



**Health Research Authority**  
Research Ethics Service

**North West - Haydock Research Ethics Committee**

3rd Floor - Barlow House  
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Tel: 0207 104 8012

11 December 2015 (Revised letter 04.04.2016)

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:** 21  
**Amendment date:** 12 October 2015  
**IRAS project ID:**

The above amendment was reviewed at the meeting of the Sub-Committee held on 08 December 2015.

**Favourable opinion**

Approval was sought for a Biologics Registers general information leaflet to be distributed in the rheumatology clinics of sites involved in the BSRBR-RA study.

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 [Biologic Registers Leaflet]	1	23 September 2015	

Letter from sponsor		11 November 2015	
Notice of Substantial Amendment (non-CTIMP)	21	12 October 2015	

### 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/>

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



**Dr Tim S Sprosen**  
**Chair**

E-mail: [nrescommittee.northwest-haydock@nhs.net](mailto:nrescommittee.northwest-haydock@nhs.net)

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

Copy to: Professor Nalin, University of Manchester

**North West - Haydock Research Ethics Committee**

**Attendance at Sub-Committee of the REC meeting on 08 December 2015**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>	
Mrs Chris Haywood	Director of Nursing	Yes		
Dr Tim S Sprosen (Chair)	Epidemiologist	Yes		

**Also in attendance:**

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