

North West - Haydock Research Ethics Committee

2 Redman Place
Stratford
London
E20 1JQ

10 April 2025

Prof Kimme Hyrich
The University of Manchester
Stopford Building
Oxford Road
Manchester
M139PT

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 31 (SA31)
Amendment date: 30 January 2025
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 31 (SA31)_]	1.6	30 January 2025
Letter from sponsor [64202 (minimal dataset) - REC Ref 00-8-053_SA31 Sponsor Approval]	N/A	31 January 2025
Other [BSRBR-RA Your Data Journey (for print) v1.0_03042024]	1.0	03 April 2024
Other [BSRBR-RA Your Data Journey (for web) v.1.0_03042024]	1.0	03 April 2024
Other [BSRBR-RA Patient Poster v.3.0_13112023]	3.0	13 November 2023

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/>

IRAS Project ID - 64202:	Please quote this number on all correspondence
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Yours sincerely



Prof Paul Eldridge
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 01 April 2025

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Professor Paul Eldridge	Retired Consultant Neurosurgeon	Yes	
Dr Irina Grouneva	Study Lab Coordinator	Yes	

Also in attendance:

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