NHS

North West Multi-centre Research Ethics Committee

Gateway House
Piccadilly South
Manchester
M60 7LP

Tel: 0161 237 2394
Fax: 0161 237 2383
Email: alison.forbes@
mchester-ha.nwest.nhs.uk

Your ref:

7th January 2003

Dr Sarah Scobie
Assistant Director
Research and Information
Commission for Health Improvement
Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8TG

Dear Dr Scobie

MREC 02/8/99 Please quote this number on all correspondence
For use in Trust's incorporating additional non-standard questionnaires

Survey of emergency departments in acute NHS hospital trusts in England

The Chairman of the North West MREC has considered the amendments submitted in response to the Committee's earlier review of your application on 12th November 2002 as set out in our letter dated 2nd December 2002. The documents considered were as follows:

- **Application form signed and dated 23/10/02**
- **Patient Information and Invitation letter no version no, undated**
- **Reminder letter no version no, undated**
- **Sample covering letter**
- **Sampling instructions**
- **Emergency department questionnaire - all possible questions**
- **Emergency department questionnaire -core questions**
- **Properties of the Picker Patient Experience questionnaire in randomised controlled trial of long versus short survey instruments**
- **Methods of initial recruitment to study**
- **CV for Dr Sarah Scobie**
- **Compensation arrangements for subjects**
- **Payments to researcher**
- **Provision of expenses for subjects**

The 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 our approval on the understanding that you will follow the conditions of approval set out below.

A full record of the review undertaken by the MREC is contained in the attached MREC Response Form. The project must be started within three years of the date on which MREC approval is given.

Conditions of Approval

- No research subject is to be admitted into the trial until agreement has been obtained from the appropriate local research ethics committees.

- You must follow the protocol agreed and any changes to the protocol will require prior MREC approval.

- If projects are approved before funding is received, the MREC must see, and approve, any major changes made by the funding body. The MREC would expect to see a copy of any final questionnaire before it is used.

- You must promptly inform the MREC and appropriate LRECs of:
  (i) deviations from or changes to the protocol which are made to eliminate immediate hazards to the research subjects;
  (ii) any changes that increase the risk to subjects and/or affect significantly the conduct of the research;
  (iii) all adverse drug reactions that are both serious and unexpected;
  (iv) new information that may affect adversely the safety of the subjects or the conduct of the trial.

- You must complete and return the standard progress report form to the MREC one year from the date on this letter and thereafter on an annual basis. This form should also be used to notify the MREC when your research is completed.

While the MREC has given approval for the study on ethical grounds, it is still necessary for you to obtain management approval from the relevant Clinical Directors and/or Chief Executive of the Trusts (or Health Boards/HAs) in which the work will be done.

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 MREC as referenced in the response form.

Local Sites

Whilst the MREC 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 MRECs are 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

Alison Forbes

Alison Forbes
Manager, MREC North West

Enclosures MREC response form
Progress report form
List of Committee members