



Health Research Authority
National Research Ethics Service

NRES Committee North West - Haydock

3rd Floor - Barlow House
4 Minshull Street
Manchester
M1 3DZ

Tel: 0161 625 7827
Fax: 0161 625 7299

12 September 2014

Katy Mowbray
Assistant Studies Coordinator
Biologic Studies Group
Unit 4 Rutherford House
Manchester Science Park
40 Pencroft Way
Manchester
M15 6SZ

Dear Katy

Study title: Prospective observational study of the long-term hazards of anti-TNF therapy in rheumatoid arthritis
REC reference: 00/8/053
Amendment number: 19
Amendment date: 25 July 2014

The above amendment was reviewed at the meeting of the Sub-Committee held on 09 September 2014.

Ethical opinion

The amendment consisted of the introduction of a poster to help with recruitment.

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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Poster]	1	25 July 2014
Covering letter on headed paper		11 August 2014
Letter from sponsor [Confirmation of sponsor support for the amendment]		11 August 2014
Notice of Substantial Amendment (non-CTIMP) [CI signature]	19	25 July 2014
Notice of Substantial Amendment (non-CTIMP)	19	25 July 2014

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.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

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



**On behalf of
Dr Tim S Sprosen
Vice-Chair**

E-mail: nrescommittee.northwest-haydock@nhs.net

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

Copy to: Professor Deborah Symmons, The University of Manchester
Professor Nalin Thakker, University of Manchester

NRES Committee North West - Haydock

Attendance at Sub-Committee of the REC meeting on 09 September 2014

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Professor Ravi S Gulati	Consultant Physician	Yes	
Dr Tim S Sprosen (Meeting Chair)	Epidemiologist	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Rachel Katzenellenbogen	REC Manager