

North West MREC
Stockport Primary Care Trust
Room 155 - Gateway House
Piccadilly South
Manchester
M60 7LP

Tel: (0161) 237 2394 / 2152
Fax: (0161) 237 2383

19 August 2006

Professor A Coulter
Chief Executive
Picker Institute Europe
2nd Floor - King's Mead House
Oxpens Road
OXFORD
OX1 1RX

Dear Professor Coulter

Study title: Trust based survey on inpatients in acute NHS hospitals
REC reference: MREC 01/8/90

Amendment number: N/A
Amendment date: 04 July 2006

The above amendment was reviewed at the meeting of the Committee held on 8 August 2006.

Ethical opinion

In preparation for the survey to be run in Autumn 2006 and be mailed to a national sample of 142,800 patients (i.e. 850 each for the 168 applicable English Acute Hospital Trusts), the amendment sought approval for the addition of 7 new questions to the core questionnaire, and the removal of 4 questions.

The amendment further sought approval for a change in Chief Investigator on the trial – from Dr Rachel Reeves to Professor Angela Coulter. A copy of Professor Coulter's CV had been submitted for review.

The Committee had no ethical difficulties with the proposed changes.

However, a signed Part B: Section 7 – Declaration of the NHS REC Application Form (i.e. signed by the new CI – Professor Coulter), must also be submitted before the change in Chief Investigator could be confirmed.

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
Notice of Substantial Amendment (non-CTIMPs)		04 July 2006
Redevelopment of the 2006 Inpatients Questionnaire	1	28 July 2006
First Mailing Letter	_V1 (with tracked changes)	04 July 2006
First Mailing Letter	_V1	04 July 2006
First Reminder Letter	_V1	04 July 2006
Second Reminder Letter	_V1 (with tracked changes)	04 July 2006
Second Reminder Letter	_V1	04 July 2006
Questionnaire: Inpatient 2006 Bank Questionnaire	V1 (with tracked changes)	28 July 2006
Questionnaire: Inpatient 2006 Bank Questionnaire	V1	28 July 2006
Questionnaire: Inpatient 2006 Core Questionnaire	V1 (with tracked changes)	28 July 2006
Questionnaire: Inpatient 2006 Core Questionnaire	V1	28 July 2006

Membership of the Committee

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

Research governance approval

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

Statement of compliance

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.

MREC 01/8/090

Please quote this number on all correspondence

Yours sincerely

Cathie Stokes
Committee Co-ordinator

E-mail: - northwest.mrec@gmsa.nhs.uk

Copy to: - Jason Boyd
Picker Institute Europe
King's Mead House
Oxpens Road
OXFORD
OX1 1RX

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