

## Trent Research Ethics Committee

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06 August 2007

Professor Julia Hippisley-Cox  
School of Community Health Sciences  
Division of Primary Care  
13<sup>th</sup> Floor, Tower Building  
University Park  
NOTTINGHAM  
N7 2RD

Dear Professor Hippisley-Cox

**Study title:** QRESEARCH – A new ethical high quality general practice derived database for research  
**REC reference:** MREC/03/4/021

**Amendment number:** Amendment 2  
**Amendment date:** 10 July 2007

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 02 August 2007.

### Ethical opinion

The members of the Committee present 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:

Document	Version	Date
Participant Information Sheet: Revised QR recruitment practice information sheet	V 1-3	10 July 2007
QR Recruitment letter	V 1.0	10 July 2007

Covering Letter		10 July 2007
Annex 2 Notification of Amendment (CTIMPs)	Amendment 2	10 July 2007

### **Membership of the Committee**

The members of the Committee who were present at the meeting are listed on the attached sheet.

### **R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

### **Statement of compliance**

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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.

03/4/021:

**Please quote this number on all correspondence**

Yours sincerely

*G. Braithwaite*

**Mrs Gill Braithwaite  
Committee Co-ordinator**

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Enclosures    List of names and professions of members who were present at the meeting and those who submitted written comments

Copy to:                    Clinical Trials Unit, MHRA (emailed)

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### Attendance at Sub-Committee of the REC meeting on 02 August 2007

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Dr Robert Bing	Consultant Physician	Expert
Mrs Jill Marshall	Research Ethics Manager	None
Mr Mike Spencer	Lay Member	Lay