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.

24 August 2017

Anthony Marshall
Drug Safety/R&D Administrator
Arthritis Research UK Centre for Epidemiology
The University of Manchester
Unit 4 Rutherford House
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:	**25**
Amendment date:	**17 July 2017**
IRAS project ID:	**64202**

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

Favourable opinion

This amendment covered 4 main points:

I. Addition of a new “Janus kinase inhibitor and targeted therapies” cohort.
II. Increase in the size of existing cohorts.
III. Introduction of an outreach study invitation letter aimed at patients being re-registered.
IV. Revision of patient facing documents.

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:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Poster for Patient Recruitment]	2	17 July 2017
Letter from statistician [Sponsor Approval]		01 August 2017
Letters of invitation to participant	1.1	17 July 2017
Non-validated questionnaire	5	17 July 2017
Non-validated questionnaire	7	17 July 2017
Notice of Substantial Amendment (non-CTIMP)	25	17 July 2017
Other [Short Baseline Form Tracked]	3.1	17 July 2017
Other [Re-consent Covering Letter]	1	17 July 2017
Other [Clinical Follow-up Form]	11.3	17 July 2017
Other [Clinical Baseline Form]	11.2	17 July 2017
Participant consent form	9.0	17 July 2017
Participant information sheet (PIS)	9.0	17 July 2017

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**

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
Ms Lynne Macrae, University of Manchester

North West - Haydock Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 22 August 2017

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr David Pilling	Consultant Radiologist	Yes	
Dr Tim S Sprosen	REC Chair - Epidemiologist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Laila Sarwar	REC Assistant