



Health Research Authority
North West - Haydock Research Ethics Committee

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Tel: 0207 104 8210

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.

29 April 2021

Professor Kimme Hyrich
Professor of Epidemiology in the Arthritis Research UK Centre for Epidemiology, part of the Centre for Musculoskeletal Research and a Consultant Rheumatologist in the Kellgren Centre for Rheumatology
The University of Manchester
Centre for Musculoskeletal Research
Stopford Building
Oxford Road
Manchester
M13 9PT

Dear Professor 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:	SA28
Amendment date:	29 March 2021
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_SA 28_]	SA 28	29 March 2021
Letter from sponsor [SA28, IRAS 64202, REC 00_8_53, sponsor approval]	N/A	07 April 2021
Other [BSRBR_RA_COVID19_Questions v1.0_02032021]	1.0	02 March 2021

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. 

Mr Stephen Edgar
Chair

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

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

Copy to: Ms Lynne Macrae, The University of Manchester

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Attendance at Sub-Committee of the REC meeting via correspondence

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr Stephen Edgar (Chair)	Designer	Yes	
Miss Annya Sekula	Nurse	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Stacey Bamford	Approvals Administrator