



National Research Ethics Service

Trent Research Ethics Committee

Research Ethics Office
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11 October 2009

Professor Elizabeth Draper
Dept of Health Sciences
22-28 Princess Road West
Leicester
LE1 6TP

Dear Professor Draper

Title of the Database: British Isles Network of Congenital Anomaly Registers (BINOCAR)
REC reference: 09/H0405/48

The Research Ethics Committee reviewed the above application at the meeting held on 1 October 2009. Thank you for attending to discuss the application.

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.

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>
Covering Letter		14 August 2009
REC application	IRAS Research Database Form V 2.3 (lock code 25660/56406/9/606)	19 August 2009
Participant Information Sheet	V 1.1	12 August 2009
Protocol	V 2.0	12 August 2009

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. 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.

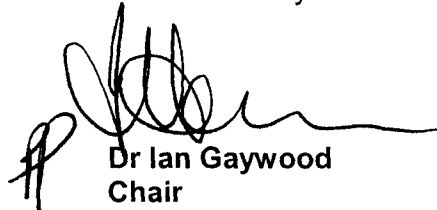
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We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk

09/H0405/48

Please quote this number on all correspondence

Yours sincerely



Dr Ian Gaywood
Chair

E-mail: jenny.hancock@derwentshareservices.nhs.uk

Enclosures:

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

Approval conditions

Trent Research Ethics Committee

Attendance at Committee meeting on 01 October 2009

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Peter Allmark	Principal Lecturer	Yes	
Mr John Beswick	Lay member	No	
Dr Tim Coleman	GP	No	
Mr Peter Fox	Principal Pharmacist	Yes	
Dr Ian Gaywood	Consultant Rheumatologist	Yes	
Ms Karon Glynn	Head of Mental Health	No	
Dr Brian Hands	General Practitioner	No	
Dr David Henson	Principal Clinical Scientist	Yes	
Mr Peter Korczak	Consultant Maxillo-facial Surgeon	Yes	
Dr Simona Lampariello	Paediatric Intensivist	Yes	
Mrs Judith Neal	Lay member	Yes	
Mr Kevin Power	Senior Lecturer in Nursing	Yes	
Dr Helen Sammons	Senior Lecturer	Yes	
Dr Nick Taub	Statistician	No	
Ms Hannah Wall	Lay member	No	
Ms Kay Wheat	Academic Lecturer	Yes	
Mr Terence Wiseman	Lay Member	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Jenny Hancock	Co-ordinator