

WoSRES
West of Scotland Research Ethics Service

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Date : 18th June 2009

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Dr S. Faisal Ahmed
Bone & Endocrine Research Group
Department of Child Health
Royal Hospital for Sick Children
Yorkhill
Glasgow
G3 8SJ

Dear Dr Ahmed

Project : 09/S0703/76 The ESPE DSD Registry 12422/37590/9/296

I should like to acknowledge the content of letter dated 16th June 2009 from you enclosing the approved amendments to the Study Design and the following approved documents as required by the Committee at the meeting on 2nd June 2009

- 1 Information Sheet for Adults and Young People Over 14yrs dated 16/06/09
- 2 Consent Form for Adults and Young People Over 14yrs dated 16/06/09
- 3 Data Protection Register – Entry Details

Yours sincerely



Andrea Torrie, Senior/Lead Administrator

c.c. R & D Department

08 June 2009

Dr S. Faisal Ahmed
Dept of Child Health
Royal Hospital For Sick Children
G3 8SJ

Dear Dr Ahmed

Title of the Database: The ESPE DSD Registry
REC reference: 09/S0703/76

The Research Ethics Committee reviewed the above application at the meeting held on 02 June 2009. Thank you for attending to discuss the application.

Ethical opinion

The committee thanked you for attending the meeting to discuss his study

The committee had several questions for you which were answered to their satisfaction

The committee require the undernoted amendments/clarifications to both the Study design and Information Sheets:

Study Design:

- a) page 17 Questions 6 is incomplete.

Information Sheets

Information for Children less than 14 years old - is satisfactory

Information for Adults and young people over 14 years old should be shortened and simplified and the main points of the study/registry as they apply to the patient/adult stated clearly and should contain the undernoted additional information;

- a) A further sentence should be added in respect of data storage.
- b) A further sentence should be added in respect of "genetic information being stored for future research. Any further research on the stored samples would require to have the approval of a Research Ethics Committee".
- c) A further sentence should be added to the effect that participants can look at the information stored in the registry through their clinician.

The above amendments/clarifications should come back to the secretary for checking and

filing.

ESPE DSR Registry Response Form should read "Consent Form" and changed so it doesn't read as if consent is presumed in advance (it can't refer to registrant until the patient is registered).

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.

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 conditions 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>
Corporate Information Security Policy and Policy with Regard to Storage and Management of Clinical Data		05 May 2009
Caldicott Guardian Recommendation		21 May 2008
Participant Consent Form		05 May 2009
Participant Information Sheet: Information for Children less than 14 years old		05 May 2009
Covering Letter		05 May 2009
Application	Version 2.2	05 May 2009
ESPE DSD Registry		05 May 2009
EuroDSD		05 May 2009
Participant Information Sheet: Adults & Young People over 14 years old		05 May 2009

Research governance

A copy of this letter is being sent to the R&D office

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. There is no need to inform Local Research Ethics Committees.

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 (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

Here you will find links to the following

- a) Providing feedback. You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.
- b) Annual Reports. Please refer to the attached conditions of approval.
- c) Amendments. Please refer to the attached conditions of approval.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk

09/S0703/76

Please quote this number on all correspondence

Yours sincerely



Dr John Hunter
Chair

E-mail: andrea.torrie@ggc.scot.nhs.uk

Enclosures:

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

Approval conditions

Copy to:

R & D RHSC (WIG)