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West of Scotland REC 1

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Date 12 January 2021
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Dear Professor Ahmed

Title of the Database:	I-DSD & I-CAH
REC reference:	19/WS/0131
Amendment number:	269776/1468915/22/25/106286 (REC Ref AM01)
Amendment date:	21 December 2020
IRAS project ID:	269776

The above amendment was reviewed by the Sub-Committee in correspondence.

Summary of Amendment

The I-DSD and I-CAH registries are supporting the needs of a sub-group within the registry that have the condition Turner Syndrome (TS). Like the CAH sub-group, a module is being developed that will capture routine clinical information that is of particular relevance to this group of patients. We are also creating TS-specific Information sheets and Consent Form - which is the purpose of this amendment request.

Ethical opinion

The Sub-Committee was content with the amendment, however it wanted on the consent form "parent" replaced with "parent/guardian/carer". This was put to the applicant on 11 January 2021. A response was received on 12 January 2021 with the document updated. The amendment was therefore approved.

The Sub-Committee also noted that the wrong version date of the PISs and consent form was noted on the notice of amendment. The version on the actual document has been used.

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 [coverletter I-TS information sheets 211220]	21/12/2020	21 December 2020
Notice of Amendment (RD) [AmendmentFormResearch Database_ReadyFor Submission]	269776/1468 915/22/25/10 6286 (REC Ref AM01)	21 December 2020
Participant consent form [I-TS Registry Consent Form]	1.1	11 January 2021
Participant information sheet (PIS) [I-TS Registry Information Sheet for adult]	1.0	21 December 2020
Participant information sheet (PIS) [I-TS Registry Information Sheet for child]	1.0	21 December 2020

Membership of the Committee

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

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

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.

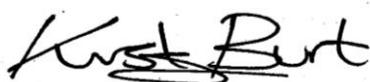
HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

IRAS Project ID: 269776

Please quote this number on all correspondence

Yours sincerely



On behalf of
Dr Malcolm Booth
Chair

Enclosures:

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

Copy to:

*Mr Tom Muir, University of Glasgow, The University of Glasgow
Confidentiality Advice Team*

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Attendance at Sub-Committee of the REC meeting scheduled for 12 January 2021 (Reviewed early on 11 January 2021)

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
Mrs Elspeth Fulton	Retired Senior Clinical Research Associate (CRA)	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Kirsty Burt	Senior Co-ordinator