

Chairman: Dr Robert Bing
Administrator: Jill Marshall

Your Ref:

9 May 2003

Dr Julia Hippisley-Cox, Senior Lecturer
School of Community Health Sciences
Division of Primary Care
13th Floor, Tower Building
University Park
NOTTINGHAM N7 2RD

Dear Dr Hippisley-Cox

MREC/03/4/021 - *please quote this number on all correspondence*
QRESEARCH – A new ethical high quality general practice derived database for research

The Chairman of the Trent MREC has considered the information/amendments submitted in response to the Committee's review of your application on 3 April 2003 as set out in our letter dated 11 April 2003 and email of 29 April 2003. The documents considered were as follows:

- Application form dated 23 January 2003
- **Studies using QRESEARCH data contained within main application form:**
- **Study 1:** Risk factors for osteoporosis in men compared with women a population based case control study
- **Study 2:** Trends in inequalities in secondary prevention for Coronary Heart Disease in General Practice longitudinal study
- **Study 3:** Uptake and effectiveness of smoking cessation treatments in primary care
- **Study 4:** Why is the burden of disease due to ischaemic heart disease declining and that due to diabetes is increasing?
- **Study 5:** Does HRT or Statins protect against Dementia?
- **Study 6:** Spouse concordance for disease: follow-up study
- Reviewer's comments re studies using QRESEARCH data – letter from Professor Avery dated 16 April 2003
- **Information sheets/covering letter**
- Practice Information Sheet Version 2 dated 24 April 2003
- Practice Consent Form Version 2 dated 24 April 2003
- Covering letter to practices dated 21 January 2003
- EMIS Information sheet re activating QRESEARCH uploads
- Notice for display in participating surgeries – Version 2 dated April 2003
- Protocol designated Version 2 dated April 2003
- Method of initial recruitment to study
- Indemnity for investigators
- Principal Investigator's CV – Dr Julia Hippisley-Cox

The members of the MREC present agreed that there is no objection on ethical grounds to the proposed study. I am, therefore, happy to give you our **approval under Section C of the DoH “No local researcher” guidelines (November 2000 version 2)** on the understanding that you will follow the conditions of approval set down below. The project must be started within three years of the date on which MREC approval is given.

While undertaking the review of your application the MREC noted the research involves the establishment of a new database for research purposes with no patient contact. **For this reason you are not required to notify any LRECs when undertaking this research.**

MREC Conditions of Approval

- The protocol approved by the MREC is followed and any changes to the protocol are undertaken only after MREC approval.
- The MREC would expect to see a copy of any finalised questionnaires before use.
- You must complete and return to the MREC the annual review form that will be sent to you once a year, and the final report form when your research is completed.

Legal and Regulatory Requirements

It remains your responsibility to ensure in the subsequent collection, storage or use of data or research sample you are not contravening the legal or regulatory requirements of any part of the UK in which the research material is collected, stored or used. If data is transferred outside the UK you should be aware of the requirements of the Data Protection Act 1998.

ICH GCP Compliance

The MRECs are fully compliant with the International Conference on Harmonisation/Good Clinical Practice (ICH GCP) Guidelines for the Conduct of Trials Involving the Participation of Human Subjects as they relate to the responsibilities, composition, function, operations and records of an Independent Ethics Committee/Independent Review Board. To this end it undertakes to adhere as far as is consistent with its Constitution, to the relevant clauses of the ICH Harmonised Tripartite Guideline for Good Clinical Practice, adopted by the Commission of the European Union on 17 January 1997. The Standing Orders and a Statement of Compliance are available on the Internet at www.corec.org.uk.

Yours sincerely

Jill Marshall
Trent MREC Administrator
on behalf of Dr Robert Bing, Chairman