NHS
Health Research Authority

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

Telephone: 0115 8839440

20 February 2013

Professor Julia Hippisley-Cox
University of Nottingham
13th floor Tower Building
University Park
Nottingham
NG7 2RD

Dear Professor Hippisley-Cox

Title of the Database:	**QSurveillance Database**
REC reference:	**13/EM/0044**
IRAS project ID:	**123096**

The Research Ethics Committee reviewed the above application at the meeting held on 07 February 2013.

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 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		24 December 2012
Other: JHC CV	1.0	09 September 2011
Other: QSurveillance Data Sharing Agreement	1.0	01 January 2013
Other: QSurveillance Practice Consent Information Sheet	1.0	01 January 2013

Other: QSurveillance Research Application Form	4.0	18 January 2011
Other: QFlu Service Protocol	2.9	13 December 2005
Other: Correspondence with the REC		26 July 2005
REC application	123096/398139/9/370	24 December 2012

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 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 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/

13/EM/0044	**Please quote this number on all correspondence**

Yours sincerely

Mr Peter Korczak (Chair)
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

NRES Committee East Midlands - Derby

Attendance at Committee meeting on 07 February 2013

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Charles Beck	Lecturer & Honorary Specialty Registrar in Public Health	Yes	
Dr Helen Busby	Researcher	No	
Mr Peter Fox	Principal Pharmacist	Yes	
Mr David Grenz	Lay Member	Yes	
Dr Brian Hands	General Practitioner	Yes	
Dr David Henson	Principal Clinical Biochemist	Yes	
Mr Phil Hopkinson	Mental Health Act Manager	Yes	
Mr Peter Korczak (Chair)	Consultant Maxillofacial Surgeon	Yes	
Mrs Janet Mallett	Lay Member	Yes	
Dr Helen Sammons (Vice Chair)	Associate Professor in Child Health	Yes	
Dr Penny Smith	Lay Member	Yes	
Dr Nick Taub	Statistician	Yes	
Mr Michael Wakeman	Consultant Pharmacist	Yes	
Mrs Anne Walker	Lay Member	Yes	
Ms Kay Wheat	Academic Lecturer	No	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Carol Marten	Coordinator

CONDITIONS OF ETHICAL APPROVAL

Research Ethics Committee:	NRES Committee East Midlands - Derby
Research Database:	QSurveillance Database
Data Controller:	Professor Julia Hippisley-Cox
Establishment:	University of Nottingham
REC reference number:	13/EM/0044
Name of applicant:	Professor Julia Hippisley-Cox
Date of approval:	07 February 2013
IRAS project ID:	123096

Ethical approval is given to the Research Database team ("Database team") based within the Establishment by the Research Ethics Committee ("the Committee") subject to the following conditions.

1. Further communications with the Committee

1.1 Further communications with the Committee are the personal responsibility of the applicant.

2. Duration of approval

2.1 Approval is given for a period of 5 years, which may be renewed on consideration of a new application by the Committee, taking account of developments in legislation, policy and guidance in the interim. New applications should include relevant changes of policy or practice made by the establishment since the original approval together with any proposed new developments.

3. Generic approval for the Research Database team

3.1 Ethical approval is given for processing of personal data by the Research Database team for the purposes described in the application. This includes specific research projects undertaken by the Database team using the data, subject to the following conditions:

3.1.1 The research project is within the fields of health or social care research

described in the application.

3.1.2 The research protocol has been subject to scientific critique, is appropriately designed in relation to its objectives and (with the exception of student research below doctoral level) is likely to add something useful to existing knowledge.

3.1.3 The processing of the data will comply with the terms of informed consent from data subjects.

3.2 Any research project requiring researchers to undertake additional procedures involving subjects, other than data collection arrangements described in the application, is not covered by generic approval for the Database. Additional research procedures should be the subject of further ethical review, either as a substantial amendment to the terms of generic approval for the Database, or separate application for ethical review of a specific project.

3.3 A Notice of Substantial Amendment form should be submitted to seek the Committee's agreement to change the conditions of generic approval for the Database.

4. Generic approval for external researchers

4.1 Data may be supplied and used in research projects to be conducted by researchers and research institutions outwith the Research Database team within the UK in accordance with the following conditions.

4.1.1 The research project is within the fields of health or social care research described in the approved application form.

4.1.2 The Research Database team should be satisfied that the research has been subject to scientific critique, is appropriately designed in relation to its objectives and (with the exception of student research below doctoral level) is likely to add something useful to existing knowledge.

