



Health Research Authority

North West - Haydock Research Ethics Committee

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

Tel: 0207 104 8001

12 August 2016
27 September 2016 (revised)

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: Substantial amendment 22
Amendment date: 07 July 2016
IRAS project ID: Null

The above amendment was reviewed on 09 August 2016 by the Sub-Committee in correspondence.

Favourable opinion

The amendment consisted of:

1. A change of the chief investigator from Professor Deborah Symmons to Professor Kimme Hyrich.
2. An extension to the study for a further 10 years to 30/09/2028.
3. An addition of a low disease activity question.

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	

Notice of Substantial Amendment (non-CTIMP)	07/07/2016	07 July 2016	
Other [Clinical follow up form]	11.2	07 July 2016	
Other [Clinical baseline form]	11.1	07 July 2016	
Other [Sponsor approval email]		11 July 2016	
Other [Short baseline form]	V3	06 April 2016	
Summary CV for Chief Investigator (CI)		01 May 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

PP



Dr Tim S Sprosen
Chair

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

North West - Haydock Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 09 August 2016

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>	
Dr Ezzat Kozman	Consultant Gynaecologist	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	