Health Research Authority
East Midlands - Derby Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

16 November 2016

Professor Joan K Morris
Wolfon Institute of Preventive Medicine
Queen Mary University of London
Charterhouse Square
EC1M 6BQ

Dear Professor Morris,

Title of the Database:	**Linked de-identified research database for congenital anomaly outcomes**
REC reference:	**16/EM/0440**
IRAS project ID:	**188069**

The Research Ethics Committee reviewed the above application at the meeting held on 03 November 2016. Thank you 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 the REC Manager Vic Strutt, NRESCommittee.EastMidlands-Derby@nhs.net.
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.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

1. Provide the Committee with the CAG approval once this has been extended for the duration of the study

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

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

Social or scientific value; scientific design and conduct of the study

The Committee commented the study was well presented as this was a complicated issue. The Committee told you there were no real issues with the application and asked the applicant if they thought the timings referred to were realistic. *You had advised the Committee that it had taken so long to get the study moving that all the funding was already in place. You continued that there was currently another project being carried out and were hoping to 'piggy back' onto that and use the expertise from the team*

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

The Committee noted that CAG (Confidentiality Advisory Group) had approved this study for the next 2 years, and as the study is due to run until 2018 would CAG also extend their approval. *You had assured the Committee that it had recently been extended so it shouldn't be a problem to get a further extension*

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*
Confirmation of any other Regulatory Approvals (e.g. NIGB) and all correspondence [PIAG approval 2015]		17 September 2015
Covering letter on headed paper [letterheadS04102016]	1	04 October 2016
IRAS Application Form [IRAS_Form_04102016]		04 October 2016
IRAS Application Form XML file [IRAS_Form_04102016]		04 October 2016
IRAS Checklist XML [Checklist_04102016]		04 October 2016
Letter from funder [Letter funding linkage]		31 March 2016
Letter from sponsor [QMUL Provisional Sponsorship]		03 October 2016
Other [Statement of Activities]		04 October 2016
Other [Schedule of events]		26 September 2016
Other [CAG Annual review 2016 email]		22 September 2016
Referee's report or other scientific critique report [Departmental Approval]		21 March 2016
Research protocol or project proposal [Protocol V4 28092016]	4	28 September 2016
Summary CV for Chief Investigator (CI) [CV JKMorris]	1	20 September 2016

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

<u>Reporting requirements</u>

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/

16/EM/0440	**Please quote this number on all correspondence**

Yours sincerely,

Dr John Fenlon
Vice Chair

E-mail: NRESCommittee.EastMidlands-Derby@nhs.net

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

Approval conditions

Copy to: *Mr Tiesheng Wu*

East Midlands - Derby Research Ethics Committee

Attendance at Committee meeting on 03 November 2016

Committee Members:

Name	*Profession*	*Present*
Dr John S Fenlon	Statistical Consultant	Yes (Vice Chair)
Dr Brian Hands	Retired General Practitioner	Yes
Dr David Henson	Principal Clinical Biochemist	Yes
Mr Phil Hopkinson	Retired Mental Health Act Manager	Yes
Mrs Janet Mallett	Retired Nurse	Yes
Dr Margaret Stone	Senior Research Fellow (Retired)	Yes
Mr Michael Wakeman	Consultant Pharmacist	Yes
Mrs Anne Walker	Voluntary worker in Health Care	Yes

Also in attendance:

Name	*Position (or reason for attending)*
Miss Victoria Strutt	REC Manager