

**North West - Haydock Research Ethics Committee**

2 Redman Place  
Stratford  
London  
E20 1JQ

19 April 2024

Professor Kimme Hyrich  
The University of Manchester  
Stopford Building  
Oxford Road  
Manchester  
M13 9PT

Dear Prof Kimme Hyrich

**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 30 (SA 30)  
**Amendment date:** 13 February 2024  
**IRAS project ID:** 64202

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

**Ethical opinion**

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>
Completed Amendment Tool [64202 (minimal dataset) - REC Ref 00-8-053_Substantial Amendment 30 (SA 30)_]	1.6	13 February 2024
Letter from sponsor [64202 (minimal dataset) - REC Ref 00-8-053_SA30 Sponsor Approval]	N/A	19 February 2024
Participant consent form [BSRBR RA Consent Form v11.0_22112023_(clean)]	11.0	22 November 2023
Participant consent form [BSRBR RA Consent Form v11.0_22112023_(tracked)]	11.0	22 November 2023
Participant information sheet (PIS) [BSRBR-RA Participant Information Sheet v11.0_22112023_(tracked)]	11.0	22 November 2023

Participant information sheet (PIS) [BSRBR-RA Participant Information Sheet v11.0_22112023_(clean)]	11.0	22 November 2023
Research protocol or project proposal [BSRBR-RA Study Protocol v2.1_13022024 (clean)]	2.1	13 February 2024
Research protocol or project proposal [BSRBR-RA Study Protocol v2.1_13022024 (tracked)]	2.1	13 February 2024

### 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.

### Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

### 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.

### HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

<b>IRAS Project ID - 64202:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely



**Chair**

E-mail: haydock.rec@hra.nhs.uk

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

*Copy to: Professor Kimme Hyrich, The University of Manchester*

**North West - Haydock Research Ethics Committee**

**Attendance at Sub-Committee of the REC meeting on 16 April 2024**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Professor Paul Eldridge	Retired Consultant Neurosurgeon	Yes	
Mrs Sue Fitzpatrick	Director	Yes	

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Joe Wakeham	Approvals Administrator