

North West Multi-centre Research Ethics Committee

13 December 2004

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Professor A J Silman
Professor of Rheumatic Disease
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The University of Manchester
Oxford Road
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Dear Professor Silman

Full title of study:	Prospective observational study of the long term hazards of anti-TNF therapy in rheumatoid arthritis
REC reference number:	MREC 00/8/053
Protocol number:	N/A
EudraCT number:	N/A
Amendment number:	Not specified
Amendment date:	17 November 2004

The above amendment was reviewed at the meeting of the Sub-Committee of the North West Multi-Centre Research Ethics Committee held on 7 December 2004.

Ethical opinion

The amendment requested approval for two questions to be added to the approved Patient Baseline Questionnaire and one question to be added to the approved Consultant Baseline Questionnaire. The additional questions related to alcohol consumption and PUVA (Psoralens & Ultraviolet A) exposure for psoriatic arthritis (PsA), and were in line with recently published guidelines from The British Society for Rheumatology, which suggested that such data should be collected.

The Sub-Committee had no ethical difficulties with the inclusion of the proposed questions in the two questionnaires.

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 form – signed and dated 17 November 2004**
- **Cover letter from Dr Kath Watson, BSRBR Study Co-ordinator – dated 15 November 2004**
- **Patient baseline questionnaire – version 4 - dated 1 November 2004**

- **Consultant baseline questionnaire – version 5 - dated 1 November 2004**
- **BSR Guideline for Anti-TNF α Therapy in Psoriatic Arthritis - dated July 2004**

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Management 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 local management 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 00/8/53

Please quote this number on all correspondence

Yours sincerely

C. A. Stokes

Cathie Stokes
Committee Administrator

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Copy to: - Dr K Watson, BSRBR Study Co-ordinator, ARC Epidemiology Unit,
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Enclosure: - List of names and professions of members who were present at the
meeting and those who submitted written comments

The names and professions of members who were present at the meeting and those who submitted written comments

Dr Brian Faragher, Alternate Vice-Chair – Medical Statistician

Ms Chris Burgess – Lay Member

Professor Alistair Burns – Professor of Old Age Psychiatry

Mrs Margaret Norval – Chief Pharmacist

Professor Munir Pirmohamed – Professor of Clinical Pharmacology

Mrs Jane Rowe – Lay Member
