NHS
Executive

North West

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Our ref: MREC 00/8/53
Your ref:

1st December 2000

**Professor Alan Silman**
**ARC Epidemiology Unit**
**Manchester University Medical School**
**Oxford Road**
**Manchester**
**M13 9PT**

Dear Professor Silman

**MREC 00/8/53 Please quote this number on all correspondence**

**Prospective observational study of the long term hazards of anti-TNF therapy in rheumatoid arthritis**

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 September as set out in our attached response form. The documents considered were as follows:

**Application form - dated 26th July 2000**
**Protocol - First draft 22nd March 2000**
**Subject Information Sheet - version 3, 1st December 2000**
**Subject Consent Form - version 1, 26th July 2000**
**ARC/BSR Prospective study of patients data form - undated**

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.

While undertaking the review of your application the MREC noted the research involves the establishment and use of a new disease or patient database for research purposes with subsequent patient contact patient. **For this reason you are asked to read carefully the sections concerning LREC involvement and local NHS management set out below as there are specific requirement involved when undertaking such research.**

## MREC Conditions of Approval

- No research procedures are undertaken until the appropriate local research ethics committees is informed of the research including the name of the local clinician involved.
- The local clinician must inform his/her NHS organisation of their co-operation in the research project.

- The protocol approved by the MREC is followed and any changes to the protocol are undertaken only after 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 the final questionnaire before it is used.

- You must promptly inform the MREC of:
  (i) any changes that increase the risk to subjects and/or affect significantly the conduct of the research;
  (ii) any new information that may affect adversely the safety or welfare of the subjects or the conduct of the trial.

- You must complete and return to the MREC the annual review form that will be sent to you once a year, and the final report form when your research is completed.

## LREC involvement

When undertaking the review of your project the MREC observed that there is limited patient contact by a local clinician who is performing technical procedures or additional data collection as described in the MREC approved protocol/ initial contact by a local clinician for purposes of recruitment. It is felt that these tasks appear well within his/her routine professional competence and adequate facilities for such procedure are available as part of his/her normal professional practice.

For this reason you are asked to only inform the appropriate LREC of the project by sending a copy of this letter and also **giving the name and contact details of the local clinician involved**. If (unusually) the LREC has any reason to doubt that the local clinician is competent to carry out the tasks required, it will inform the clinician and the MREC that gave ethical approval giving full reasons.

You are not required to wait for confirmation from the LREC before starting your research.

## Local NHS Management

The local clinician must inform his/her NHS organisation of their co-operation in the research project and the nature of their involvement. Care should be taken to ensure with the NHS organisation that local indemnity arrangements are adequate.

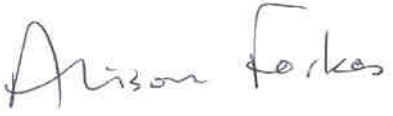
## Legal and Regulatory Requirements

It remains your responsibility to ensure in the subsequent collection, storage or use of data or research sample you are not contravening the legal or regulatory requirements of any part of the UK in which the research material is collected, stored or used. If data is transferred outside the UK you should be aware of the requirements of the Data Protection Act 1998.

## 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 http://dspace.dial.pipex.com/mrec.

Yours sincerely



Alison Forbes
Manager, MREC North West

Enc. MREC Response Form
Annual Review Form