06 August 2007

Professor Julia Hippisley-Cox
School of Community Health Sciences
Division of Primary Care
13th 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:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant Information Sheet: Revised QR recruitment practice information sheet</td>
<td>V 1-3</td>
<td>10 July 2007</td>
</tr>
<tr>
<td>QR Recruitment letter</td>
<td>V 1.0</td>
<td>10 July 2007</td>
</tr>
</tbody>
</table>
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

E-mail: gill.braithwaite@derwentsharedservices.nhs.uk

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)
Trent Research Ethics Committee

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Profession</th>
<th>Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Robert Bing</td>
<td>Consultant Physician</td>
<td>Expert</td>
</tr>
<tr>
<td>Mrs Jill Marshall</td>
<td>Research Ethics Manager</td>
<td>None</td>
</tr>
<tr>
<td>Mr Mike Spencer</td>
<td>Lay Member</td>
<td>Lay</td>
</tr>
</tbody>
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