



Health Research Authority
National Research Ethics Service

NRES Committee North West - Haydock

North West Centre for Research Ethics Committees
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13 June 2012

Professor Deborah Symmons
The University of Manchester
Arthritis Research UK Epidemiology Unit
The 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:	17 May 2012

The above amendment was reviewed at the meeting of the Sub-Committee held on 12 June 2012.

Ethical opinion

The amendment (dated 17 May 2012) sought approval for an extension to the recruitment and follow-up period. The approved extension period was intended to run until the end of 2013. However, the register has been opened up to include additional cohorts and - as with all participants in the study – participants in these newly opened cohorts will also be followed-up for at least five years. Thus additional funding has been secured to follow-up all participants until the study ends which is anticipated will be until at least the 30 September 2018. As participants consented to be involved in the study for at least five years there is no requirement to re-consent. In addition, as study invitation letter had also been submitted for review.

A concise and clear rationale had been submitted in support of the amendment.

The Sub-Committee noted that the proposal had been endorsed by the BSRBR Steering Committee.

The Sub-Committee identified no ethical issues with the proposed amendment.

The members of the Committee taking part in the review 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
Covering Letter from Katy Mowbray, Assistant Studies Co-ordinator		23 May 2012
Notice of Substantial Amendment (non-CTIMPs)		17 May 2012
Letter of invitation to participant	1	17 May 2012
Sponsor Statement of Support from Lynne MacRae, Research Practice Co-ordinator, University of Manchester		18 May 2012

Membership of the Committee

The members of the Committee who took part in the review 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 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



On behalf of:-

Professor Ravi S Gulati
Chair

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

Enclosures: List of names and professions of members who took part in the review

Copy to:

Dr Katy Mowbray
Assistant Studies Co-ordinator
BSRBR
Biologics Study Group
Unit 4 Rutherford House
Manchester Science Park
M15 6SZ

Professor Nalin Thakker
Associate Vice-President (Research Integrity)
University of Manchester
Oxford Road
Manchester
M13 9PL

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Attendance at Sub-Committee of the REC meeting on 12 June 2012

Present:

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Mrs Linda Ashcroft	Senior Statistician	Expert
Dr Caroline Carlisle	Research Nurse	Expert
Mr Stephen Edgar	Designer	Lay
Dr Michael U Eshiett	Consultant Physician	Expert
Professor Ravi S Gulati (Chair)	Consultant Physician	Expert
Mrs Chris Haywood	Nurse and Head of Hospice Services	Expert
Dr Simon Marwood	Senior Lecturer in Physiology	Expert
Dr David Pilling	Consultant Radiologist	Expert
Mrs Sandra Reilly	Retired Headteacher	Lay

Also in attendance:

Name	Position (or reason for attending)
Mr Noel Graham	Committee Co-ordinator
Miss Jo Foxall Dant	Assistant Co-ordinator