

**National Research Ethics Service
North West Research Ethics Committee**

NHS North West
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Manchester
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11 May 2007

**Professor Deborah Symmons
ARC Epidemiology Unit
School of Medicine
The University of Manchester
Oxford Road M13 9PT**

RECEIVED
17 MAY 2007

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: 12 March 2007

The above amendment was reviewed at the meeting of the Sub-Committee of the North West REC held on 01 May 2007.

Ethical opinion

The amendment sought approval for a change in Chief Investigator on the study " from Professor Alan Silman to Professor Deborah Symmons. A copy of Professor Symmons CV had been submitted for review. In addition Dr Kimme Hyrich had been appointed as a principal investigator. A copy of Dr Hyrich CV had also 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)		12 March 2007
Signed Declaration Page of NHS REC Application Form		12 March 2007
Investigator CV	For Professor Deborah Symmons	12 April 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: northwest.mrec@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 1 May 2007

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Dr Donal Manning – Chair	Consultant Paediatrician	Expert Member
Mr Barry Clift	Senior Occupational Therapist	Expert Member
Mr Alan Rigby	Medical Statistician	Expert Member

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Noel Graham	Deputy Committee Co-ordinator