

North West - Haydock Research Ethics Committee

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Tel: 0207 104 8012

14 October 2016

Prof Kimme Hyrich
University of Manchester
Arthritis Research UK Epidemiology Unit
2nd Floor Stopford Building
Oxford Road
Manchester
M13 9PL

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: 23
Amendment date: 12 July 2016
IRAS project ID: 64202

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

Favourable opinion

This amendment consisted of two new documents, a new invitation letter and a letter explaining why participants were being asked to re-consent to the participant follow-up.

The sub-committee did not raise any 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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Letter from sponsor [Sponsor approval email]		13 July 2016
Notice of Substantial Amendment (non-CTIMP)	23	12 July 2016
Participant consent form [Re-consent letter]	1	12 July 2016
Participant consent form [Re-consent reminder letter]	1	12 July 2016
Participant consent form [Consent invitation letter]	1	12 July 2016

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: Ms Lynne MacRae, University of Manchester

North West - Haydock Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 11 October 2016

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	REC Chair - Epidemiologist	Yes	

Also in attendance:

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