WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

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Date 09 September 2019
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Dear Professor Ahmed

Title of the Research Database: **I-DSD & I-CAH**
REC reference: **19/WS/0131**
IRAS project ID: **269776**

Thank you for responding to the Committee's request for further information on the above research database and submitting revised documentation.

The further information has been considered on behalf of the Committee by a member of staff.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study

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.

This application was for the renewal of a Research Database application. The previous REC Reference number for this application was 14/WS/1050.

Duration of ethical opinion

The favourable opinion is given for a period of five years from the date of this letter 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:

Document	*Version*	*Date*
Covering letter on headed paper [Coverletter I-DSD I-CAH 2019]		05 August 2019
Other [Corporate Level Security Policy]	1	29 July 2019
Other [Data Flow]		29 July 2019
Other [Caldicott Guardian Approval]		31 July 2019
Other [CV of PI - Syed Faisal Ahmed]		
Other [Question 33 Text]		16 August 2019
Participant consent form [I-CAH Consent Form]	4	09 September 2019
Participant consent form [I-DSD Consent Form]	6	09 September 2019
Participant information sheet (PIS) [I-DSD PIS Child]	1	29 July 2019
Participant information sheet (PIS) [I-CAH PIS Child]	1	29 July 2019
Participant information sheet (PIS) [I-DSD PIS Adult]	6	06 September 2019
Participant information sheet (PIS) [I-CAH PIS Adult]	4	06 September 2019
Protocol for management of the database [Management Protocol]	1	29 July 2019
REC Application Form [RD_Form_20082019]		20 August 2019
Response to Request for Further Information [Ethics provisional opinion feedback]		
Summary of research programme(s) [Summary of research]	1	05 August 2019

Research governance

Under the UK Policy Framework for Health and Social Care Research, 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

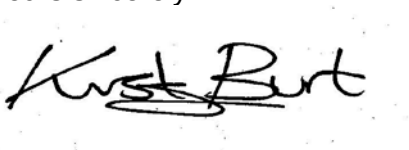
The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the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

HRA 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/

19/WS/0131	**Please quote this number on all correspondence**

Yours sincerely



On behalf of
Dr Malcolm Booth
Chair

Enclosures: *Approval conditions*

Copy to: *Mr Tom Muir, University of Glasgow The University of Glasgow*