



National Research Ethics Service
NRES Committee North West - Haydock

North West Centre for Research Ethics Committees
3rd Floor - Barlow House
4 Minshull Street
Manchester
M1 3DZ

Tel: 0161 625 7832
Fax: 0161 625 7299

22 November 2011

Professor Deborah Symmons
The University of Manchester
arc Epidemiology Unit
School of Medicine
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:
Amendment date: 26 October 2011

The above amendment was reviewed at the meeting of the Sub-Committee held on 22 November 2011.

Ethical opinion

The Sub-Committee reviewed the above amendment which sought approval for modifications to two clinician completed questionnaires. This was in order to better suit the needs of the study and to clarify the consent process. The time to consent has also been changed so participants no longer have to have the information sheet for a week before they can give consent. There is now no minimum time that must be taken to decide but the participant would be given as much time as they needed. The Sub-Committee agreed that this was sensible and found no ethical issues with the 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 Dr Kath Watson, BSRBR Study Co-ordinator		26 October 2011
Notice of Substantial Amendment (non-CTIMPs)		26 October 2011
Clinical Baseline Form	9	10 August 2011

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

Yours sincerely

PP 
Professor Ravi S Gulati
Chair

E-mail: helen.penistone@northwest.nhs.uk

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

Copy to: **Dr Kath Watson**
BSRBR Study 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

NRES Committee North West - Haydock

Attendance at Sub-Committee of the REC meeting on 22 November 2011

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Professor Ravi S Gulati	Consultant Physician	Expert
Mrs Chris Haywood	Head of Hospice Services	Expert

Written comments received from:

<i>Name</i>	<i>Position</i>
Mr Alan Rigby	Medical Statistician
Dr Tim S Sprosen	Chief Scientific Officer