



Health Research
Authority

North West - Haydock Research Ethics Committee

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

Tel: 0207 104 8004

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

21 December 2018

Anthony Marshall
The University of Manchester
Unit 4 Rutherford House
Manchester Science Park
40 Pencroft Way
Manchester
M15 6SZ

Dear Anthony,

Study title:	Prospective observational study of the long-term hazards of anti-TNF therapy in rheumatoid arthritis
REC reference:	00/8/053
Amendment number:	27
Amendment date:	06 December 2018
IRAS project ID:	64202

The above amendment was reviewed by the Sub-Committee in correspondence.

Favourable opinion

This amendment consisted of the introduction of the new electronic database.

No material ethical issues were raised.

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)	27	06 December 2018
Other [Sponsor Approval]		10 December 2018
Other [System Level Security Policy (SLSP)]	1	05 December 2018
Other [Stakeholders Responsibilities]	1	05 December 2018
Research protocol or project proposal [tracked]	2	05 December 2018
Research protocol or project proposal [clean]	2	05 December 2018

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

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 Research Ethics 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



PP 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: Dr Kimme Hyrich, Manchester University
Lynne Macrae, University of Manchester

North West - Haydock Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 18 December 2018

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr Stephen Edgar	Designer	Yes	
Dr Tim S Sprosen	REC Chair - Epidemiologist	Yes	

Also in attendance:

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