

Multi-Centre Research Ethics Committee for
Scotland

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Deaconess House
148 Pleasance
Edinburgh
EH8 9RS
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Dr Rachel Reeves
Advice Centre Manager
Picker Institute Europe
King's Mead House
Oxpens Road
Oxford
OX1 1RX

Date: 15 May 2003
Your Ref.:
Our Ref.: MREC/03/10/16

Enquiries to: Walter Hunter
Extension: 89026
Direct Line: 0131 536 9026
Email: walter.hunter@lhb.scot.nhs.uk

Dear Dr Reeves

MREC/03/10/16: Trust-based survey of users of specialist mental health services on Care Programme Approach (CPA) registers in English NHS Mental Health Trusts.

I refer to our telephone conversation about whether the above study was covered by the supplementary operational guidelines for NHS Research Ethics Committees dated November 2000.

Having taken advice from the Chairman I can confirm that this particular study is covered by the terms of the new guidelines. There is therefore no requirement to obtain individual LREC approval but they should be informed of the study.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Walter Hunter'.

WALTER HUNTER
MREC Administrator
cc: Sarah Scobie
Commissions for Health Improvement
1st Floor Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8TG

Chairman Professor Patricia Peattie
Vice-Chairman Mr Paul Rogers

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Dr Rachel Reeves
Advice Centre Manager
Picker Institute Europe
King's Mead House
Oxpens Road
Oxford
OX1 1RX

Date: 2 May 2003
Your Ref.:
Our Ref.: MREC/03/10/16

Enquiries to: Walter Hunter
Extension: 89026
Direct Line: 0131 536 9026
Email: walter.hunter@lhb.scot.nhs.uk

Dear Dr Reeves

MREC/03/10/16: Trust-based survey of users of specialist mental health services on Care Programme Approach (CPA) registers in English NHS Mental Health Trusts.

The Vice-Chairman of the Multi-Centre Research Ethics Committee for Scotland has reviewed the documents enclosed with your e-mail of 29 April 2003. The documents considered were as follows:

Service user questionnaire: version 2 dated 4 March 2003
Service user questionnaire: version 3 dated 27 March 2003

The Vice-Chairman, acting under delegated authority, is satisfied that these accord with the decision of the Committee and has agreed that there is no objection on ethical grounds to the proposed study. I am, therefore, happy to give you the favourable opinion of the Committee on the understanding that you will follow the conditions of approval set out below. A full record of the review undertaken by the Committee is contained in the attached MREC Response Form. The project must be started within three years of the date of this letter.

Conditions of Approval

- You do not recruit any research subject within a research site unless favourable opinion has been obtained from the relevant local research ethics committees.
- You do not undertake this research in an NHS organisation until the relevant NHS management approval has been obtained as set out in the Framework for Research Governance for Health and Community Care (Research Governance for Health and Social Care in England).

Chairman Professor Patricia Peattie
Vice-Chairman Mr Paul Rogers

- You do not deviate from, or make changes to, the protocol without prior written approval of the Committee, except where this is necessary to eliminate immediate hazards to research participants or when the change involves only logistical or administrative aspects of the research. In such cases the Committee should be informed within seven days of the implementation of the change.
- You complete and return the standard progress report form to the Committee one-year from the date of this letter and thereafter on an annual basis. This form should also be used to notify the Committee when your research is completed. In this case the form should be sent to the Committee within three months of completion of the research.
- You must complete and return the standard progress report form to the Committee one year from the date on this letter and thereafter on an annual basis. This form should also be used to notify the Committee when your research is completed.
- If you decide to terminate this research prematurely you must send a report to the Committee within 15 days, indicating the reason for the early termination.
- You advise the Committee of any unusual or unexpected results that raise questions about the safety of the research.

Local Submissions

It is your responsibility to ensure that any local researcher seeks the approval of the relevant LREC before starting their research. To do this you should submit the appropriate number of copies of the following to the relevant LRECs:

- this letter
- the MREC Application Form (including copies of any questionnaires)
- the attached MREC response form
- Annex D of the Application Form
- one copy of the protocol
- the final approved version of the Patient Information Sheet and Consent Form

It is important to check with the respective LRECs the precise numbers of copies required as this will vary and failure to supply sufficient copies could lead to a delay. In addition, you should submit to LRECs only the revised paperwork reflecting the requirements of the Committee as referenced in the response form.


Local Sites

Whilst the Committee would like as much information as possible about local sites at the time you apply for ethical approval it is understood that this is not always possible. You are asked, however, to send details of local sites as soon as a researcher has been recruited. This is essential to enable the MREC to monitor the research it approves.

ICH GCP Compliance

The Committee is 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 were included on the computer disk containing the guidelines and application form and are available on request or on the Internet at www.corec.org.uk

Yours sincerely



WALTER HUNTER
MREC Administrator
cc: Sarah Scobie
Commissions for Health Improvement
1st Floor Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8TG

RESPONSE FORM

DETAILS OF APPLICANT:

1. Name and address of Principal Researcher:

Dr Rachel Reeves
Advice Centre Manager
Picker Institute Europe
King's Mead House
Oxpens Road
Oxford
OX1 1RX

2. Title of project:

Trust-based survey of users of specialist mental health services on Care Programme Approach (CPA) registers in English NHS Mental Health Trusts.

