

NRES Committee North West - Haydock

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

Tel: 0161 625 7827
Fax: 0161 625 7299

16 March 2015

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: 20
Amendment date: 16 February 2015
IRAS project ID:

The above amendment was reviewed at the meeting of the Sub-Committee held on 10 March 2015.

Favourable opinion

Approval is sought for the addition of bio-similar drugs to the study and to increase the size of the antiTNF comparison cohort.

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>
Notice of Substantial Amendment (non-CTIMP)	20	16 February 2015
Other [CI signature on NoSA]		01 March 2015

Other [Clinical baseline form]	11	16 February 2015
Other [Clinical follow-up form]	11	16 February 2015
Other [NRAS position paper on biosimilar medicines]		14 August 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

Dr Tim S Sprosen
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, University of Manchester*

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Attendance at Sub-Committee of the REC meeting on 10 March 2015

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Valerie E Siddall	Retired Senior Manager - Pharmaceutical Industry	Yes	
Dr Tim S Sprosen	Epidemiologist	Yes	Chair

Also in attendance:

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