WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

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West of Scotland REC 4
Research Ethics
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Date 11 September 2017
Direct line 0141 232 1808
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Dear Professor Ahmed

Title of the Database:	**E-Reporting Of Rare Endocrine Conditions (e-REC)**
REC reference:	**17/WS/0178**
IRAS project ID:	**230815**

The Research Ethics Committee reviewed the above application at the meeting held on 01 September 2017. Thanks to Dr Jillian Bryce for attending to discuss the application.

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 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.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research database on the basis described in the application form and supporting documentation, subject to the conditions specified below.

Research governance

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.

Summary of discussion at the meeting

- **Favourable risk benefit ratio; anticipated benefit/risks for research participants (present and future)**

  The Committee observed that there were no risks to the participant or the clinician. They did ask the applicant what would happen if an individual was registered for Endo-ERN as a result of being diagnosed with a particular condition which later turned out to a be a mis-diagnosis.

  Dr Bryce was not certain of what would happen in this instance and would ask the clinicians involved to report back to the project team in the event of such an occurrence. She added that a unique ID was given to each new patient and this could be reversed.

  The Committee asked how the researchers would ensure that individuals weren't registered twice in error.

  Dr Bryce said she had not considered this and would investigate to avoid this happening.

  The Committee was satisfied with these responses.

- **Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity**

  The Committee was satisfied that only anonymised data would be used and that it would be held by MVLS IT services with suitable supporting information from the Caldicott Guardian and the NHS.

The Committee asked the applicant about the data that was being collected.

Dr Bryce explained that they were collecting data on the number of patients seen at each centre in one month with particular medical conditions.

The Committee asked why they were not collecting more.

Dr Bryce replied that this was a preamble to a larger study. They planned to collect metadata and then set up a registry in future.

The Committee asked about the process for data-sharing.

Dr Bryce stated that the data would be shared with the Endo-ERN office in Leiden and via them to CHAFEA (Consumers, Health, Agriculture & Food Executive Agency of the EU). She added that other healthcare professionals could request the data via the Endo-ERN Office in Leiden.

The Committee asked Dr Bryce why CHAFEA would receive the data.

The data would be passed onto CHAFEA because they provided the funding for the project.

The Committee was satisfied with these responses.

Other ethical issues were raised and resolved in preliminary discussion before your attendance at the meeting.

Please contact the REC Manager if you feel that the above summary is not an accurate reflection of the discussion at the meeting.

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:

Document	*Version*	*Date*
Covering letter on headed paper [Cover letter]		25 July 2017
Other [lay info sheet]		25 June 2017
Other [Caldicott approval]		18 July 2017
Other [Faisal Ahmed CV July 2017]	July 2017	
Other [screen shot of sign up form]		31 July 2017

Document	*Version*	*Date*
Participant information sheet (PIS) [Participant info sheet]		25 June 2017
Protocol for management of the database [Protocol for management]	1.0	20 July 2017
REC Application Form [RD_Form_01082017]		01 August 2017
Summary of research programme(s) [project summary]		20 July 2017
Summary of research programme(s) [List of centres]		25 July 2017
Summary of research programme(s) [Data Flow]		20 July 2017

Membership of the Committee

The members of the Ethics Committee who were present at the meeting 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.

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/

Yours sincerely

On behalf of
Dr Ken James
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: *Ms Isobel Brown, The University of Glasgow*

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Attendance at Committee meeting on 1 September 2017

Committee Members:

Name	*Profession*	*Present*	*Notes*
Miss Lynda Brown	Public Health Adviser	No	
Ms Ammani Brown	Nurse Manager	No	
Dr Grace Campbell	Lead Clinician, Prison Healthcare	No	
Ms Cristina Coelho	Lead Pharmacist Clinical Effectiveness	Yes	
Wendy Cohen	Speech & Language Therapist	Yes	
Dr Michael Fail	Consultant Geriatrician	No	
Dr Judith Godden	Scientific Adviser	No	
Dr Kay Greenshields	Account Manager for Scottish Enterprise	Yes	
Dr Ken James	Consultant Anaesthetist	Yes	Chair
Dr Agata Kochman	Consultant Pathologist	Yes	
Dr Karen Lang	Clinical Project Manager	No	
Dr Rachael MacIsaac	Senior Biostatistician	Yes	
Miss Fiona Mackelvie	Retired Administrator	Yes	
Dr Christine Milligan	Retired – Pharmaceutical Industry	Yes	
Ms Aileen Scullion	Retired Head Teacher	No	
Dr Subra Viswanathan	Consultant GI Radiologist	Yes	
Mr John Woods	Retired Project Co-ordinator	Yes	
Mr Iain Wright	Retired - Technical Manager	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Sophie Bagnall	REC Assistant
Ms Rozanne Suarez	REC Manager

Written comments received from:

Name	*Position*
Dr Karen Lang	Clinical Project Manager