

North West Multi-centre Research Ethics Committee

Your ref:

Gateway House
Piccadilly South
Manchester
M60 7LP

27 November 2003

Tel: 0161 237 2394

Fax: 0161 237 2383

Email: northwest.mrec@gmsa.nhs.uk

Professor A J Silman
Professor of Rheumatic Disease
ARC Epidemiology Unit
Stopford Building
The University of Manchester
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

- Letter from Professor Alan Silman and Professor Deborah Symmons – dated 9/10/03
- Revised Patient Information Sheet and Consent Form – version 5 - undated
- Consultant baseline questionnaire/ankylosing spondylitis – version 1 – dated 18/9/03
- Bath Ankylosing Spondylitis disease activity index – version 1 - dated 18/9/03
- Revised protocol - dated 6/10/03
- Abstract submitted to the ACR 2003 (BSRBR: appropriateness of comparison cohort)

The amendment, as detailed, to the above named study has been reviewed by a sub-group of the North West MREC at their meeting on 11 November 2003.

The amendment sought approval for two proposed changes to the original approved study protocol, as follows: -

1. An extension of the inclusion group for the study.
2. A change in the method of recruitment of the control group.

The sub-committee had no difficulty with either of the proposed changes or the supporting documentation provided.

The sub-committee had no ethical objections to the amendment and I am therefore happy to give you approval on the understanding that you will follow the protocol as agreed.

You are advised to inform the host organisation of this amendment, and if applicable, to inform all LRECs who reviewed the main application for locality issues.

Yours sincerely

C.A. Stokes

Cathie Stokes
Administrator
North West MREC

Copy to: Professor D Symmons, Professor of Rheumatology and
Musculoskeletal Epidemiology, ARC Epidemiology Unit,
Stopford Building, The University of Manchester, Oxford Road,
MANCHESTER, M13 9PT