

North West - Haydock Research Ethics Committee

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

Tel: 02071048248

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.

22 September 2022

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

Dear Prof 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 29 (SA 29)
Amendment date: 19 May 2022
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	1.6	19 May 2022

00-8-053_Substantial Amendment 29 (SA 29)_]		
Letter from sponsor [64202 (minimal dataset) - REC Ref 00-8-053_SA29 Sponsor Approval]	N/A	24 June 2022
Participant consent form [BSRBR-RA Consent Form v10.0_19052022_(tracked)]	10.0	19 May 2022
Participant consent form [BSRBR-RA Consent Form v10.0_19052022_(clean)]	10.0	19 May 2022
Participant information sheet (PIS) [BSRBR-RA Participant Information Sheet v10.0_19052022_(tracked)]	10.0	19 May 2022
Participant information sheet (PIS) [BSRBR-RA Participant Information Sheet v10.0_19052022_(clean)]	10.0	19 May 2022

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
pp.



Mrs Sue Fitzpatrick
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 20 September 2022 via correspondence.

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Sue Fitzpatrick	Director	Yes	
Mrs Lesley France	Statistician	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Lucie Conway	Approvals Administrator