

19 September 2005

**Dr R Reeves
Manager
Surveys Advice Centre
Picker Institute Europe
King's Mead House
Oxpens Road
OXFORD OX1 1RX**

Dear Dr Reeves

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

Amendment number: Not specified
Amendment date: 30 August 2005

The above amendment was reviewed at the meeting of the Sub-Committee of the North West Multi-Centre Research Ethics Committee held on 13 September 2005.

Ethical opinion

The amendment sought approval for changes to the In-Patients questionnaire and covering letters. The changes were being proposed following the results of the pilot survey and further dialogue with the Healthcare Commission and the Department of Health.

It was further proposed that additional information on all sampled patients would be requested from trusts, i.e. currently, trusts were asked to provide the patient's year of birth, gender, ethnic group and date of discharge. In future, they would also be asked to provide details of the patient's date of admission, main specialty on discharge, and the code for primary care trust where they were registered with a GP. Reassurance had been provided that all necessary steps would be taken to ensure that it would not be possible to identify individual patients from the information held about them, and that the Healthcare Commission would not receive any patient name or address information.

Members agreed that it would be considered good ethical practice to inform all participants of the type of information that was being collected about them. However, the Sub-Committee had no major ethical difficulties with the proposed changes.

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: -

- **Notice of Substantial Amendment – signed and dated 30 August 2005**
- **Cover letter from Dr Rachel Reeves - dated 12 August 2005**
- **Inpatients 2005 Core Questionnaire – version 10 - dated 9 August 2005**
- **Inpatients Question Bank 2005 – version 10 - dated 9 August 2005**
- **Inpatients 2005 Core Questionnaire - version 10 comparison to version 4 - dated 9 August 2005**
- **Inpatients 2005 Question Bank - version 10 comparison to version 2 - dated 9 August 2005**
- **Covering Letter “Inpatients 2005 First Mailing – version 5” - dated 12 August 2005**
- **First Reminder “Inpatients 2005 First Reminder – version 1” - dated 21 April 2005**
- **Covering Letter “Inpatients 2005 Second Reminder – version 5” - dated 12 August 2005**
- **Inpatient 2005 First Mailing tracked changes version 1 to version 5 - dated 12 August 2005**
- **Inpatient 2005 Second reminder tracked changes version 1 to version 5 - dated 12 August 2005**

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 01/8/90

Please quote this number on all correspondence

Yours sincerely

Cathie Stokes
Committee Co-ordinator

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

List of names and professions of members who were present at the meeting

Dr Paul R Kelsey – Chair – Consultant Haematologist

Mrs Arlene Blanchard – Lay Member

Ms Chris Burgess – Vice-Chair & Lay Member

Mrs Margaret Norval – Chief Pharmacist

Dr Jane Pearson – Research & Development Manager / Registered Nurse

Professor Liz Perkins – Lay Member

Mrs Jane Rowe – Lay Member