

Trent Multi-centre Research Ethics Committee

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19 July 2004

Mrs Elizabeth Draper
Director, East Midlands and South Yorkshire Congenital
Anomalies Register (BINOCAR)
Department of Health Sciences
University of Leicester
22-28 Princess Road West
LEICESTER
LE1 6TP

Dear Mrs Draper

Full title of study: The regional and national registration of congenital anomalies in England, Scotland and Wales - the British Isles Network of Congenital Anomaly Registers (BINOCAR).

REC reference number: 04/MRE04/25

Protocol number: Designated 1

Thank you for your letter of 08 July 2004, responding to the Committee's request for further information on the above research.

The further information has been considered on behalf of the Committee by the Chairman.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully. **I confirm that this is a 'No Local Investigator' study, therefore no site specific assessment need be sought from LRECs.**

Management approval

You should arrange for all relevant host organisations to be notified that the research will be taking place, and provide a copy of the REC application, the protocol and this letter.

All researchers and research collaborators who will be participating in the research must obtain management approval from the relevant host organisation before commencing any research procedures. Where a substantive contract is not held with the host organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

Notification of other bodies

We shall notify the research sponsor that the study has a favourable ethical opinion.

Statement of compliance (from 1 May 2004)

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.

REC reference number: **04/MRE04/25** Please quote this number on all correspondence

Yours sincerely

Dr Robert Bing
Chairman, Trent MREC