4.1.3 Research must be conducted in circumstances such that data subjects are not identifiable to the external researchers. Data must be effectively anonymised or pseudonymised prior to release to external researchers. The researchers should undertake to treat datasets in confidence and not to attempt re-identification of data subjects through linkage with other datasets.

4.1.4 A data sharing agreement must be in place with all external researchers to ensure processing of the data in accordance with the terms of the ethical approval and any other conditions required by the Research Database team.

4.2 A research project using data from the Database in accordance with these conditions will be considered to have ethical approval from the Committee under the terms of this approval.

4.3 Any research project requiring external researchers to be able to identify data subjects for purposes of linkage with other datasets, or in order to collect further data from subjects or their care records or undertake other research procedures involving subjects, is not covered by this approval. Such projects should be the subject of further project-specific application for ethical review.

4.4 The Research Database team may require any researcher to seek specific ethical approval for their project. Such applications should normally be made to the Committee.

5. Records

5.1 The establishment should maintain a record of all internal and external research projects using data from the Database. The record should contain at least the full title of the project, a summary of its purpose, the name of the Chief Investigator, the sponsor, the location of the research, the date on which the project was approved by the establishment, a brief summary of the dataset released (including any sensitive data), whether the data was accessed by the researcher in identifiable form, and any relevant reference numbers. For external research, the record should indicate whether data has been released under the terms of the generic approval for the Database or for a project with specific ethical approval.

5.2 The establishment should maintain a risk register and a record of any serious adverse events (see also paragraph 7.1).

5.3 The Committee may request access to these records at any time.

5.4 The Research Database team should maintain a publicly accessible register of research projects using data from the Database.

6. Annual reports

6.1 An annual report should be provided to the Committee listing all projects for which data has been released in the previous year. The list should give the full title of each project, the name of the Chief Investigator, the sponsor, the location of the research and the date of approval by the establishment. The report is due on the anniversary of the date on which ethical approval for the Database was given.

6.2 The Committee may request additional reports on the management of the Database at any time.

7. Substantial amendments

7.1 Substantial amendments should be notified to the Committee and ethical approval sought before implementing the amendment. A substantial amendment generally means any significant change to the arrangements for the management of the Database as described in the application to the Committee and supporting documentation.

7.2 The NRES Notice of Substantial Amendment form should be used to seek approval. The form should be completed in the Integrated Research Application System.

7.3 The following changes should always be notified as substantial amendments:

7.3.1 Any significant change to the policy for use of the data in research, including changes to the types of research to be undertaken or supported by the establishment.

7.3.2 Any significant change to the types of data to be collected and stored, or the circumstances of collection.

7.3.3 Any significant change to informed consent arrangements, including new/modified information sheets and consent forms.

7.3.4 Any proposed change to the conditions of approval

7.3.5 Any other significant change to the location, management or governance of the Database.

8. Serious adverse events

8.1 The Committee should be notified as soon as possible of any serious adverse event or reaction, any serious breach of security or confidentiality, or any other incident that could undermine public confidence in the ethical management of the data.

9. Changes in responsibility

9.1 The Committee should be notified of any change in the contact details for the applicant or where the applicant hands over responsibility for communication with the Committee to another person at the establishment.

10. Closure of the Database

10.1 Any plans to close the Database should be notified to the Committee as early as possible and at least two months before closure. The Committee should be informed of the arrangements to be made for destruction of the data or transfer to another research database or archive, and of the arrangements to notify data subjects where appropriate.

10.2 Where data is transferred to another research database ("the second database") or archive, the ethical approval for the Database is not transferable. Where the second database is ethically approved, it should notify the responsible Research Ethics Committee. The terms of its own ethical approval would apply to any data it receives. If the second database is not ethically approved, the responsible establishment may seek ethical approval by submitting a new application to the Committee.

10.3 Where data is transferred to another research database, any projects already underway using data supplied from the Database in accordance with these conditions continue to have ethical approval for the duration of those projects.

11. Compliance with approval conditions

11.1 Oversight mechanisms should be in place to ensure these approval conditions are complied with. Compliance is the personal responsibility of the Data Controller.

11.2 The Committee should be notified as soon as possible of any breach of these conditions.

11.3 Where serious breaches occur, the Committee may review its ethical approval and may, exceptionally, suspend or terminate the approval.