

North West Research Ethics Committee

North West Strategic Health Authority
Room 155 - Gateway House
Piccadilly South
Manchester
M60 7LP

Tel: 0161 237 2152

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1 February 2007

**Professor A Silman
ARC Epidemiology Unit
The University of Manchester
Stopford Building
Oxford Road
MANCHESTER M13 9PT**

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:	N/A
Amendment date:	15 January 2007

The above amendment was reviewed at the meeting of the Sub-Committee of the North West REC held on 30 January 2007.

Ethical opinion

The members of the Committee present decided that it could not give a favourable ethical opinion of the amendment, for the following reasons:

The amendment sought approval for the British Society for Rheumatology Biologics Register (BSRBR) to collect drug adherence data on patients with rheumatoid arthritis (RA), via a "Views on Illness, Treatment and General Health" questionnaire. In addition a page on drug adherence had been added to the 6 month follow-up questionnaire.

Drug adherence remained a problem in this disease group and the role of psychosocial factors in predicting adherence, and the role of adherence in predicting treatment response, warranted investigation.

A comprehensive, clear and well written rationale had been submitted in support of the amendment.

The Sub-Committee whilst in agreement that the proposed amendment was a worthwhile addition to the BSRBR and may potentially yield valuable information on drug adherence, sought clarification and further action on the following:

1. It was recognised that the "Views on Illness, Treatment and General Health" questionnaire was an amalgamation of excerpts from a number validated questionnaires. However, further clarification was sought as to whether the questionnaire had been validated in its current amalgamated format, or whether it had been piloted and was suitable for the intended purpose.
2. Following on from the above. The approved patient information sheet should be amended to reflect the introduction of questionnaires which are intended to collect quality of life data. The possibility that patients may be asked questions of a sensitive nature should highlighted. An amended Patient Information Sheet should be submitted for review.

I regret to inform you that the amendment is therefore not approved. The study should continue in accordance with the documentation previously approved by the Committee.

Modifying the amendment

You may modify or adapt the amendment, taking into account the Committee's concerns. Modified amendments should be submitted on the standard notice of amendment form. The form should indicate that it is a modification of the above amendment.

A revised notice of amendment must be submitted at least 14 days before you plan to implement the amendment. The Committee will then have 14 days from the date of receiving the notice in which to notify you that the amendment is rejected, otherwise the amendment may be implemented.

Documents reviewed

The documents reviewed at the meeting were:

Document	Version	Date
Covering Letter	From Dr Kath Watson	15 January 2007
Notice of Substantial Amendment (non-CTIMPs)		15 January 2007
Protocol	1	04 January 2007
Questionnaire: Views on Illness, Treatment and General Health	1	04 January 2007
Questionnaire: Patient 6 Month Follow-up	6	04 January 2007

Membership of the Committee

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

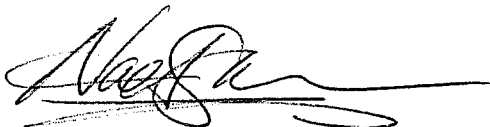
Statement of compliance

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 00/8/053:

Please quote this number on all correspondence

Yours sincerely



Noel Graham
Deputy Committee Co-ordinator

E-mail: northwest.mrec@northwest.nhs.uk

Copy to: Dr Karen Shaw
Head of University Research Office
University of Manchester
Oxford Road
Manchester M13 9PL

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

North West Research Ethics Committee

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14 March 2007

Professor A Silman
ARC Epidemiology Unit
The University of Manchester
Stopford Building
Oxford Road
MANCHESTER M13 9PT

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: N/A
Amendment date: 05 March 2007

Thank you for submitting the above amendment, which was received on 07 March 2007. It is noted that this is a modification of an amendment previously rejected by the Committee (our letter of 01 February 2007 refers).

The modified amendment has been considered on behalf of the Committee by the Chair (Dr Donal Manning).

Ethical opinion

I am pleased to confirm that the Committee has given a favourable ethical opinion of the modified amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved are:

Document	Version	Date
Modified Amendment		05 March 2007
Covering Letter: From Dr Kath Watson, BSRBR Study Co-ordinator		05 March 2007

Protocol	1	04 January 2007
Questionnaire: Patient 6 Month Follow-up	6	
Questionnaire: Views on Illness, Treatment and General Health and How This Impacts on Your Life	1.1	05 March 2007
Participant Information Sheet	6	05 March 2007

Membership of the Committee

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

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

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00/8/053:

Please quote this number on all correspondence

Yours sincerely



Noel Graham
Deputy Committee Co-ordinator

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Sub-Committee Attendance Sheet – 30 January 2007

Member	Profession	In attendance	Written comments submitted
Dr Donal Manning	Chairman Consultant Paediatrician	✓	
Mr Alan Rigby	Medical Statistician	✓	
Mr Robert Woodward	Consultant Oral & Maxillofacial Surgeon	✓	

In Attendance:

Noel Graham – Deputy Committee Co-ordinator