



## Health Research Authority

### North West - Haydock Research Ethics Committee

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

Tel: 0207 104 8001

**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.**

02 December 2016

Dr Kimme Hyrich  
Senior Lecturer in Rheumatic Disease Epidemiology and Consultant Rheumatologist  
Manchester University  
Arthritis Research UK Epidemiology Unit  
2nd Floor Stopford Building  
Oxford Road  
Manchester  
M13 9PT

Dear Dr Hyrich

<b>Study title:</b>	<b>Prospective observational study of the long-term hazards of anti-TNF therapy in rheumatoid arthritis</b>
<b>REC reference:</b>	<b>00/8/053</b>
<b>Amendment number:</b>	<b>Amendment 24</b>
<b>Amendment date:</b>	<b>26 October 2016</b>
<b>IRAS project ID:</b>	<b>64202</b>

The above amendment was reviewed on 22 November 2016 by the Sub-Committee in correspondence.

#### **Favourable opinion**

This amendment consists of updates to the participant information sheet and the consent form, including:

1. The addition of a section about the risks and benefits of participating in the research study.

2. Clarification regarding which items of personal identifiable data are shared with other organisations and for what purpose.
3. The addition of how long data will be kept for at the end of the 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>
Letter from sponsor [Sponsor approval letter]		31 October 2016
Notice of Substantial Amendment (non-CTIMP)	Amendment 24	26 October 2016
Other [Email clarification of amendment]		14 November 2016
Participant consent form	8.0	19 October 2016
Participant information sheet (PIS)	8.0	19 October 2016

### 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/>

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

*Ms Lynne Macrae*

**North West - Haydock Research Ethics Committee**

**Attendance at Sub-Committee of the REC meeting on 22 November 2016**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Ezzat Kozman	Consultant Gynaecologist	Yes	
Dr Valerie E Siddall	Retired Senior Manager - Pharmaceutical Industry	Yes	Alternate Vice-Chair
Dr Tim S Sprosen	REC Chair - Epidemiologist	Yes	

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Ewan Waters	REC Assistant