

East Midlands - Derby Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

04 February 2019

Joachim Tan
Statistician, EUROlinkCAT
Population Health Research Institute
St George's University of London
Cranmer Terrace London SW17 0RE

Dear Mr Tan

Title of the Database:	Linked de-identified research database for congenital anomaly outcomes
REC reference:	16/EM/0440
Amendment number:	1
Amendment date:	19 December 2018
IRAS project ID:	188069

The above amendment was reviewed 31 January 2019 by the Sub-Committee in correspondence.

Ethical opinion

There were no ethical issues raised.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Notice of Substantial Amendment (RD)		19 December 2018
Protocol for management of the database [Clean]	5	19 December 2018
Protocol for management of the database [Tracked]	5	19 December 2018

Membership of the Committee

The members of the Ethics Committee who took part in the review are listed on the attached sheet.



Health Research Authority

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.

We are pleased to welcome researchers and R & D staff at our NRES committee members' 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 S Fenlon
Chair

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

Enclosures: List of names and professions of members who took part in the review

*Copy to: Mr Tiesheng Wu, Wolfon Institute of Preventive Medicine
Confidentiality Advice Team*



Health Research Authority

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Attendance at Sub-Committee of the REC meeting on 31 January 2019

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr John S Fenlon (Chair)	Statistical Consultant	Yes	
Mrs Janet Mallett	Retired Nurse	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Silje Dybing	REC assistant (Minutes)