3. Name and address of Sponsor:

Sarah Scobie
Commissions for Health Improvement
1st Floor Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8TG

DETAILS OF MREC:

4. MREC for Scotland
Deaconess House
148 Pleasance
Edinburgh
EH8 9RS

5. MREC Reference Number: MREC/03/10/16

6. Listed below is a complete record of the review undertaken by the Committee

with the decisions made, dates of decisions and the requirements at each stage of the review:

Date of review: 13 February 2003

Committee members in attendance:

Professor P Peattie (Chairman)(Nurse)
Dr K Beard (Consultant Physician)
Professor C Bond (Consultant in Pharmaceutical Public Health)
Ms F Campbell Statistician)
Mr A C Fraser (Lay)
Dr B Holland (Consultant Paediatrician)
Mrs H Millar (Lay)
Mrs J Munro (Allied Health Professions)
Dr R Pearsall (General Practitioner)
Mrs F Phab (Statistician)
Dr J Robins (Consultant Obstetrician/Gynaecologist)
Mr P Rogers (Consultant Surgeon)
Mr I Smith (Lay)

Outcome of review: Deferred

Documents reviewed:

Application form dated 7 February 2003
Guidance manual: updated 5 February 2003
Letter to service user: version 1 dated 7 February 2003
First reminder letter: version 1 dated 8 February 2003
Second reminder letter: version 1 dated 8 February 2003
Mental health questionnaire: version 1 dated 7 February 2003
CV

Changes/Information requested:

1. Provide the finalised versions of documents once the pilot study results have been analysed.
2. Justify the sample size not by using formal calculations but by explaining the logic.
3. Confirm the arrangements for the consent of 16-18 year olds.
4. The second reminder letter refers to a survey instead of a questionnaire as in the first reminder letter.

Date of review: 13 March 2003

Committee members in attendance:

Dr K Beard (Consultant Physician)

Professor C Bond (Consultant in Pharmaceutical Public Health)
Dr M Booth (Consultant Anaesthetist)
Ms F Campbell Statistician)
Mr A C Fraser (Lay)
Dr B Holland (Consultant Paediatrician)
Dr I McKee (General Practitioner)
Mrs H Millar (Lay)
Mrs J Munro (Allied Health Professions)
Dr R Pearsall (General Practitioner)
Mrs F Phab (Statistician)
Dr J Robins (Consultant Obstetrician/Gynaecologist)
Mr P Rogers (Consultant Surgeon)(in the Chair)
Mr I Smith (Lay)

Outcome of review: Deferred

Documents reviewed:

Letter of response dated 5 March 2003
Service user questionnaire: version 2 dated 4 March 2003
Covering mailing for first mailing: version 2 dated 4 March 2003
First reminder letter: version 2 dated 4 March 2003
Second reminder letter: version 2 dated 4 March 2003

Changes/Information requested:

- The results from the pilot study should be provided before the application could be approved.

Date of review: 10 April 2003

Committee members in attendance:

Professor P Peattie(Nurse) (Chairman)
Dr K Beard (Consultant Physician)
Professor C Bond (Consultant in Pharmaceutical Public Health)
Dr M Booth (Consultant Anaesthetist)
Ms F Campbell Statistician)
Mr A C Fraser (Lay)
Dr B Holland (Consultant Paediatrician)
Dr I McKee (General Practitioner)
Mrs J Munro (Allied Health Professions)
Dr R Pearsall (General Practitioner)
Dr J Robins (Consultant Obstetrician/Gynaecologist)
Mr P Rogers (Consultant Surgeon)

Outcome of review: Approved subject to change

Changes/Information requested:

The Committee noted that the principal researcher had indicated to the Vice-Chair that the results from the pilot study had indicated that significant changes to the questionnaire were not required. The Committee agreed that the study could be approved provided the questionnaire was acceptable and delegated authority to the Vice-Chair to approve on receipt.

Documents reviewed by Vice-Chairman:

Service user questionnaire: version 3 dated 27 March 2003

Date approved by Vice-Chairman: 1 May 2003

7. THE FINAL DOCUMENTS AND ARRANGEMENTS APPROVED BY THE MREC

The following items have been approved by the Multi-Centre Research Ethics Committee for Scotland:

Guidance manual: updated 5 February 2003
Covering mailing for first mailing: version 2 dated 4 March 2003
First reminder letter: version 2 dated 4 March 2003
Second reminder letter: version 2 dated 4 March 2003
Service user questionnaire: version 3 dated 27 March 2003
Methods of initial recruitment to study
Compensation arrangements for subjects
Payments to researcher
Provision of expenses for subjects

Walter Hunter

**Walter Hunter
Administrator
Multi-Centre Research Ethics Committee for Scotland
Date: 2 May 2003**
