

CONDITIONS OF ETHICAL APPROVAL

Research Ethics Committee:	Trent Research Ethics Committee
Research Database:	British Isles Network of Congenital Anomaly Registers (BINOCAR)
Data Controller:	Professor Elizabeth Draper
Establishment:	University of Leicester
REC reference number:	09/H0405/48
Name of applicant:	Professor Elizabeth Draper
Date of approval:	01 October 2009

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 and in other countries 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.