases in the NHS. Applications to NHS R&D offices through IRAS are not required as all NHS organisations are expected to have included management review in the process of establishing the database.

Research permission is also not required by collaborators at data collection centres (DCCs) who provide data under the terms of a supply agreement between the organisation and the database. DCCs are not research sites for the purposes of the RGF.

Database managers are advised to provide R&D offices at all DCCs with a copy of the REC application for information, together with a copy of the favourable opinion letter when available. All DCCs should be listed in Part C of the REC application.

NHS researchers undertaking specific research projects using data supplied by a database must apply for permission to R&D offices at all organisations where the research is conducted,

whether or not the database has ethical approval.

Site-specific assessment (SSA) is not a requirement for ethical review of research databases.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached standard conditions give detailed guidance on reporting requirements for research databases with a favourable opinion, including:

- Notifying substantial amendments
- Submitting Annual Progress reports

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: <http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

14/WS/1050	Please quote this number on all correspondence
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Yours sincerely

Abibat Ackwumi

On behalf of

Dr Malcolm Booth
Chair

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

Approval conditions

Copy to: Dr John Watt, The University of Glasgow Confidentiality Advise Team

West of Scotland 1

Attendance at Sub-Committee of the REC meeting on 25 August 2014

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Rosemarie Davidson	Consultant in Clinical Genetics	Yes	
Dr Jane Gow	Researcher (retired)	Yes	
Dr Peter Hutchison	GP (Vice Chair)	Yes	Chair of meeting

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Abibat Adewumi	Co-ordinators Assistant