

**Wales Research Ethics Committee 1
Cardiff**

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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

10 February 2023

Prof Reza Razavi
King's College London
Room 5.31 James Clerk Maxwell Building
57 Waterloo Road, London
SE1 8WA

Dear Prof Razavi

Study title: The UK-Irish atopic eczema systemic therapy cohort (A*STAR)
REC reference: 18/WA/0200
Protocol number: A*STAR
Amendment number: Substantial Amendment 3 (SA03)
Amendment date: 01 July 2022
IRAS project ID: 237309

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:

Document	Version	Date
Completed Amendment Tool [237309 - Substantial Amendment 3 (SA03)]	1	01 July 2022
Copies of materials calling attention of potential participants to the research [A-STAR Recruitment Poster - V1.0 (01JUL2022)]	1.0	01 July 2022
Covering letter on headed paper [18-WA-0200 - Substantial Amendment 3 Cover Letter (IRAS ID 237309)]	1	27 January 2023

<i>Document</i>	<i>Version</i>	<i>Date</i>
Letter from sponsor [Elizabeth Bruna - Sponsor Approval]	1.0	27 January 2023
Research protocol or project proposal [A-STAR Protocol V4.0 (01JUL2022) - Clean]	4.0	01 July 2022
Research protocol or project proposal [A-STAR Protocol V4.0 (01JUL2022) - Tracked]	4.0	01 July 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 - 237309:	Please quote this number on all correspondence
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Yours sincerely



pp
Mr John Gibson
Chair

E-mail: Wales.REC1@wales.nhs.uk

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

Copy to: Dr Carsten Flohr, St John's Institute of Dermatology - carsten.flohr@kcl.ac.uk

Wales REC 1

Attendance at Sub-Committee of the REC meeting on 10 February 2023

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Kathie Fisher	Retired Company Director, Kingfisher Music	Yes	
Mr John Gibson	Specialist Trainee in Plastic Surgery	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Deborah Burch	Approvals Administrator