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West of Scotland REC 1
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Date 02 February 2015
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Dear Professor Ahmed

Title of the Database:	The I-DSD Registry v2.0
REC reference:	14/WS/1050
Amendment number:	SOP v4.0 010115 (REC Ref AM01)
Amendment date:	19 January 2015
IRAS project ID:	153634

The above amendment was reviewed by the Sub-Committee in correspondence. The amendment relates to an updated protocol. The changes within the protocol include revised definition of the Research Users and inclusion of a new section for participant Access. A new document in the form of participant access guide is also included in the submission. The Adult IDSD and ICAH PIS's have been updated in line with the changes. The ICAH PIS was not included in the renewal application for the study. This was previously documented and approved in the previously linked application.

Ethical opinion

The Committee supports the need to give the participants or their guardian access to a subset of the registry.

The Committee suggested that you might want to consider adding an extra layer of security as e-mail addresses can be mis-transcribed and the activation link sent to the wrong person. Although the committee acknowledge that the data that can be accessed by the participant is relatively limited. This extra security could either be in the form of entering the e-mail address twice into the system or sending a text with a code to the participants' mobile phone similar to online banking checks.

The Committee thought that you might want to consider an option for those who do not have online access, with perhaps having access at the clinic. Although, the Committee acknowledge the statement in the consent form relating to requiring online access.

The Committee had no other issues with the other aspects of the amendment.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

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		19 January 2015
Notice of Substantial Amendment (RD)	SOP v4.0 010115 (REC Ref AM01)	19 January 2015
Other [Participant Access Guide]	1.0	01 January 2015
Participant consent form [I-CAH Adult (Track Changes)]	2.0	01 January 2015
Participant consent form [I-DSD Adult (Track Changes)]	4.0	01 January 2015
Participant information sheet (PIS) [I-CAH Adult (Track Changes)]	2.0	01 January 2015
Participant information sheet (PIS) [I-DSD Adult (Track Changes)]	4.0	01 January 2015
Protocol for management of the database [Track Changes]	4.0	01 January 2015

Membership of the Committee

The members of the Ethics Committee who took part in the review are listed on the attached sheet.

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.

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

14/WS/1050

Please quote this number on all correspondence

Yours sincerely

Abibat Akewumi

On behalf of
Dr Malcolm Booth
Chair

Enclosures: List of names and professions of members who took part in the review

Copy to: Dr John Watt, The University of Glasgow

West of Scotland REC 1

Attendance at Sub-Committee of the REC meeting on 26 January 2015

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Malcolm Booth	Consultant in Anaesthesia and Intensive Care (Chair)	Yes	Chair of Meeting
Dr Colin Campbell	Consultant Radiologist (Alternate Vice Chair)	Yes	
Dr Jane Gow	Researcher (retired)	Yes	
Mr Jim McHugh	Independent Financial Adviser	Yes	

Also in attendance:

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