



National Research Ethics Service
North West Research Ethics Committee

NHS North West
Room 155 - Gateway House
Piccadilly South
Manchester
M60 7LP

Tel: 0161 237 2394 / 2152
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06 May 2008

Professor D Symmons
The University of Manchester
arc Epidemiology Unit
School of Medicine – Stopford Building
Oxford Road
MANCHESTER
M13 9PT

Dear Professor Symmons

Study title: Prospective observational study of the long-term hazards of anti-TNF therapy in rheumatoid arthritis
REC reference: 00/8/053
Amendment number: N/A
Amendment date: 14 March 2008

The above amendment was reviewed at the meeting of the Sub-Committee of the North West REC held on 22 April 2008.

Ethical opinion

The amendment requested approval to extend the consultant questionnaire follow-up of all patients to the end of the study in 2013.

A comprehensive rationale had been submitted in support of the amendment. In addition a revised Protocol, Extension to Follow-up Questionnaire (version 2 dated 11/02/08) and amended Participant Information Sheet and Consent form (version 6 dated 05/03/08) had been submitted for review.

The Sub-Committee had no ethical difficulties with the proposed amendment.

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:

Document	Version	Date
Notice of Substantial Amendment (non-CTIMPs)		14 March 2008
Protocol		06 October 2003



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Questionnaire: Extended Follow-up Questionnaire	2	11 February 2008
Participant Information Sheet	6	05 March 2007
Participant Consent Form	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

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.

00/8/053:	Please quote this number on all correspondence
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Yours sincerely



Noel Graham
Deputy Committee Co-ordinator

E-mail: noel.graham@northwest.nhs.uk

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

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

North West Research Ethics Committee

Attendance at Sub-Committee of the North West REC meeting on 22 April 2008

Name	Profession	Capacity
Dr Donal Manning – Chair	Consultant Paediatrician	Expert
Dr Sally Furnish	Chartered Clinical Psychologist	Expert
Mrs Margaret Norval	Chief Pharmacist	Expert
Mr Alan Rigby (written comments)	Medical Statistician	Expert

Also in attendance:

Name	Position (or reason for attending)
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Noel Graham Deputy Committee Co-ordinator